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Quality Laboratory Services – Is it Related to Personal Credentials?

Maria Dannessa Delost

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This is to certify that the dissertation prepared by Maria D. DeLost, entitled "*Proficiency Test Performance: Is it Related to Personnel Credentials?,*" has been approved by her committee as satisfactory completion of the dissertation requirement for the degree Doctor of Philosophy.

[redacted]

Teresa S. Nadder, Ph.D., Dissertation Committee Chair
School of Allied Health Professions

[redacted]

Greg Miller, Jr., Ph.D., Dissertation Committee Member
School of Medicine

[redacted]

William J. Korzun, Ph.D., Dissertation Committee Member
School of Allied Health Professions

[redacted]

Guang-Hwa Chang, Ph.D., Dissertation Committee Member
Youngstown State University

[redacted]

Cecil B. Drain, Ph.D., Professor and Dean
School of Allied Health Professions

[redacted]

Douglas F. Boudinot, Ph.D., Dean
VCU Graduate School

July 22, 2005
Date

Quality Laboratory Services – Is it Related to Personal Credentials?

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Health Related Sciences at Virginia Commonwealth University.

by

Maria Dannessa Delost
Master of Science in Biology, The University of Akron, 1985
Bachelor of Science in Applied Science, Youngstown State University, 1979

Teresa S. Nadder, Ph.D., Assistant Professor
Department of Clinical Laboratory Sciences

Virginia Commonwealth University
Richmond, Virginia
July 22, 2005

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Abstract

QUALITY LABORATORY SERVICES: IS IT RELATED TO PERSONNEL CREDENTIALS?

By: Maria Dannessa Delost, Ph.D.

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2005

Teresa S. Nadder, Ph.D., Associate Professor,
Department of Clinical Laboratory Sciences

Performance on proficiency test (PT) surveys provides an objective and consistent evaluation of laboratory quality. The goal of the study, a retrospective review of existing PT results (2003) from six clinical laboratories in northeastern Ohio and western Pennsylvania was to determine the relationship of PT performance to the personnel credentials of the laboratory testing personnel. Predictor variables included the practitioner's major area of study, degree, certification and years of laboratory experience.

The study group consisted of 174 testing personnel and 11,689 proficiency-testing results, of which 11,233 were valid and included in the study. Of the 11,233 results, there

were 11,120 results graded acceptable (99.0%) and 113 results were unacceptable (1.0%). The most common type of error was a technical problem (35, 31.0%) Logistic regression analysis of the full model (n=11,233, $\chi^2 = 20.416$, p=0.002) with all predictors included, showed statistical significance for the predictor, clinical laboratory major (p=0.018). Those individuals without a clinical laboratory major (EXP $\beta = 1.820$) were almost twice as likely to produce an unacceptable result when compared to those individuals with a clinical laboratory major.

The study supports the hiring of laboratory personnel who have completed a formal clinical laboratory education program. As the laboratory workforce shortage intensifies, the performance of laboratory personnel with limited years of clinical experience or those lacking a clinical laboratory major or educational degree may be important. An opportunity exists for health care facilities to investigate the benefits of clinical laboratory education programs to replenish qualified and experienced laboratory personnel.

CHAPTER I - INTRODUCTION

Significance of Laboratory Quality

According to Sunderman (1992), a pioneer in laboratory proficiency testing,

> There can be no more important task for the director of a clinical laboratory than to assess the precision and accuracy of the analytical procedures under his/her care. Maintenance of high standards of analysis not only serves as a scientific stimulus for the laboratory but is also of direct benefit to patients (p. 1205).

Adverse outcomes associated with medical errors, including those that occur in the clinical laboratory are associated with significant morbidity and mortality (Centers for Disease Prevention and Control; 2002; Kizer, 2001) and financial impacts on the health care system in the United States. Testing personnel who perform inaccurate proficiency testing (PT) are more likely to perform laboratory analyses that ultimately cause the patient harm according to Lunz, Castleberry, & James (1992). Astion (2003) has stated that preventable laboratory errors lead to patient dissatisfaction and poor outcomes, including patient injuries and relates these errors to the incompetence of individuals and failures and inadequacies of the system. Monahan (2001) reported that the clinical laboratory contributed to nearly 23% of all reported medical errors, although many of these errors occur outside of the laboratory department during the preanalytical phase of

analysis. However, few studies exist that relate adverse medical outcomes or the impact of laboratory problems to patient care. In one such study, Ross and Boone (1991) noted 363 laboratory incidents at a single hospital. Examination of the patients' medical records revealed there was no effect on patient care in 70% of the cases, while 24% of patients were subjected to additional blood drawing; and 6% were not harmed, but were exposed to improper or inappropriate care. Nutting, et al., (1996) reported 180 problems in laboratory testing in primary care physicians' offices, yielding an approximate rate of 1.1 problems per 1000 visits. In the judgment of the practice staff, 27% of these problems had an impact on patient care.

Good performance by health care personnel is more likely to result in good outcomes for patients (Wallace & Klosinski, 1998). Regulations, such as laws, rules, and standards of practice (SOP) are instituted to protect physicians and patients from illegal or unethical medical practices. Public and media concern with the quality of laboratory services and accuracy of test results resulted in CLIA'88 amendments, a federal mandate that required all clinical laboratories in the United States to be identified and approved in order to receive authorization to operate.

In 1994, the estimated cost for laboratory testing in the United States was $30 to $35 billion (Hoerger, Eggleston, Lindrooth, & Basker, 1997). Further, the estimated total national testing volume for the US in 1996 was 7.25 billion tests (with a standard error of 1.09 billion) according to the National Inventory of Clinical Laboratory Testing Services (NICLTS) as reported by Steindel, Rauch, Simon & Handsfield, (2000). While the direct costs of pathology and laboratory medicine reflect a small percentage of total health care

expenditures, diagnostic procedures and testing comprise a significant amount of secondary healthcare spending related to additional procedures, interventions, adverse effects, inconvenience, and anxiety for patients (Bacher, 1999).

NICLTS inventoried the distribution of laboratories in the United States by geographical location and by laboratory type (Steindel, et al., 2000). The main outcome measure of this stratified random sample of laboratories was the laboratory testing distribution in 1996 by analyte, method, and specimen type. Hospital laboratories performed 48.5% of the laboratory testing in the US in 1996 while independent laboratories and blood banks provided an additional 16.3%. Thus, prior to CLIA'88, regulated laboratories (hospital laboratories and blood banks) performed 64.8% of all US laboratory testing. The remaining 35.2% was performed in less regulated settings including Physician Office Laboratories (POLs, 10.1%), ambulatory care units, such as community clinics, home health and student health agencies (1.7%) hospice/nursing home facilities (1.0%), and specialty facilities, such as ancillary testing sites, health fairs, industrial and mobile units which accounted for 22.4% of laboratory testing. Studies have shown that laboratory testing performed in sites other than hospital laboratories may be of lower quality when compared to that performed in hospital laboratories (Hurst, Nickel, Hilborne, 1998 & Nutting, et al., 1996).

There is an urgent need to reduce healthcare errors through a focus on quality. Quality health care in the United States has received attention due to increases in cost, information relating the frequency of medical errors, and the public demand to resolve increasing costs while maintaining quality care (Moore & Foss, 2003). Healthcare errors

have been reported as a leading cause of death in America according to Kizer (2001) in *Patient Safety: A Call to Action: A Consensus Statement from the National Quality Forum* and in the Institute of Medicine's (IOM), *To Err is Human: Building a Safer Health System* (2000). Kizer presents a summary of an in-depth review of healthcare errors based on studies conducted by The Institute of Medicine (IOM) and the Presidential Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. In this report, Kizer indicated that the IOM estimated that between 44,000 and 98,000 deaths each year in the United States result from medical care errors in acute care hospitals. Furthermore, the overall impact of healthcare errors is much larger when both nonfatal and fatal events are included and when long-term care, ambulatory care, and non-hospital settings are considered (Kizer). The IOM also reported that medical errors, including those that occur in laboratories, may cost the US health system as much as $17 - $29 billion annually as reported in the Centers for Disease Control and Prevention's (CDC) Seven *Healthcare Safety Challenges* (CDC, 2001). Also, medical errors are believed to be underreported and that the published cost of medical errors does not include costs in terms of opportunity costs, such as money spent to repeat diagnostic tests and to counteract medication errors. Further, those errors resulting in loss of trust or diminished satisfaction by patients or health professionals cannot be measured monetarily.

Physicians base 80% of their diagnostic decisions on laboratory results, yet laboratory personnel standards vary widely between states, laboratory type, and level of testing performed (ASCP, 2001). Although the cost of the laboratory operations accounts for

less than 5% of the total institutional budget, it has been estimated (Forsman, 2002) that the laboratory contributes significantly to the objective data in a clinical record. Currently, only 12 states (California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee, West Virginia, and Puerto Rico) require licensure of laboratory personnel. The absence of licensure requirements for laboratory personnel in most states permits individuals to work in laboratories without clinical laboratory education or certification.

Additionally, laboratory managers have no uniform definition of competency (Peddedord, 1996); yet do recognize technical skills, professionalism, and productivity as essential skills for laboratory personnel. The current need to assess educational level, experience and expertise is critical as the clinical laboratory attempts to balance the effects of automation, managed care, the expanding menu of complex methods, medical and financial impact of healthcare errors, and the shortage of laboratory personnel in the changing healthcare environment of managed care. The laboratory staffing issue is a complex issue, which begins by attracting individuals to the profession, followed by enrollment and completion of academically demanding programs and eventual employment and retention in the field. As enrollments decline, medical laboratory programs are forced to close which further impedes attracting prospective students to the profession. In fact, between 1990 and 2001, there was a 40% loss in medical technology/clinical laboratory science programs, resulting in the closure of 168 programs (Mass, 2002). Further, unused student capacity has increased because of the shortage of student applicants to clinical laboratory programs. The contribution of laboratory

practitioners who have completed a clinical laboratory program may impact the performance of laboratory testing as there are less programs available to educate current and future students.

Quality laboratory processes are dependent upon proficiency in the preanalytical, analytical, and postanalytical phases of laboratory testing. This study determined the extent of contributions of education, certification and clinical experience in the three phases of laboratory quality through an examination of existing proficiency testing data in clinical laboratories that employ testing personnel of a variety of education, certification, and experience levels. Although proficiency testing measures quality in all three phases of laboratory analysis, PT particularly probes the analytical component of testing. Proficiency testing has been demonstrated as an effective measure for characterizing analytical performance and has been a significant component of the Clinical Laboratory Improvement Amendments (CLIA) of 1967 and 1988 (Rej &Jenny, 1992). This study is different from prior studies because the individual and not the laboratory was the unit of analysis (Lunz, Castleberry, James, & Stahl, 1987; Lunz, Castleberry, & James, 1992). A demographic survey ensured that laboratories met requirements for test and personnel diversity. Further, the information provided through the demographic survey were utilized to analyze other relationships between personnel mix and laboratory performance on PT surveys. The study analyzed diverse levels of laboratory professionals with varying certification credentials. Prior studies of Lunz, et al., (1987, 1992) reviewed performance of bachelor level medical technologists with only ASCP certification. The data analyzed were post-CLIA'88 such that effects on

regulations can be evaluated, after personnel standards have been implemented. Further, the data analyzed included private, physician office, and traditional hospital laboratories to provide a diverse mix of testing sites and personnel.

Background and Rationale for this Study: Measurement of Laboratory Quality

Many variables affect the quality of laboratory results. Thus, measurement tools of laboratory quality are not easily defined. Westgard and Klee (2001) describe quality as conforming to the needs of users or customers and subsequent satisfaction of their expectations. In most general terms, quality refers to accuracy and precision of laboratory testing. Accuracy is described as the extent to which the value of an analyte agrees with its "true" value while precision refers to the closeness of agreement between replicate assays of the sample. The measures of precision and accuracy are easily quantifiable and consistently measured through quality control and proficiency testing.

Donabedian (1980) described quality health through structure, process, and outcomes. Structure refers to the setting in which the care is delivered and includes facilities, equipment, physical and organizational settings, technology, and personnel qualifications. Structure involves the human, physical, and financial resources utilized in providing healthcare. Process refers to the procedure performed for the patients, and outcomes are the effects of the care on the patients. In this model, good structure increases the likelihood of good process and the subsequent potential for good outcomes. Outcome refers to a change in the patient's current and future health status that can be attributed to health care structure and process. Thus, qualified laboratory personnel are a contribution to structure, which increases the probability of good process and improved patient

outcomes. However, because patient outcomes are far removed from the laboratory process and because of numerous confounding variables, it is difficult to relate patient outcomes to a laboratory event.

Traditionally, laboratory quality has been evaluated in terms of internal laboratory quality indicators, such as turn around time, performance in quality assurance programs, laboratory accreditation processes, cost, repertoire of tests, productivity and staffing and skills mix. Other laboratory quality indicators include performance in the accreditation process, internal and external quality control or proficiency testing, personnel credentials, patient outcomes and consumer satisfaction. The use of daily quality control (QC) with written corrective actions or action step documentation when QC suggests an error are important quality indicators according to St. John, Lipman, Krolak, and Hearn (2000). Quality might be measured by the laboratory's use of audit activities, test to request ratios, productivity, and the skills mix of the laboratory staff (Galloway & Nadin, 2001). Quality assurance programs, such as the Q-Probes program of the College of American Pathologists (CAP) are based on benchmarks provided through external peer comparisons with laboratories of comparable size and workloads. Since 1989, Q-Probes has developed benchmarks for over 90 indicators of quality for practices in pathology and laboratory medicine (Howanitz and Cembrowski, 2000).

Personnel, quality control and quality assurance standards, and proficiency testing (PT) form the framework for the Clinical Laboratory Improvement Amendment (CLIA) regulatory model (CDC -- MMWR, 1996). Quality control, a component of quality assurance, probes the quality of laboratory results reported during the analytical phase.

Quality control measures identify deviation from the mean and standard deviation of normal and abnormal controls and are the laboratory's primary mechanism for ensuring precision in analysis. Quality assurance not only includes a review of work processes, workload, performance, and productivity but also addresses the effects of policy revisions on laboratory quality. In the CLIA regulatory model, PT serves as a surrogate measure for laboratory performance. Regulation of laboratory testing is mandated in the United States by regulatory law with the most recently enacted regulations dictated by CLIA'88. Previous assessments, including those of Jenny and Jackson (1993) have established PT performance as an indicator of a laboratory's performance on patient samples.

Benchmarking and total quality management (TQM) are also measurements of laboratory quality. Benchmarking is defined as the process of measuring products, services, and practices against leaders in the field, which identify the best practices and result in sustained and improved performance. Galloway and Nadin (2001) describe how benchmarking is used to assess laboratory performance. Total quality management (TQM) focuses on processes and process improvement as a method to satisfy customer needs and requirements. TQM principles comprise customer focus, management commitment, training, process capability and control, and measurement through quality improvement tools. When applied to the clinical laboratory, Westgard and Klee (2001) state that TQM principles include quality laboratory processes (analytical processes, general policies, practices, procedures) that define how all analyses are performed, quality control (statistical control procedures, linearity checks, reagent and standard checks, temperature monitors), and quality assurance measures of laboratory performance

(specimen identification, turn-around times, appropriate test utilization, patient identification). Quality management also includes a structured problem-solving process as well as a method to standardize and document the solution.

Peddecord (1996) critically reviewed existing literature relative to personnel standards of laboratory testing personnel and identified educational requirements for competent laboratory personnel. The relationship between laboratory testing personnel and analytic proficiency test performance was also investigated. While noting that better PT results were usually associated with higher personnel qualifications, other factors must be considered which included supervision, management system, quality control and quality assurance, continuous quality improvement activities, technology, and the concentration of expertise in larger, more specialized laboratories.

Identification and investigation of the sources of errors in laboratory testing provide another quality measurement tool. Limitations in this quality tool include the reluctance of laboratorians to report errors and difficulty in identifying errors especially those that do not result in patient adverse outcomes. Valenstein and Meier (1999) acknowledge that there are few studies of error rates in clinical practice and most deal with medication prescription or dispensing errors. In addition, those errors that occur in the preanalytical and postanalytical phases of laboratory testing often occur outside of the laboratory setting and are the result of actions of other healthcare providers; such error rates are infrequently reviewed. Of note is one study of preanalytical accuracy where outpatient order accuracy was analyzed in a CAP Q-Probes study of 660 institutions which showed

that a total of 5514 (4.8%) of 114,934 outpatient requisitions were associated with at least one order entry error (Valenstein & Meier, 1999).

Winkleman and Mennemeyer (1996) cite the limitations in using traditional methods, such as direct inspection, proficiency testing and staff credentials to measure laboratory quality. Although CLIA'88 mandated the federal licensure of all clinical laboratories, the emphasis remains on process with limited emphasis on laboratory outcomes. The laboratory must provide clinicians with medically important laboratory information; poor laboratory quality may misguide a physician into the wrong diagnosis or to provide inappropriate treatment. Winkleman and Mennemeyer used downstream event monitoring (DEM) to determine how patient outcomes may be used to screen for laboratory errors. DEM refers to the identification of adverse events, such as death, hospitalization, or the administration of additional tests or procedures that occur if the laboratory made an error in testing (Mennemeyer, 1998). An incorrect reported level for a particular analyte that results in inappropriate alterations in a medication and leads to an unstable condition or adverse drug reaction is one example of laboratory DEM. While patient outcomes have become increasingly important measures of the quality of patient care, there have been few studies of patient outcomes related to laboratory testing presumably, because laboratory testing is one of several inputs into the medical diagnosis and treatment of the patient. Using a Medicare claims database and DEM, Winkleman and Mennemeyer identified adverse patient outcomes associated with prothrombin and digoxin levels.

Yet, others (Bonini, Plebani, Ceriotti, & Rubboli, 2002) state that the lack of a universally accepted error rate and an "allowable error rate" reduce the possibility of evaluating the impact of laboratory error on patient outcomes. Waise and Plebani (2001) concede that although the use of outcome assessments to evaluate the effectiveness of care is increasing, its use is difficult to implement for the majority of laboratory services. Patient outcomes are complex to assess and may best be summarized by performance of the correct laboratory test at the appropriate time and attaining an accurate and thorough result. (Haun & Leach, 2003).

Another measure of laboratory quality may be identified through measurement of employee competence and performance based assessment (Boone, 2000; Howanitz, Valenstein, & Fine, 2001). CLIA'88 regulations also require that laboratories assess the competency of all individuals who perform laboratory tests (Christian, Peddecord, Francis, & Krolak, 1997). According to Howanitz, Valenstein, and Fine (2001), a competency measurement must relate to the quality of care that a patient receives; the people within an organization provide a major measure of the quality of the organization and the products and services it provides. In a CAP 1996 Q-Probes study of 522 institutions, employee competence assessment practices in departments of pathology and laboratory medicine were surveyed. This three-part study consisted of a questionnaire about current competence practices, an evaluation of compliance with the competence practices using personnel records of 30 employees, and a written appraisal of five specimen-processing staff members per institution. The survey showed that 89.8% of the participating institutions had a written competence plan and 98.1% reviewed employee

competence once annually. Methods to review competence included direct observations (87.5%), review of test or quality control results (77.4%), review of instrument preventive maintenance (60.0%), written testing (52.2%), as well as other methods (20.8%). The study concluded that opportunities for improvement in employee competence assessment are numerous and that a consistent assessment of competence would be difficult to develop and perform.

In a nonrandom stratified sample of 20 laboratories, Christian, et al., (1997) collected information about the history and development of the laboratories' competency assessment programs and activities; the relationship of competency assessment with performance appraisals, cost, benefits; and the assessment methods and tools used. No consistent method of competency assessment implementation was found, and the study concluded that competence of laboratory personnel is a complex issue unique to each laboratory setting. Factors noted in the appraisal of a laboratory employee include quality improvement, productivity, competency, reliability, interpersonal relationships, initiative and resourcefulness, and work behaviors (Clinical Laboratory Management Review, 1997). Technical aspects, ethics, safety, competence assurance as well as the quality and quantity of analysis are also methods to evaluate an employee's performance quality. Career development and goals, workshops and conferences attended are also used to assess employee competence.

According to Howanitz, et al., (2001), the quality of laboratory work is affected by the competence of any employee. Lack of competence may result from an individual's

inability or the lack of adequate training to perform the task. However, no clear definition to measure employee competence is available for the clinical laboratory practitioner.

Introduction to Study and Design

It is hypothesized that quality laboratory service is related to the credentials of the laboratory testing personnel. The purpose of this study is determine if a relationship exists between the quality of laboratory services as defined by successful events in proficiency testing (PT) and the credentials of the individual laboratory testing personnel, including level of education, certification and the number of years of clinical experience. Proficiency testing is an external quality control process where simulated patient samples are analyzed by participating laboratories, and individual laboratory performance is assessed by comparison to the collective performance of all of the participants (Stull, Hearn, Hancock, Handsfield, & Collins, 1998). The objectives of PT are to determine the appropriateness of laboratory protocols and to evaluate the laboratory personnel's ability to perform the analysis satisfactorily. Proficiency testing is also referred to as external quality assessment (EQA); PT may be used to indicate the regulatory process while EQA is used to refer to the process of self-assessment and improvement (Miller, 2003).

The study was a nonexperimental, retrospective review of proficiency test (PT) performance at participant laboratories. Existing PT survey data was reviewed and related to the personnel credentials of the individual laboratory testing personnel. Logistic regression analysis was used to determine if a statistical relationship exists between the levels of education (degree and major), years of clinical experience, presence and level certification, and accurate test performance.

CHAPTER II - LITERATURE REVIEW

History of Proficiency Testing

According to Sunderman (1992), proficiency testing began as a voluntary process in Philadelphia in 1945 between laboratory directors who were concerned about intralaboratory and interlaboratory accuracy. This first PT process involved 10 -15 laboratory directors whose laboratories analyzed serum samples with values unknown to the testing personnel. Severe inadequacies and discrepancies were revealed in the laboratory analyses. In 1946, carefully prepared solutions were distributed throughout hospital laboratories in the State of Pennsylvania to assess the accuracy of laboratory testing. The results were reported anonymously and summarized in 1947 by W.P. Belk and F.W. Sunderman in the *American Journal of Clinical Pathology*, indicating inconsistent agreement between the participants and generally unfavorable results.

The College of American Pathologists (CAP) was founded in 1946, and one of its first initiatives was the National Proficiency Surveys, whose purpose was to evaluate the accuracy and interlaboratory variation of participant laboratories. These first surveys were developed and reviewed by Sunderman. The findings of these 1947-1948 surveys were unfavorable and sent to CAP but never released. The need for additional professional surveillance to maintain high clinical laboratory standards and accuracy became increasingly apparent to laboratory directors. The most practical method to assess

analytical performance was the analysis of prepared solutions with unknown concentrations by laboratory testing personnel (Sunderman, 1992). Thus, Continuous Professional Assessment or Proficiency Testing (PT) became the early foundation to evaluate the standards of laboratory work that developed into a system of self-auditing PT service for the clinical laboratory. In 1949, the Sunderman PT Service provided unbiased and critical assessment of a laboratory's proficiency in relation to approximately 2000 clinical laboratories in the United States and other countries. This system of self-auditing was endorsed by the American Society of Clinical Pathology (ASCP) in 1952 and by the Association of Clinical Scientists in 1957 and 1968. A goal of these original surveys was to improve the quality of laboratory analysis through encouraging laboratory directors to analyze performance and to take corrective actions to determine any causes of inaccuracy. Because reference methods were not available, agreement of results between laboratories was an early goal of the proficiency testing process (Miller, 2003). Since 1962, laboratories have participated in interlaboratory comparison programs such that patient results are comparable in different laboratory settings (Tholen, et al., 1995). The Sunderman PT Service continued for several years until The College of American Pathology eventually assumed the role as PT provider..

Regulatory Implications

Legislation to provide the public with assurance that laboratory data was trustworthy resulted in federal regulations concerning the operation of clinical laboratories. In 1967, the Clinical Laboratory Improvement Amendment (CLIA '67) was enacted, based largely on the testimony of the Director of the Communicable Disease Center (CDC, later the

Centers for Disease Control and Prevention) who testified on the poor performance of clinical laboratories. This testimony was disputed by many pathologists (Sunderman, 1992). CLIA'67 federally mandated that hospital and reference laboratories must participate in the accreditation process, including proficiency testing and other regulatory standards.

Physician office laboratories remained generally unregulated until 1988 because CLIA '67 did not address personnel standards and proficiency testing in nonhospital laboratories. Concern with the lack of regulation and poorer quality of POLs was addressed by CLIA'88 (Boone, 1992). This federal mandate, implemented in 1992, required all testing sites to undergo inspection on behalf of the Health Care Finance Administration (HCFA) and to apply for a certificate issued for each category of tests that the facility performed. CLIA'88 standards address personnel qualifications, patient test management, facilities, equipment, supplies, quality assurance, and quality control (Q.C.), record keeping, and participation in a proficiency testing program. Because many laboratory entities, such as physician office laboratories and clinics, were previously not subject to regulation, some of the requirements of CLIA'88 were included as 'phased-in' standards (CAP, 2003). These phase-in standards for CLIA compliance included limited quality control for moderate complexity testing, board certification for high complexity doctoral degreed directors, and Food and Drug Administration (FDA) review of manufacturers' test system QC instructions. Phase-in dates permitted time for small facilities to comply although the deadlines for compliance were extended four times, until December 31, 2002. The final CLIA rule published in the Federal Registry on January

24, 2003 provided one set of QC standards for nonwaived testing and reduced QC testing in most of the specialty and subspecialty areas. This final CLIA rule also removed the prospective FDA review of manufacturers' QC instructions for compliance with CLIA that was to occur after the end of the 'phase in' period, eliminated redundancy, clarified and simplified language, and reorganized the existing requirements to more logically pattern the processing and accessioning of patient specimens through the laboratory to prevent errors (CAP, 2003).

The Proficiency Testing Process

Participation in a proficiency testing program is required by CLIA and provides an avenue to assist laboratories in addressing potential problems in testing as well as opportunities for corrective action (CDC -- MMWR, 1996). An important component of quality assurance, PT permits an external check to verify the accuracy of a laboratory's results by providing specimens with unknown values for the laboratory to analyze (Clinical Laboratory Management Association, 2002). PT performance trends also assist laboratory professional organizations to plan educational programs to improve the quality of laboratory testing. According to Hamlin (1999), the goal of PT is continual performance improvement through the processes of peer review and education.

Participation in external quality assessment programs such as PT is one tool that provides objective evidence that a laboratory is producing satisfactory results. According to CAP, laboratories are required to participate in PT for all analyte for which PT is available. A subset of analytes is regulated by the Centers for Medicare and Medicaid (CMS). PT providers are required to offer five challenges for regulated analytes at a

frequency of three times annually. A challenge is a specific test event to be performed on specimens sent by the PT provider to the participant laboratories (CAP, 2004). The laboratory's results are then compared with a homogeneous group of other laboratories that are using the same method and instrument. The accurate analysis of four of the five challenges for each analyte in microbiology, diagnostic immunology, chemistry, hematology, immunohematology and each discipline's subspecialties is required for satisfactory performance. For ABO and Rh Blood Grouping and compatibility testing, a 100% pass rate is required. "Unsatisfactory performance" is defined as more than one unacceptable result for any given analyte during any single testing challenge. Under CLIA'88 regulations, "unsuccessful performance" results when the laboratory performs unsatisfactorily for the same analyte in two out of three consecutive PT periods (CAP, 2004). Further, a laboratory is classified as "suspended" if more than two incorrect scores are produced on any analyte or if the overall score is less than 80% on two of three consecutive surveys. Subsequently, all testing in that category must be ceased until the method is corrected; and the analyte is reinstated. For each challenge that is not correctly analyzed, the laboratory must identify the type of error, when possible, and suggest possible corrective actions. Error categories include methodologic problems, technical problems, and clinical errors, problems with survey materials, other types of error, or no explanation after investigation.

CLIA'88 regulations established fixed limits for PT performance as percentages or absolute values from target values. Target values are based on the mean of all responses for all participants (after removing outliers > 3 standard deviations from the original

mean) or the mean established by the definitive or reference methods acceptable in the National Reference System for the Clinical Laboratory by the Clinical and Laboratory Standards Institute (CLSI, formerly the National Committee for Clinical Laboratory Standards) . A reference or definitive method is that method for a particular analyte that is accepted by CLSI as the standard method to evaluate and compare laboratory results. If definitive or reference methods are not available, a comparative method may be used (Westgard & Klee, 2002). Indeed, reference methods do not exist for many controlled analytes; and in some cases, values obtained for some analytes do not agree with the reference methods due to differences in matrices or analyte forms. In such cases, peer group means are used as the target value and accepted analyte result.

The Relationship of Reimbursement and Managed Care to the Clinical Laboratory

Historically, under "fee for service" reimbursement practices, total health care expenditures increased in the United States from 26.9 billion dollars in 1960 to 247.2 billion dollars in 1980, representing an increase from 5.1% to 8.9% in the gross national product (Takemura & Beck, 2001). With "fee for service" practices, there is payment of fees to physicians that are established by the physician or by each reimbursement agency for each service performed. This rapid increase in healthcare costs is attributed to new technology, an increase in the elderly population, and financial incentives for hospitals and physicians under "fee for service" practices.

The development of automation and technology in the clinical laboratory over the past 30 years permitted the laboratory profession to keep pace with the rapidly increasing

workload. The laboratory test menu expanded as new technology provided additional clinical laboratory procedures as well as innovative methodologies. Further, there was increased utilization of previously existing laboratory procedures. However, it was the opinion (Plebani, 2002) that the focus was primarily on the analytical component of the profession and the clinical value of laboratory testing as related to patient outcomes was minimized.

Plebani (2002) states that the value of laboratory professionals in the total scope of health care and their contribution to medical outcomes was hindered by the focus on technology and attention to the analytical phase of testing. Other issues that contribute to quality laboratory services such as test and method selection, specimen handling, test interpretation and utilization were not considered as important laboratory services. Laboratory professionals were reluctant to include these issues in their scope of practice, which lead to poor communication between the laboratory and clinicians and the resultant increased error rates in both the pre-analytical and post-analytical phases. Underestimating the clinical value of laboratory testing has led to the belief that laboratory quality is the same everywhere (Plebani, 2002). Administrators have evaluated laboratory services primary in terms of cost and not as a significant contributor to medical outcomes or as a part of the institution's goals for cost-effective patient care.

Under "fee-for-service" reimbursement, the clinical laboratory was viewed as a revenue center for the hospital and health care system. Pricing policies were not related to real costs or services offered, until the need to control unnecessary costs associated with laboratory testing became apparent with the advent of the prospective payment system

(PPS) which was based on diagnostic related groups (DRGs). The PPS permitted hospitals a predetermined sum to cover all expenses for a patient for a given hospitalization based largely on the patient's diagnosis at discharge. The DRG fee created incentives for hospitals to shorten the length of the hospital stay, decrease the number of admissions, and reduce unnecessary services. With the institution of the DRG/PPS in 1983, the laboratory was transformed into a cost center. Although revenues were still generated by outpatient laboratories, some hospitals responded by reducing operating expenses of the laboratory by constraining laboratory growth and development (Plebani, 2002; Takemura & Beck, 2001).

Cost reductions were sought in the clinical laboratory, with no reduction in the number of tests performed. Technological approaches, such as consolidation of laboratories, larger laboratory units, improved automation, and decreasing the costs of reagents were used to reduce the costs of clinical laboratory testing. Reduction in the number of laboratory positions, career opportunities, economic incentives, research opportunities, continuing education, and other professional activities resulted. Additionally, authority in technical decision-making was shifted from the laboratory to the hospital administrators (Plebani, 2002).

Shorter inpatient stays and discouraging patient admissions with a shift toward testing in the outpatient environment have also impacted the volume of hospital laboratory analysis. In the past, hospital laboratories focused on inpatient testing, high technical quality, rapid turn-around time for the acutely ill, quality improvement, accreditation, and providing quality patient care. This focus resulted in a high unit cost

for hospital laboratory testing when compared with the high volume, batched testing performed in commercial reference laboratories (CRL).

The shift to off-site laboratory testing and growth in new health care settings, such as diagnostic clinics, outpatient care centers, and urgent care facilities produced a negative effect on traditional hospital laboratories. Laboratory services have become dispersed throughout healthcare networks with a variety of personnel who do not hold clinical laboratory degrees performing the analyses. From 1986 to 1996, tests performed in hospital laboratories have decreased from 52% to 46% while tests performed in CLRS have nearly doubled since 1986 and now comprise 39% of the total. (Takemura & Beck, 2001).

At the same time, the volume and types of laboratory tests performed in POLs and their expenditures have increased since Congress passed the DRG/PPS for Medicare inpatient reimbursement in 1983. Technological advances that reduced the size and cost of laboratory equipment have also supported this growth in POL testing. In the POL, kits and simpler analyzers that required less expertise replaced analysis previously performed by trained and experienced laboratory personnel. Further spurring this escalation of laboratory testing within the physician office setting was the fact that POLs were exempt from any state or federal regulations under the Clinical Laboratory Improvement Amendments of 1967 (CLIA'67). While hospital and reference laboratories were federally regulated and participated in accreditation processes, including proficiency testing and other standards imposed through CLIA'67, POLs were able to perform laboratory tests at minimal costs while receiving the same reimbursement as the regulated

laboratories (Plebani, 2002). An expanding volume of CLIA waived tests has increased the volume and scope of laboratory analysis in POLs since CLIA'88 (Steindel, et al., 2000).

Laboratory Quality

Laboratory quality is dependent upon proficiency in three phases of clinical laboratory analysis, which are the preanalytical, analytical, and postanalytical phases. Errors in any phase of testing may compromise laboratory quality and, subsequently, adversely affect patient care and outcomes. Errors that occur in the preanalytical phase are those that occur prior to testing. Examples of preanalytical errors include errors in test initiation, failure of communication regarding test wanted, misidentification of patient samples or mislabeled samples, delay in specimen collection or processing, inappropriate specimen collected, deterioration of analyte during transportation, specimen sent to wrong laboratory, specimen lost or insufficient quantity, and specimen clotted or hemolyzed. Additional variables that may result in preanalytical errors include inappropriate test utilization or practice guidelines, and patient preparation. Analytical errors occur during the testing procedure. Types of analytical errors are errors in specimen preparation, analyzing the wrong specimen, authorizing results in spite of poor quality control, inaccurate testing process, instrument malfunction, error in instrument operation, calculation errors, unsuitable reagents or controls, premature authorization of results that require further action, and quality control errors. The personal characteristics and techniques of individual analysts may affect certain analytical methods significantly, particularly manual methods (Westgard & Klee, 2001). For example, completion of a

program in clinical laboratory sciences with emphasis on the significance of laboratory testing may impact an individual's performance in the clinical laboratory when compared to the performance of a practitioner who has not completed a clinical laboratory major. Additionally, attainment of professional certification or additional laboratory experience may alter an individual's decision process in performance of laboratory testing. Errors in the postanalytical phase include errors in recording and reporting results, misplaced results, invalid or improper reference comment, inappropriate reference range, failure to alert results outside of critical limits, uninterpretable or incomplete reports, the failure to interpret results correctly, and delayed turn around times.

Medical error is one of the few areas in which the clinical laboratory is visible to the public (Bissell, 2000). As clinical laboratories become more automated and laboratory personnel become more productive, their errors have the potential to adversely impact a larger number of patients who could be negatively impacted by one mistake. Bissell notes that sources of these errors are faulty maintenance-related decisions or in poor managerial decisions, such as inadequate procedures, insufficient operator training, lack of supervision, and flawed policy-making. The management response to quality and safety problems caused by human error may be to either deny that the error occurred or to acknowledge that the error is important, to repair any damage through public relations and service recovery, or reform through communication and process improvement as is exhibited through total quality management (TQM). Error management principles, such as learning from errors, are an integral component to training laboratory personnel.

Laboratory Error Reduction

The CDC, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) have created the Patient Safety Task Force, which is a federal initiative to monitor and promote patient safety in the United States. Through the CDC's Division of Healthcare Quality Promotion (DHQP), major healthcare challenges have been identified with the publication of the CDC's Seven Healthcare Challenges published in 2001. Within five years, the CDC's DHQP plans to accomplish seven challenges that involve the protection of patients and healthcare personnel and the promotion of safety, quality, and value in the healthcare delivery system. These challenges include a 50% reduction in adverse events relative to catheters (Challenge 1), surgery (Challenge 2), and nosocomial pneumonia (Challenge 3). Further challenges are related to healthcare providers and include the elimination of occupational needlestick (Challenge 6) and 100% adherence to the Advisory Committee on Immunization Practices (ACIP) guidelines for immunization of healthcare personnel (Challenge 7). An important component of this initiative is to identify and eliminate laboratory errors through Challenge 5 that addresses the need to eliminate laboratory errors leading to adverse patient outcomes (CDC, 2001). Additionally, laboratory testing plays a key role in Challenge 4 of the CDC's DHQP Seven Healthcare Safety Challenges, which is "to reduce targeted antimicrobial-resistant bacterial strains by 50% through appropriate diagnosis and treatment" (CDC, 2001). The need for reduction in laboratory errors is illustrated through the cooperative, national effort that emphasizes the significance of quality laboratory performance.

Specific examples of laboratory errors and the resulting negative outcomes further illustrate the concern for quality laboratory analysis. Boone, Steindel, Herron, and Howanitz (1995) surveyed transfusion medicine practices in 1990 to determine the distribution of errors and related complications and to recommend improvements in the transfusion process. The mailed survey to hospital, independent laboratories, and blood centers revealed that over 6.2 million units of blood and blood products were processed with over 88,000 errors detected. Of these errors, 41% were noted in the preanalytical phase of testing, 55% in the post analytical phase of testing, and 4% in the analytical phase of testing. The most commonly reported sources of error included misinterpretation of orders, misidentification of specimen containers or requisitions, incomplete testing of units prior to release, incorrect charting of results, exceeding defined turnaround times, and not performing or recording a patient's vital signs during transfusion. The study recommended the application of TQM to all phases of laboratory testing, including the preanalytical and postanalytical phases to eliminate errors in blood processing.

Nutting, et al. (1996), performed a descriptive study in which participating office-based clinicians reported each occurrence of any laboratory incident during a six-month study. The participants were 124 primary care clinicians in 49 practices of the Ambulatory Sentinel Practice Network (ASPN). In the study, 180 problems were reported, producing a rate of 1.1 problems per 1000 patient visits. Results suggested that 56.7% of the laboratory problems occurred during the preanalytical phase, and 13.3% and 30.0% for the analytical and postanalytical phase of testing, respectively. Problems attributed to the analytical phase varied from 40% for physician office laboratories to

4.4% for tests sent to reference laboratories. Forty-nine (26.9%) of the reported problems had an effect on patient care, with 45.4% judged to be clinically significant, impacting patient care, with the remainder generally requiring specimen recollection and retesting. The study concluded that problems associated with laboratory testing that are apparent to the practice are relatively infrequent, but patient care is affected in about 27% of the occurrences. The majority of the problems were related to communication and specimen management, especially those specimens that were sent to a reference laboratory for analysis. Thus, a greater number of preanalytical errors occurred in the reference laboratory when compared to other laboratory types. Limitations of this study include a design that examined laboratory problems from the practice perspective, which may have resulted in underreported errors. Yet, these limitations permit an assessment of the problem in terms of clinical decision-making and impact on the patient. A self-report system may also have contributed to underreporting problems so that the practice could avoid self-inculpation. In addition, the total number of laboratory tests ordered by site was not recorded so that the percentage of problems with each site could not be determined. Demographic information regarding the credentials of the testing personnel, including degree, major, years of laboratory experience, and certification were not included in the study.

Plebani and Carraro (1997) reviewed the types and frequency of mistakes in a stat laboratory. Total quality management concepts were applied to the total laboratory process in this study of stat testing that monitored different departments of a university hospital in Italy. Of the 40,490 analyses, 189 laboratory errors (0.47%) were identified.

The distribution of the mistakes revealed 68.2% to be preanalytical, 13.3% to be analytical, and 18.5% to be postanalytical. While most of these errors (74%) did not affect patients' outcomes, the remaining 26% of the mistakes either resulted in inappropriate investigations (37 cases or 19.6%) or inappropriate care or inappropriate modification of therapy (12 cases or 6.4%), which adversely affected patient outcomes.

Witte, VanNess, Angstadt, and Pennell (1997), studied 219,353 clinical chemistry results and compared each result with its replicate, comparative, or repeat value to identify differences from expected values. Values that varied by ≥ 7 standard deviations (SDs) or coefficient of variation (CV) from the expected value were identified as unacceptable results. Of the 219,353 analytes tested, 98 differed from the expected value by over 7SDs and 79 additional results differed from the expected value by 4.0 to 6.9 SDs. Malfunction of automated analytical instruments was cited as the major cause for these unacceptable results. The potential laboratory outcome of unacceptable quality-control specimens is generally a repeated analytical run (Witte, et al., 1997). Many of the unacceptable patient results did not cross typical decision points or were not independent tests for decision-making. Other results did cross decision-making values but would not alter patient management. However, of those results that differed from the expected value by 4.0 or more SDs, nine results had potential to cause errors in patient management. These included an incorrect adjustment in therapeutic drug concentration, test results erroneously reported as normal, and an error in a glucose measurement, leading to an errant report of hypoglycemia. These nine results translate to 41 parts per million (ppm).

Further, 14 of the results differing by 4.0 or more SDs were judged to cause confusion to patient management, which translates to 64 ppm.

Multiple misdiagnoses of tuberculosis attributed to due laboratory error from sample cross-contamination were reported in *Morbidity and Mortality Weekly Report* (CDC, 1997 & 2000). Eighteen cases of a false positive diagnosis of tuberculosis were reported in Wisconsin (seven cases, 1996) and in New Jersey (11 cases, 1998). These misdiagnosed cases of tuberculosis illustrate the medical and financial burden of erroneous laboratory results, as many of the patients received costly, toxic antituberculosis medications, which were not warranted. In the scenarios in Wisconsin and New Jersey, laboratory error could have been prevented through using standardized laboratory procedures that avoided contamination of specimens or instruments through proper handling of laboratory cultures and supplies. This example further illustrates the need for laboratory expertise in an era characterized by increasing cases of tuberculosis as well as the use of complex molecular techniques in the microbiology laboratory.

In Pennsylvania in the summer of 2001, a laboratory testing error resulted in three patient deaths and several related patient morbidities. Physicians routinely monitor the anticoagulant drug, warfarin (Coumadin^{R}) by following two laboratory results, the prothrombin time (PT) and the International Normalized Ratio (INR). The World Health Organization recommends the INR to standardize PT results among various manufacturers, reagents, and laboratories. The cited hospital laboratory reported 2146 tests with correct PTs, but falsely decreased INRs, which were identified as the cause of the error. Because of this error, some physicians increased the dose of warfarin that led to

three deaths, as well as numerous other patient morbidities (MMWR, 2001). Furthermore, this self-reported error resulted in a $447,000 fine levied against the hospital by the Pennsylvania Department of Health based on the hospital's failure to provide accurate lab tests to 843 patients over a 52-day period, equaling a penalty of $500 per patient plus an additional $500 for every day inaccurate testing was conducted (Robeznieks, 2001). Quality laboratory performance as measured by correct reagent preparation, calculations, and instrument calibration may have prevented the laboratory error and associated adverse outcomes.

Bonini, Plebani, Ceriotti, & Rubboli (2002) conducted an extensive literature review of laboratory errors, finding great variation in study designs, little available data, and a lack of a universal definition of "laboratory error." The review was limited to studies accessed in the last eight years and confirmed that most laboratory errors occur in the preanalytical phase of testing. Even with different study designs, patient numbers, and discovery techniques used, the distribution of errors across the different phases of the testing process was very similar. The studies included in the review revealed that a large percentage of laboratory errors occurred in the pre- and post-analytical phases. Specifically, preanalytical errors accounted for 31.6% to 75% of the errors; analytical errors ranged from 13.3 % to 31%; postanalytical errors ranged from 9% to 30.8%. Errors rates were reported as often as one in every 33-50 events (McSwiney & Woodrow, 1969) and as infrequently as one error for every 8300 laboratory results or 2000 patients (Lapworth & Teal, 1994). A limitation in this review was that most of the studies focused on analytical errors and represented only a portion of all testing errors. A second

limitation was that the most frequent types of preanalytical errors (inappropriate choice of laboratory test or test panel) and postanalytical errors (inappropriate interpretation and utilization of laboratory results) were outside of the scope of the laboratory's control and needed to be corrected through improved communications with clinicians. The third limitation cited was that laboratories are reluctant to report their own errors and that error detection is difficult because many errors produce neither detectable abnormal results nor raise suspicions for the laboratory practitioner.

Although there have been tremendous technological advances in laboratory automation, significant sources of error that may contribute to adverse clinical outcomes exist in the hematology laboratory (Sandhaus, 2003). Sandhaus reported that "most" laboratory personnel who rotate through a local hematology laboratory admitted to making an error within the last month. The most frequent error was inappropriate verification of results that should have received further evaluation. While the hematology analyzer produces numeric and graphic data, a competent technologist must also correlate and interpret the data. Incomplete or incorrect data correlations may result from inadequate training, insufficient staffing, and pressure to meet turn around times.

The need to measure and improve laboratory-related patient outcomes requires methods that analyze the total testing process. Improvement in analytical quality, documented through proficiency testing, should guarantee that the actual laboratory performance is suitable to improve the patient's health (Bonini, et al., 2002). Emphasis toward error reduction in the preanalytical phase and postanalytical phase of laboratory testing is essential to improve patient's clinical outcomes. However, pioneers in the

clinical laboratory caution against becoming too complacent with the analytical phase of testing. Dr. Arnold Beckman, who invented the acidometer, pH meter, and DU^{R} spectrophotometer, has emphasized the need for excellence in laboratory analysis (Beckman-Coulter, 2004). Tietz (1994) has expressed concern that laboratorians have lost their focus on the need for procedures to be accurate, precise, specific, and comparable among laboratories cautioning that quality 'may not' be the same everywhere.

The Relationship of Laboratory Errors, Testing Site, and Personnel Credentials

Advances in automation and technology combined with the reluctance of laboratorians to participate in decisions related to pre-analytical and post-analytical factors and decision making with other health care providers has led many individuals in healthcare management to minimize the value of quality laboratory services. According to Plebani (2002), some individuals in healthcare management believed that laboratory quality was the same regardless of the testing site or personnel. Others (Kisabeth, 2001; Takamura & Beck, 2001) have questioned the quality of laboratory analysis performed in sites that employ individuals who are not educated in the clinical laboratory discipline.

Various studies have attempted to relate the percentage of laboratory errors to the type of laboratory testing site or the credentials of the testing personnel. Stull, Hearn, Handcock, Handsfield, & Collins (1998) reported the variation in proficiency testing (PT) performance by testing site during the first year of mandatory participation under CLIA'88. The study design consisted of all 1994 PT score data reported to the Health Care and Finance Administration (HCFA) as a component of compliance with the CLIA regulations. Over 1.2 million PT event scores from 17,058 unique testing sites were

divided into two groups based on the type of testing facility, which included hospitals and independent laboratories (43% of sample) and all other testing sites, such as POLs and clinics, (57% of sample). The main outcome measure was satisfactory or unsatisfactory performance rates for each analyte or test. The aggregate rates of satisfactory test performance for all regulated analytes and specialties were 97% for hospital and independent laboratories and 91% for all other testing sites. The aggregate odds ratio for unsatisfactory PT event performance for the individual analytes was 2.89 (range of 2.19 to 7.51). The results of this analysis indicated disparate PT performance between traditional laboratories and alternative testing sites. Unsatisfactory test event performance rates for the three most commonly offered and regulated tests and specialties among the other testing sites were particularly striking. These unsatisfactory test events were glucose (15%), hemoglobin (9.1%) and bacteriology (7.2%). Previously unregulated alternative testing sites may lack laboratory professionals who hold expertise in quality control, quality assurance, and proficiency testing (Stull, et al., 1998). Further a physician who does not have expertise in quality laboratory practices may direct alternative testing sites. According to the authors, the varied performance by the groups may also be explained by economic, technical, or other managerial factors.

In another study, Hurst, Nickel, and Hilborne (1998) compared the quality of laboratory data reported in physician office laboratories to that produced in other laboratory settings. The study sample consisted of all California clinical laboratories that participated in the American Association of Bioanalysts (AAB) proficiency test program in 1996. The laboratory facilities were divided into three types, POLs (159), POLs using

clinical laboratory scientists (129), and non-physician office laboratories (437). The study reviewed the PT performance data for 11 analytes that are commonly performed in both POLs and non-POLs. Specific analytes were glucose, potassium, lipids, thyroid-stimulating hormone, digoxin, erythrocyte and leukocyte counts, prothrombin time, and urine cultures, and the infectious mononucleosis screen. These analytes chosen for the study were clinically important, widely ordered by physicians, and used both for preliminary patient screening and monitoring common clinical conditions. "Unsatisfactory performance" was defined for the analytes used in this study as a score of less than 80% for any given analyte during any single testing challenge or a score of less than four acceptable results for each set of five unknown specimens. "Unsuccessful performance" was defined as two or more consecutive unsatisfactory scores or two unsatisfactory scores of any three consecutive testing events for each analyte.

According to Hurst, Nickel, and Hilborne (1998), the unsatisfactory performance rate for POLs (21.5%) was nearly three times as great as that of the non-POLs (8.1%) and about 1.5 times that of the POLs staffed with CLS/MTs (14.0%) as either testing or supervisory personnel ($p<0.001$). The unsuccessful performance rates ($p<0.001$) revealed a POL failure rate (4.4%) over four times that of the non-POLs (0.9%) and twice that of the POLs using CLS/MTs (1.8%). The study also showed that unsatisfactory performance for each PT testing event was three times the failure rate ($p<0.001$) for each of the three testing challenges for POLS (8.5%, 9.5%, 10.8%) when compared to non-POLs (2.5%, 3.3%, 3.8%). Unsatisfactory scores for chemistry and hematology by testing challenges also revealed similar findings.

In 1994, the CDC studied 17,058 laboratories enrolled in the seven largest Department of Health and Human Services (DHHS) - approved PT programs and whose PT results were reported to HCFA in compliance with their CLIA certificates of registration. The participating laboratories reported approximately 1.2 million PT scores and included 43% hospital laboratories, 36% POLs, and 21% other types of laboratories (which included 20 other laboratory types, such as community clinics, ambulatory surgery centers, and ancillary testing sites). Overall success rates were 97%, 89%, and 94% for the hospital laboratories, POLs, and other laboratory types, respectively. Data analyzed for the ten most common tests showed PT failure rates of 1.2% for hospital laboratories, 4.1 – 15.9% for POLs, and 2.1 – 11.6% for other laboratory types. Further, logit odds ratios of unsatisfactory PT performance (95% confidence interval) for these common analytes ranged from 2.4 to 6.0 for POLs and 1.4 to 3.6 for the other laboratory types when compared to hospital laboratories. The use of PT performance as an indicator of laboratory quality is limited because PT primarily assesses the analytic and not the preanalytical or postanalytical steps in laboratory test. Further, although the study included findings from the two largest DHHS-approved PT programs, which are AAB and the College of American Pathologists (CAP)], the findings may not be representative because scores from all DHHS-approved PT programs were not available for analysis. Additionally, demographic information and credentials of the testing personnel, laboratory experience with the proficiency testing process, size of the laboratory and level of testing expertise were not included in the study. Presumably, these are some of

the factors that may have resulted in the higher failure rates exhibited by POLs and other laboratory types when compared to hospital laboratories.

POL volume grew prior to implementation of CLIA'88 regulations with limited regional and state regulation. Even though POL testing has leveled off since 1992, it is estimated that 571-899 million laboratory tests were performed through POL testing in 1996. Using a sampling frame of the National Ambulatory Medical Care Survey (NAMCS), St. John, et al. (2000) used quality indicators to collect data before and after implementation of CLIA'88. The study used enrollment in a proficiency program and daily quality control with corrective action as quality indicators and as the dependent variables. Independent variables analyzed included the type and specialty of the medical practice, whether or not a medical technologist or medical laboratory technician was on site, whether only simple testing or if at least one complex test was performed, the year of the survey, and volume of testing. The data was collected and analyzed for years 1989, 1991, 1993, and 1994. Simple tests included in the study were urinalysis, urine pregnancy, hemoglobin, hematocrit, glucose, and occult blood. Complex tests included leukocyte count, prothrombin time, uric acid, blood urea nitrogen, cholesterol, creatinine, sodium, potassium, triglycerides, urine colony counts, theophylline, and streptococcus screens.

Logistic regression was used to determine if significant increases in the quality practice indicators were related to the implementation of CLIA'88 in 1992. Statistically significant changes in laboratory testing practices were observed relative to 1992 as the study concluded that enrollment in PT programs increased from 32.4% to 52.7%

($p<0.001$). Further, use of daily quality control samples increased from 79.2% to 89.0% ($p<0.001$) and use of daily quality control with written instructions for action increased from 62.6% to 77.2% ($p<0.001$) relative to the implementation of CLIA'88.

The presence of a medical technologist or technician in the office laboratory was also significantly and independently associated with each of the quality indicators. For example, performance of testing by a medical technician or medical technologist was positively associated with successful performance in PT. Testing personnel prior to1992 included physicians, (27%), nurses (30%), medical assistants (18%), medical technicians (20%), medical technologists (12%), and 'other' testing personnel, including physician's assistants (3%). There was no statistical difference ($p = 0.43$) found in the percentages or the demographics of the types and credentials of testing personnel relative to CLIA'88. However, statistically significant improvements in all three quality indicators (daily QC, corrective action for QC, participation in PT) were noted relative to 1992 when a medical technologist or technician was on site. These improvements may be the direct result of the imposition of CLIA'88 regulations as an effort by the medical community to comply with regulations to meet the minimal quality standards. Further, trained personnel may facilitate compliance with minimum quality standards as noted by others (Hurst, Nickel, & Hilborne, 1998; Lunz, Casteberry, & Stahl, 1987).

According to Westgard and Klee (2001), the technical competence of personnel should be checked, although such assessment may be difficult. Periodic monitoring of competency from incident reports and results from internal and external quality control checks can identify specific problems. Proficiency test results are used to assess both the

accuracy and reliability of testing because PT is required of all laboratories performing moderate or high complexity testing. PT performance is not a perfect surrogate (Hurst, Nickel, & Hilborne, 1998) for actual laboratory quality but has been shown useful to identify concerns in analytical performance. Jenny and Jackson (1993) have shown that proficiency test performance is a valid predictor of accuracy of routine patient testing for theophylline levels. Thus, a relationship would seem to exist between the type of testing site and credentials of the testing personnel to proficiency test performance.

Laboratory Personnel Credentials

Prior studies (CDC, 1994; Stull, et al., 1998; Hurst, Nickel, & Hilborne, 1998) have shown that performance on proficiency test surveys varies with the type of laboratory as well as the characteristics of the testing personnel including education, training and attainment of a MT/CLS degree. Further, a variety of testing personnel are utilized in clinical laboratory analysis; these include medical laboratory professionals as well as those not trained in the laboratory profession, such as medical assistants and nurses. Testing personnel may hold no post-secondary education, an associate degree, a baccalaureate degree, or a graduate degree.

Certification is currently available through various national certification agencies; the majority of certification occurs through the National Credentialing Agency (NCA) and the American Society of Clinical Pathology (ASCP). Certification levels include the Clinical Laboratory Assistant (CLA), Clinical Laboratory Technician/Medical Laboratory Technician (CLT/MLT), Categorical (Hematology, Microbiology, Blood Banking and Chemistry), Clinical Laboratory Scientist/Medical Technologist (CLS/MT). Furthermore,

specialty examinations in specific departments, such as hematology, blood banking, or management are also available. Individuals may receive formal training from accredited programs for laboratory sciences to become medical laboratory technicians (clinical laboratory technicians) or medical technologists (clinical laboratory scientists). Individuals who attain an associate degree from an accredited medical laboratory technician (MLT) or clinical laboratory technician (CLT) program are eligible to take the certification examination at the MLT/CLT level. Those obtaining a baccalaureate degree in clinical laboratory science (CLS) or medical technology (MT) from an accredited program are eligible to become certified by successfully passing a certification examination at the MT/CLS level. Individuals may also become eligible to take certification examinations in MLT/CLT or MT/CLS through alternative routes that combine educational background and years of clinical laboratory experience. Thus, laboratory practitioners may become eligible to take a certification examination by obtaining an associate or bachelor's degree followed by a required number of years of clinical laboratory experience. In this case, an individual can become certified without graduating from an accredited laboratory program, yet must meet minimal educational requirements and clinical experiences.

As clinical laboratories continue to experience difficulties in filling vacancies with qualified clinical laboratory professionals, some laboratories have hired individuals without formal laboratory education and provided on the job training (OJT) (Mass, 2001). While OJTs might provide a quick remedy to the shortage of qualified laboratory professionals, such individuals lack the understanding of the clinical laboratory, limiting

their effectiveness as the number of tasks that they can perform. It is also believed that OJTs (Mass, 2001) have a greater potential for making errors and actually increase the cost of healthcare by requiring additional training, increasing the chances of litigation, and increasing the number of repeat tests. Consolidation of workload and downsizing of staff have also been used by laboratory managers to contain costs in the healthcare industry. As a result, many dedicated laboratory workers have left the clinical laboratory for other opportunities that provide greater respect and financial rewards.

To define and differentiate the roles of individuals with formal training in the clinical laboratory sciences, Doig, Beck, and Kolenc (2001) performed a national job analysis of tasks for the clinical laboratory scientist (CLS) and for the clinical laboratory technician (CLT). The survey was mailed to 1200 individual practitioners, educators, and laboratory managers with a 33% return rate for CLT and 21% return rate for CLS respondents. The reliability rating based on average interclass correlation coefficients of 0.86 for CLT respondents and 0.82 for CLS respondents. There were over 1100 tasks on the original survey with an overlap of 722 tasks (76%) between CLT and CLS content, verifying that the distinction between CLS and CLT practitioners has often blurred in clinical practice. However, the survey revealed that CLS and CLT positions are distinct at job entry level, with the CLS performing a broader range of technical, communication, and management tasks. At entry level, the CLT was found to perform more of the routine laboratory tasks, according to protocol, while the CLS held more specialized job responsibilities, including problem solving, quality assurance, and consulting functions. However, in contrast to the American Society of Clinical Laboratory Science (ASCLS) model of laboratory practice,

it was concluded that CLTs also perform higher level cognitive tasks related to technical problems and clinical correlation, such as problem solving and quality assurance. Further, although a distinction is drawn between the two levels of practice, it does not appear to be as clear as in the past. Doig and Beck also confirmed that comprehensive and diverse educational skills are required for laboratory practitioners at both the CLT and CLS levels. As the scope of laboratory practice extends to a variety of testing personnel, it is important to assess the contributions of education to the practitioner's performance in the clinical laboratory. Thus, the level of education is an important variable to consider in relation to the depth and quality of laboratory performance.

Years of experience may also impact the quality of work performed by clinical laboratory personnel. The lack of experienced personnel and learning curve present for new employees may impact the quality of an individual's performance. Additionally, according to the 2003 Wage and Vacancy Survey of Medical Laboratories (Steward, Ward-Cook, and Tannar, 2005), insufficient staff are entering the work force to replace the laboratory staff expected to retire in three to five years. The relationship of inexperienced personnel, as well as those who have been in the work force for many years to performance on PT surveys provides another measure of personnel performance.

Regulation of the Profession

In addition to education and years of clinical laboratory experience, certification through a national organization is another mechanism to predict the competence of health care personnel (Lunz, Castleberry, James, & Stahl, 1987). Certification is described as a process whereby a nongovernmental agency or association grants recognition, usually to

an individual who has met pertinent qualifications specified by that agency or association, such as passing a national certification examination (Waller, 2003). Certification is generally a voluntary process and is increasingly used by employers as a way of ensuring that their employees are of high quality and is knowledgeable (Duncan, 1999). Certification is the process through which a nongovernmental agency or association grants recognition of competence to individuals that meet predefined qualifications, which are specified by that agency or association (ASCP, 2005). Licensure is a governmental activity taken on in behalf of the public to protect the public from potential harm. A license authorizes by legal permit or formal permission from a constituted authority, such as a state or federal agency (ASCLS, 2005). If a license is required to practice a profession, it is unlawful to engage in the work without a license. In the clinical laboratory, certification is not always a requirement to be employed as a laboratory practitioner except in those 12 states that require licensure. Lack of certification may limit an applicant's ability to find employment, but it is not unlawful to work without certification in most states. However, certification may be used as a mechanism to determine an employee's competence or ability to perform at a particular level or to be promoted to a higher level position within the laboratory, and may also affect that individual's salary.

Certification examinations for laboratory personnel are objective and include questions at all taxonomy levels. The examinations are based on competency and test knowledge regarding laboratory principles and methodologies, problem solving, error detection, and clinical significance. Theoretically, examinees that can demonstrate the

knowledge and skill to pass a certification examination should be able to apply that knowledge to the practical laboratory setting and perform accurate test analyses (Lunz, Castleberry, James, & Stahl, 1987). Thus, certification credentialing through a national organization may be an important indicator for laboratory quality.

Shortage of Qualified Laboratory Personnel

The clinical laboratory relies on a skills mix of personnel who hold a variety of educational backgrounds, certification types and levels, and years of laboratory experience. Vacancy rates continue to increase in many laboratory disciplines, as reported in "*The 2000 Wage and Vacancy Survey of Medical Laboratories*" conducted by the American Society of Clinical Pathology and its Board of Registry (ASCP-BOR, 2001). Table 1 summarizes the percent vacancy rates for laboratory professionals from 1996 to 2003. Increasing vacancy rates in three of the four clinical laboratory professions listed as well as the double-digit vacancy rates in each of the personnel categories further illustrate the critical shortage of laboratorians.

The 2002 vacancy survey, which reports the average national vacancy rates display some easing of the staffing shortage, yet vacancy rates varied widely depending on the employer type and practice setting. In particular, difficulty in filling shifts for evenings, nights, and weekends was noted by laboratory managers. Further, many laboratory managers reported increased use of per diem or temporary staff. Per diem staffing is not always budgeted in the same manner as regular full or part-time staff (Ward-Cook, Chapman, & Tannar, 2003) and, thus, may have led to an underestimation of vacancy rates. In addition, the total number of budgeted positions for all categories reported was

Table 1

Mean Percent (%) Annual Vacancy Rates for Laboratory Professionals

Position	1996	1998	2000	2002	2003
Medical Technologist, Staff	8.2%	10.2%	11.1%	7.0%	4.3%
Medical Technologist, Supervisor	8.6%	9.3%	12.5%	5.9%	3.3%
Medical Technologist, Manager	7.7%	15.4%	13.3%	3.7%	1.9%
Medical Laboratory Technician	9.4%	11.1%	14.3%	8.6%	5.9%

Note: Summarized from ASCP-BOR "2000 Wage and Vacancy Survey of Medical Laboratories", 2001; "2002 Wage and Vacancy Survey of Medical Laboratories," 2003; and 2003 Wage and Vacancy Survey of Medical Laboratories, 2005.

lower in 2002 when compared to 2000, which has been attributed to either budget constraints or difficult-to-fill positions. Thus, the lower vacancy rate in 2002 may be partially attributed to the elimination of laboratory positions, which would no longer be reported as a vacancy, thus reflecting declining vacancy rates.

According to the 2003 Wage and Vacancy Survey of Medical Laboratories (Steward, Ward-Cook, & Tannar, 2005), vacancy rates continue to decline. The report also indicated the need to investigate additional areas of laboratory staffing, such as the hiring of non-certified staff to fill positions that once required certification. Additionally, one third of the laboratories reported that applicants lacked the necessary skills and education to provide quality laboratory services. The need to redefine the skill requirements of the laboratory profession in the increasingly complex laboratory was also noted. As noted in the prior study (Ward-Cook, Chapman, & Tannar, 2003), budgeted positions continue to

be eliminated which creates difficulty in the determination of the actual vacancy rate in medical laboratories.

Further, as the number of retirements increase, the effects of these shortages will become more pronounced as the profession feels the effects of decreased numbers of experienced technologists and technicians. The impact of years of laboratory experience is also an important indicator of laboratory quality. The skills and experience of a new employee, a practitioner with a moderate level of experience, and a laboratory veteran are varied and may impact the quality performance of that practitioner.

The Effects of CLIA'88 and Proficiency Testing

Congress adopted the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) that mandated compliance with national quality standards as specified in these federal regulations. The goal of the CLIA '88 was to establish universal standards for clinical laboratory analysis such that quality patient care would be assured in all laboratory settings. CLIA '88 was implemented in 1992 and required all testing sites, including physician office laboratories (POLs) to be inspected by state agencies acting on behalf of the Health Care Financing Administration (HCFA). Also, all laboratories were required to obtain a certificate issued by the Department of Health and Human Services (HSS) for each category of tests performed (Boone, 1992). CLIA'88 designated various levels of laboratory analysis, each with its own federal guidelines and laboratory quality standards. The final CLIA regulations, published in 1992, are based on the complexity of the test method; thus, the more complicated the test, the more stringent the personnel testing requirements. Three categories of tests have been established though CLIA: low

complexity, moderate complexity (which includes the subcategory of Provider Performed Microscopy or PPMP), and high complexity.

All laboratories performing moderately to highly complex testing must participate in a CLIA approved PT program. Currently, there are currently six CLIA approved organizations that oversee the laboratory accreditation processes for proficiency testing. These organizations are the Commission of Office Laboratory Accreditation (COLA), the College of American Pathologists (CAP), the Joint Commission of Accreditation of Health Care Organizations (JCAHO), the American Osteopathic Association (AOA), the American Association of Blood Banks (AABB), and the American Society for Histocompatability and Immunogenetics (ASHI). Most hospital and reference laboratories participate in PT through CAP while POLs generally participate in PT through COLA. According to CMS (2005), there are 14 CLIA approved PT providers that supply PT survey materials to participant laboratories and perform assessment of submitted results. CLIA approved providers include CAP, the External Comparative Evaluation for Laboratories (EXCEL through CAP), the Medical Laboratory Evaluation Program (MLE), the American Association of Bioanalysts (AAB), the American Proficiency Institute (API), and others.

Those laboratories that perform low complexity testing defined as waived testing (Certificate of Waiver – COW) are not required to participate in proficiency testing. Those laboratories that perform provider-performed microscopic procedures (PPMP) are required to participate in proficiency testing twice annually. The number of tests waived under CLIA'88 has increased from eight tests to approximately 40 tests since the

implementation of CLIA in 1992 according to the CMS-CLIA Waived PPMP Laboratory Project of 2002. Further, the number of laboratories performing waived tests has grown from 20% to 54% of the total 171,000 laboratories currently enrolled through CLIA'88 regulations. PPMP laboratories currently represent 22% of the laboratories in the United States; thus, 76% of laboratories are either performing waived testing (54%) or are PPMP laboratories and, thus, have no direct routine oversight (HCFA, 2002). CLIA'88 regulations, however, provide for inspections of waived or PPMP laboratories under specific circumstances.

In a pilot study (CMS/CLIA Waived/PPMP Laboratory Project, 2001) and as reported by Szabo (2001), CMS used focused inspections to investigate numerous complaints in waived laboratories. The states of Colorado and Ohio initiated on-site inspections of a random sample of CLIA waived and PPMP laboratories. Over 50% of the laboratories were reported to have serious quality and certification problems. Additionally, 10% of Ohio laboratories and 7% of Colorado laboratories were testing beyond the certificate level for which they were enrolled. These laboratories were performing moderately complex tests and if properly enrolled in CLIA, would have been required to participate in biennial inspections and a proficiency testing program.

In an expanded pilot study of CLIA waived and PPMP laboratories, CMS inspected laboratories in eight additional states and found similar alarming results. The four major categories of personnel performing waived testing were registered nurses, physicians, licensed practical nurses, and medical assistants, personnel who do not receive formal clinical laboratory education. This pilot study also noted that very few medical

technologists or medical laboratory technicians were involved in the performance of waived testing. CMS also determined that 32% of the waived laboratories failed to have manufacturer's instructions, 32% did not perform quality control as required by the manufacturer or CDC, 16% failed to follow manufacturer's instructions, 23 % had certificate problems, 19% used personnel who were neither trained nor evaluated, and 6% used expired reagents (Szabo, 2001). The pilot study further found quality problems in PPMP laboratories with 38% failing to participate in proficiency testing twice annually as required by CLIA'88, 36% revealed no microscope or centrifuge maintenance, 28% had no standard operation procedure manual, 25% did not document personnel competency or use quality assurance methods, and 23% had certificate issues (Szabo). This report highlighted the association of quality problems in laboratory testing with the lack of professionally trained laboratory testing personnel in both CLIA waived and PPMP laboratories.

Proficiency Testing as a Measure of Laboratory Quality

Intralaboratory variation refers to variation in testing within one laboratory while interlaboratory variation refers to variation in testing between laboratories. Intralaboratory and interlaboratory variations in proficiency testing (PT) are the hallmark of laboratory quality assurance efforts. External quality assessment (EQA) is an important component in laboratory quality management and improvement (Miller, 2003). Thus, proficiency testing programs should assure the public of accurate and precise laboratory results regardless of where the testing is performed (Hurst, Nickel, Hilborne, et al., 1998). PT is an external quality control tool where simulated patient samples are

analyzed by participating laboratories, and individual laboratory performance is assessed by comparison to the collective performance by all participants (Stull, Hearn, Hancock, Handsfield, & Collins, 1998). The objectives of PT are to determine the clinical acceptability of laboratory results (Miller, 2003), to assess the appropriateness of laboratory protocols and to evaluate the laboratory personnel's ability to perform the analyses satisfactorily (Isenberg & D'Amato, 1996). Jenny & Jackson (2000) describe PT as a point sampling of laboratory output that is used to judge the quality of laboratory testing.

Performance in proficiency testing surveys provides a method to evaluate primarily the accuracy of the analytical phase of clinical laboratory testing (St. John, Lipman, Krolak, & Hearn, 2000). Theoretically, a laboratory that performs well on PT will also provide accurate testing results to clinicians, which aids in the appropriate patient diagnoses and effective treatment. Indeed, CLIA '88 regulations specify, "proficiency test specimens must be analyzed in the same manner as patient samples,"(Lunz, et al., 1992), providing a valid surrogate for laboratory analysis. Test materials for PT must mimic patient specimens and evaluation criteria must be consistent with current standards of practice (Jenny & Jackson, 1998). Further, all technical staff members who analyze patient samples are required to participate in PT to comply with CLIA'88 mandates. Government and accrediting agencies continue to use PT as an objective measure of the quality of laboratory analysis.

Each unacceptable PT result submitted to a PT provider must be investigated by the testing laboratory as a CLIA'88 regulation. An exception response form with supporting

documentation of the investigation of the problem must be submitted. The exception report is required to address how the laboratory investigated the problem, the conclusion as to the cause of the unacceptable result, specific corrective action to prevent a recurrence, and evidence that the problem was successfully corrected (*Arch Pathol Lab Med,* 1987). Quality control data, calibration and instrument service records may also be submitted as supporting documentation. The cause of the unacceptable result is an important aspect of the exception report. Table 2 summarizes common causes of unacceptable results (Hoeltge, et al., 2005).

Jenny and Jackson-Tarentino (2000) investigated the causes of unsatisfactory performance in PT by analyzing data from the New York State Department of Health PT program to evaluate toxicology testing. Two classes of error were reported; these were spurious results and common-cause analytic error. Of the 206,060 PT results reviewed, 106 spurious results were noted (300 per million assays or 0.03%). Causes of spurious results included inaccurate mathematical correction for specimen dilution, misinterpretation of instrument codes, instrument sampling errors, and transcription error. Common-cause analytic error accounted for 154 unsatisfactory events in 20,830 analyte challenges or 7000 per million assays (0.7%). Common cause errors included calibration drift, which indicates systematic error generally resolved by recalibration; method bias, which is often related to systematic error unique to a particular instrument or method; reportable range errors, which indicates significant analytical bias near the limits of the reportable range of the method; instability, which may indicate a component of the system (sample probe, reagent) is not performing properly; and random events,

Table 2.

Summary of Unacceptable PT Results

Cause of Unacceptable Result	Examples
Methodologic Problems	Instrument problem identified Instrument repaired or replaced Faulty standard or other reagent Incorrect calibration Other problem with method
Technical Problems	Misinterpretation or misidentification Dilution error Incorrect pipetting Delay between reconstitution and analysis Calculation error Run accepted in nonlinear range Run accepted although controls were out of range Samples mix-up Other technical problem
Clerical Errors	Transcription error Transposition error Incorrect peer-group code entered Failure to submit results
Problems with PT Materials	Hemolyzed specimen Bacterial contamination Perceived survey bias Poor growth in culture Unstable PT material Matrix effect incompatible with method No comparable peer group Acceptable range too low Late shipment
No explanation after investigation	Use only when a thorough investigation has yielded no satisfactory explanation

nonreplicatable events whose origin cannot be identified. Most of the participant failures (~60%) were attributable to analytical error, calibration drift being the most frequent cause of analytical error (48% of cases). The study indicated that approximately one-half

of the laboratories used an allowable error for quality control that exceeded the threshold error specified by manufacturers for stable instrument performance. The investigators concluded that allowable error in quality control and the manufacturer's specification must be consistent in order to insure intrinsic quality in laboratory testing (Jenny & Jackson, 2000). Further, ongoing competency testing of analysts is required when analyst intervention is necessary to reduce the causes of spurious testing in automated systems.

PT has been used as an analytical outcome in several early studies to assess personnel standards (Peddecord 1989, 1996; Lunz et al., 1987, 1992). As a quality indicator, PT data has several strengths. PT analysis is federally mandated for laboratories performing moderately to highly complex analysis, and performance data is readily available. PT provides a consistent and objective evaluation method utilized by diverse types of clinical laboratories. Acknowledging its limitations, PT remains an attractive indicator of analytical outcomes due to its availability and its history (Peddecord, 1996). Additionally, PT surveys must comply with state and federal requirements (Hurst, Nickel, & Hilborne, 1998) offering some consistency across various PT survey organizations and diverse laboratory settings. However, PT performance is not limited to a single provider and peer group stratifications and definitions influence the pass rate in various agencies.

PT is useful to identify analytical performance concerns and has been shown to reflect the quality of actual patient specimen testing (Hoeltge & Duckworth, 1987; Jenny & Jackson, 1993). Hoeltge and Duckworth (1987) reported that of 583 assessable PT errors, 78 (13.4%) were attributed to errors in methodology that had first been identified by PT. Subsequent correction of these errors would presume to positively impact the

quality of laboratory analysis of patient specimens. Jenny and Jackson (1993) used PT performance as a predictor for accuracy of patient testing for theophylline. In the study, split samples were used to evaluate the ability of conventional proficiency testing to predict laboratory performance. The study included 412 patient samples and 200 laboratories with theophylline concentrations at the subtherapeutic, therapeutic, and toxic levels. One objective of the study was to determine if accuracy in proficiency testing for theophylline was consistent with the quality of testing recorded by the PT program. Also, the predictive value of PT performance as related to the quality of routine patient testing was evaluated. Specifically, the study utilized patients' split samples and hand-carried PT specimens to determine if mail distributed PT samples accurately predicted the theophylline level in the patients' sera. The hand-carried specimens were introduced into the daily workload at each laboratory, thus, receiving no special treatment. Once analyzed, these on-site specimen values were paired with the results previously reported for the mail-distributed challenge. Paired t statistical analysis was used to determine if a statistical difference existed between the paired samples. At a 95% confidence level, no statistical difference was observed between the means. Using regression analysis, good agreement was found between the split-sample and PT data, which suggested that mail-distributed PT specimens provided a reliable estimate of the accuracy of routine patient testing (Jenny & Jackson, 1993).

In the analysis of theophylline, the PT program successfully identified all true negatives as there were no cases where the PT program judged the laboratory

determinations as unacceptable when the accuracy of the patient testing was found to be acceptable. Thus, the specificity of the PT program was 100% (n=374), indicating that the PT program judged laboratory performance as acceptable when the quality of testing was, likewise, acceptable. The sensitivity of the PT program, defined as the likelihood that the program would judge laboratory performance as unacceptable when the quality of the patient testing is marginal or unacceptable, was 34%. The predictive value of substandard performance in the study or the ability of the PT program to predict substandard reliability of routine patient testing was found to be 100%. Also, the predictive value of acceptable performance in PT or the ability of acceptable PT performance to exclude substandard reliability of routine patient testing was 94%. Given this high predictive value, Jenny & Jackson (1993) concluded that PT performance is a valid predictor of the accuracy of routine theophylline testing in patients. The study, however, was limited in analyzing a single analyte, and a single PT provider.

Keenlyside, et al. (1999) compared proficiency test results with the work performance of screeners of Papanicolaou smears. The screeners' performance on a glass-slide proficiency test was compared to the screeners' performance through rescreening of their work. A positive correlation was found between proficiency test scores and work performance providing a certain degree of validation for using proficiency tests in individual performance evaluations. However, the authors qualified their findings by noting the number of critical preanalytical and postanalytical events that can ultimately affect the quality of the result.

Limitations of Proficiency Testing as a Quality Indicator

There are limitations of using Proficiency Testing as a quality indicator. Used as a surrogate for patient samples, proficiency test materials are prepared in batch quantities with large volume uniformity, which may not truly simulate patient specimens. Variables, including the quality of the specimen, transportation, analyte deterioration, environmental conditions, and human error may all influence the quality of the survey material (Isenberg & D'amato, 1996). For example, proficiency test samples for microbiology typically contain single species when actual microbiological specimens contain large numbers of normal flora and pathogens from clinical sites that cannot be accurately represented in the PT materials. The commutability, matrix effects, and traceability of proficiency test materials may further affect the accuracy of performance on PT surveys.

Commutability

Commutability is the property of a stabilized material to produce results that, within the uncertainty of measurement, react in a similar manner as patient specimens when using two different analytical procedures. (Ricos, et al., 1999). Commutability allows an EQA/PT material to be used as a surrogate for a clinical specimen; noncommutability limits the evaluation of EQA/PT results through alteration of the specimen matrix because of processing (Miller, 2003). Thus, commutable PT materials have an equivalent value to that of a clinical specimen that contains the same quantity of the analyte measured using the same methodology (Miller, et al., 2005). Surrogates are required for EQA/PT because true clinical specimens are not suitable or available for large PT

surveys. Concerns with the use of clinical specimens include instability, insufficient volumes, risk of infectious agents, and contaminants.

Methods utilized to preserve the integrity of the specimen, such as the addition of stabilizers, lyophilization, or freezing also affect physico-chemical properties of the specimen and its commutability. The commutability properties of processed EQA/PT materials are generally not known and providers rely on a peer group mean for the target value with limits based on acceptable clinical variation (Miller, 2003). Currently, most PT survey materials are not designed to be commutable due to limitations of volumes needed and cost of preparation (Miller, 2005). Because commutability may affect the accuracy of performance on PT, the use of commutable controls may reduce divergent results obtained by different laboratories that use the same methods. For example, Klee and Forseman (1988), in a study of PT surveys at the Mayo Clinic, reported that over 50% of the errors on surveys were related to survey deficiencies, such as invalid specimens and inappropriate evaluation criteria while only 28% of the survey deficiencies could be related to specific analytical problems.

Matrix Effects

Matrix effects refer to those properties that calibrator and control materials develop which cause the materials to react and behave differently from patient specimens in certain instrument or reagent system (Eckfeldt & Copeland, 1993). The system matrix refers to all of the components in the specimen except the analyte (Miller, 2003). Matrix effects are unique to particular calibrator or control materials and occur because of various factors, including the addition of nonhuman additives or preservatives. Further,

matrix modifications of survey materials may result from contact of the specimen with red blood cells or the fibrin clot during blood collection, reconstitution of serum from plasma, dialysis, concentration, freeze-thaw cycles and filtration (Miller, 2003). In a study by Ross, Miller, Myers, & Praestgaard (1998), matrix effects biased the results reported from 69% of the 644 peer group/survey specimen pairs evaluated in the study. Specificity is the extent to which a method measures the analyte and no other compound is erroneously measured. According to Miller, to ensure analytical specificity, the matrix must not interfere with the analyte of interest.

In 2003, the CAP directed a study to ascertain the PT differences between carefully collected human serum and routine CAP-PT materials. The serum used in the study closely resembled clinical samples used in routine patient care (Klee & Killeen, 2005). As a part of this study, Palmer-Toy, et al (2005) concluded that some analytical methods are more susceptible to matrix effects when analyzing proficiency testing material compared to actual patient specimens. Palmer-Toy determined the extent to which CAP-PT specimens simulate human serum for cortisol and immunoglobulin E (IgE) in a participant blinded prospective study. To assess the performance of proficiency testing material and variation in methods, pooled fresh frozen serum was included as one challenge in the CAP 2003 surveys for cortisol and IgE. Bias among laboratories using the same method (peer group) relative to the median of the method means, imprecision measured by the standard deviation and coefficient of variation about each method mean, and total error across laboratories were determined for the fresh frozen serum and proficiency testing material. Bias and imprecision were less than 10% for IgE, which

compares favorably for PT performance limits. The proficiency test material for cortisol methods showed greater bias, but comparable precision with the fresh frozen serum. Additionally, selected methods revealed significant differences in both degree and direction of bias among fresh frozen serum and proficiency testing material. This finding confirmed the concern that proficiency testing material may not necessarily reflect performance on actual patient specimens (Palmer-Toy, 2005). However, the use of peer group grading corrects for this deficiency. If 10 or more subscribers use a given method, a peer group mean is used to calculate the mean and standard deviation and the eventual boundaries for acceptable or unacceptable results for a particular analyte and method. This study analyzed one year of CAP-PT data for two analytes and cannot be generalized to other analytes or methods.

Traceability

Traceability indicates that a measurement can be related to national or international standards through an unbroken chain of comparisons, all having stated uncertainties (Ricos, et al., 1999). The transferring of trueness from a reference to the routine measurement includes a number of intermediate steps (Franzini & Ceriotti, 1998). This chain of traceability, affected by commutability, must be intact to demonstrate the trueness of laboratory results (Ricos, et al.). Materials used as links to ensure trueness include calibrators and controls (Franzini & Ceriotti). Vertical traceability is determined by calibration and horizontal traceability is determined by participation in EQA programs (Ricos, et al.).

CLIA'88 regulations specify that PT specimens must be treated in the same manner as patient specimens, and laboratory practitioners must attest that they have complied with this regulation. Yet, by their very nature, PT specimens must be treated in manners, which differ from the treatment of patient samples. PT specimens may be lyophilized, requiring reconstitution or may be provided in sealed containers. The preanalytical and postanalytical testing phases also differ from those of patient testing when considering the collection, processing, preparation, and reporting of the results.

PT analytes are easily recognized as PT surveys, and thus, often receive special considerations while analyzed. Some laboratories may analyze PT samples in duplicate or use extraordinary means to obtain an accurate result (Isenberg & D'Amato, 1996) when threatened with penalties or other punitive actions due to PT failures. When faced with the loss of license to provide services, laboratories are additionally pressured to perform satisfactorily in PT surveys. Further, Cembrowski and Vanderlinde (1988) reported that prior to such strict prohibition or special treatment of PT samples as dictated through CLIA'67, approximately 54% of laboratories indicated that they handled PT surveys in an atypical manner through replicate analysis or through reporting the mean or median value obtained. Others, such as Gambino (1990) have minimized the outcomes of replicate testing by illustrating that such special treatment replicated the analytical bias; and the PT outcome was the same whether the initial, replicate, or mean value was reported.

Another limitation is that PT primarily measures only the analytical phase of testing and is not significantly affected by pre-analytical or post-analytical errors and effects. PT

is an effective method to evaluate analytical performance, but is generally insensitive to non-analytical processes according to Rej and Jenny (1992). However, studies have shown that the majority of laboratory testing errors have been documented to occur in the pre-analytical and post-analytical phases. For example, Boone et al. (1995) reported that 96% of transfusion errors occur in either the preanalytical or postanalytical phases of testing. Yet, Carlson (2003) reported that the most frequently reported cause of poor performance in CAP-PT surveys is clerical error, a postanalytical testing problem. These clerical errors are most often attributed to failure to read, understand, or follow the directions for completing the result forms and returning to the PT provider. Carlson further notes other common sources of errors in PT include preanalytical errors, such as inappropriate reconstitution of materials. Carlson further cites postanalytical errors, including the failure to convert units of measurement from the laboratory's method to those required by the PT provider, and late return of response sheets as common PT errors. Thus, it may be argued that PT does measure some aspects of quality of testing in all three phases of analysis.

Further, uncertainty exists as to whether performance of PT surveys actually rotate throughout all laboratory-testing personnel as mandated by CLIA'88. Laboratories with more experience in the PT process have lower rates of unacceptable results, which may represent either improved laboratory accuracy or improved ability to perform proficiency testing (Tholen, et al., 1995). To determine whether PT performance improved over time in a survey population, Tholen examined unacceptable results in a large interlaboratory proficiency test program designed for small hospitals, clinics, and POLs using the

College of American Pathologists (CAP) Excel Survey data from 1987 – 1993. The study sample included 632 laboratories that performed surveys in routine chemistry, categorical hematology, quantitative hematology, and common immunology. There were 62 analytes included in the study. Laboratories were divided into two groups, which were classified as "new" institutions ($\leq$ 3 years participation in PT) and "old" institutions ($\geq$ 4 years participation in PT). The outcome variable was the yearly rate of unacceptable PT results for each laboratory for all challenges within a specialty. Repeated measures analysis of the variance (ANOVA) was used to track laboratory performance on PT surveys annually for each year of the study. The study revealed that those laboratories with more experience had lower rates of unacceptable results and unacceptable rates decreased with each year of PT performance. The data also showed consistent and statistically significant ($p<0.05$) improvement in performance for the first three to four years of participation. This study speculated that, perhaps, declining error rates in proficiency testing over time may be attributed to a learning curve for successfully performing PT and might not be necessarily associated with improved laboratory accuracy. However, continued improvement over time might also be attributed to other factors, such as the ability to perform dilutions and process specimens and to correctly calibrate, operate and perform maintenance on instruments (Tholen, et al.1995).

Yet, in spite of consistent feedback on proficiency test failures, does a learning curve exist for laboratory practitioners who would improve their performance in PT? Novak (2002) found that there was no significant change in participant performance, in spite of consistent feedback, from the PT provider for one, specific bacteriological challenge. To

test the hypothesis that a secondary result of a proficiency testing is improvement over time of laboratory performance, participants in a large proficiency testing program (EXCEL), designed for clinics and office laboratories, on a specific problematic competence (the ability to differentiate group A streptococcus from group C streptococcus) was monitored during a six year period (1996-2001) for changes in participant performance. With each testing cycle, feedback on performance relative to peers and an educational discussion analyzing performance and suggesting best practices were submitted to participants. Despite consistent feedback, there was no significant change (using the Pearson Chi Square probability, likelihood ratio Chi Square probability, and Mantel-Haenszel test for linear association) in participant performance throughout the period studied. Unacceptable performance rates for the six study years (1996 to 2001) were 19.6% (1996), 16.7% (1997), 19.5 % (1998), 18.2% (1999), 20.8% (2000), and 19.0% (2001). Novak concluded the results indicate a 'less than optimal' use of PT results in improving laboratory quality. The study was limited by testing of a single PT analyte challenge and by the population sample analyzed, which consisted of clinic and physician office laboratories. Further, high participant turnover and the lack of an experience factor were cited as another study limitation.

Hoeltge, Phillips, Styer, and Mockridge (2005) assessed whether laboratories correct PT problems when contacted by the Laboratory Accreditation Program (LAP) of CAP concerning repeated unacceptable performance. Using the Proficiency Testing Exception Summary (PTES) algorithms, a retrospective analysis of the CAP's PTES for 2002-2003 was performed. There were 6300 accredited laboratories and 1,205,000 analytes

(3,500,000 PT challenges) included in the study. Initially, there were 14,085 PTES reports and 1304 cases of repeated PT failures after initial correspondence with the PT provider. After the second correspondence, there were 119 cases of unsatisfactory results on subsequent PT events. All systematic problems were resolved after the third correspondence with the PT provider. The study findings confirmed that the laboratory investigated and corrected the problem by the time the provider receives the PTES. The study further confirmed the significance of the PTES report as a process to document and correct systematic problems that may have gone undetected.

Laboratory Quality and Personnel Testing Credentials

Limited studies are available that explore the relationship between laboratory quality and the credentials of the testing personnel. Lunz, Castleberry, James, and Stahl (1987) compared the performance of CAP-PT scores of medical technologists certified through ASCP with those technologists who were not ASCP certified. The sample was collected in Illinois laboratories and consisted of eight laboratories that employed only non-ASCP certified technologists and 21 laboratories that employed all ASCP-certified technologists. An accuracy score was calculated for each laboratory based on its performance on a variety of PT survey analytes. The accuracy score on CAP-PT surveys for those laboratories with 100% ASCP certified technologists was 95% $\pm$4SD compared to an accuracy score of 75% $\pm$3SD for those laboratories with 0% ASCP certified technologists. The study concluded (Mann-Whitney U Test = 43.01, $p < 0.05$) that those laboratories that employ all ASCP-certified technologists produced statistically

significant more accurate results than those laboratories that employ non-certified ASCP technologists.

Because, many laboratories employ a mix of ASCP-certified and non-ASCP certified technologists, the study (Lunz, et al., 1987) determined the relationship between the proportion of ASCP-certified technologists employed by a laboratory and success on CAP-PT testing. The authors reported a statistically significant correlation (Spearman *r* correlation = 0.34, $p < .001$) between PT scores and the proportion of ASCP certified technologists. Generalizability of this study was compromised due to sampling limitations. These included sampling only in the state of Illinois and the inclusion of only medical technologists; medical laboratory technicians and other testing personnel were not included in the sample. Furthermore, laboratorians with national certification only through ASCP were included in the study; those with certification from other agencies including National accrediting Agency for Clinical Laboratory Science (NCA) and American Medical Technologists (AMT) were not ascertained.

Lunz, Castleberry, and James (1992) expanded the study of laboratory staff qualifications and accuracy of proficiency test results by examining laboratories on a national level, hypothesizing that laboratories employing a higher percentage of ASCP certified medical technologists produce significantly more accurate test results than those laboratories that do not employ ASCP certified technologists. A questionnaire was attached to the CAP-PT survey for the last quarter of 1988, which requested demographic information concerning the number of ASCP-certified and ASCP- noncertified medical technologists, the number of medical technicians, and the number of "other" testing

personnel. CAP - PT data were reviewed and an accuracy score was calculated for each participating laboratory. The laboratories were divided into two groups; those employing all ASCP certified technologists and those employing laboratorians with no ASCP certification. The nonparametric Wilcoxon significance test was used to determine differences in the accuracy of test results for laboratories from the two groups. Significant differences were found for the basic and comprehensive PT surveys. For those laboratories employing all ASCP certified technologists, an accuracy score of 98.3% was found for the basic surveys and 98.6% for the comprehensive surveys as compared to scores of 91.4% for the basic surveys and 95.1% for the comprehensive surveys for the laboratory group employing no ASCP certified technologists. Statistical significance ($p<0.001$) was found for both the basic and comprehensive surveys.

The study of Lunz, Castleberry, and James (1992) was again limited by only considering certification through ASCP and excluding technicians and other testing personnel from the accuracy score. Reviewing data from only one quarter and selection bias through self-report on the questionnaire were further limitations. The study concluded that those laboratories hiring only ASCP-certified technologists produced results that are more accurate.

Limitations of both of these studies contributed to the failure to provide the information needed to support the conclusion that, "staffing with qualified technologists does contribute to maximizing the quality of laboratory services that are offered to the public." Significant information linked to laboratory performance, such as the size of the laboratory, volume of laboratory testing, and degree of specialization was not provided in

the studies. An important aspect of assessing laboratory quality is the incremental value of increasing the percentage of certified technologists and whether there is a point of diminishing returns (Hammond, 1993). Additionally, the issue of multicollinearity between the all-or-nothing certified technologist variable and other variables contributing to laboratory performance were not addressed. An additional question, which could not be answered, involved the relationship between laboratory size and the use of certified technologists. One would suspect that certified technologists play a more vital role in proficiency test accuracy in small laboratories where bench personnel are generalists when compared to larger laboratories where specialization exists (Hammond, 1993).

Peddecord (1996) selectively reviewed existing published studies that evaluated the relationship between laboratory personnel regulations and laboratory performance. The purpose of the review was to determine minimal educational requirements in an era of cost-containment and increasing government regulations. To be included in this analysis, the published study must have appeared in a refereed journal, included laboratories in more than one state, and studied multiple specialty areas that evaluated PT surveys in a variety of laboratories. Because all of the studies were cross-sectional, no causal inferences could be made and conclusions were limited regarding the association between the independent variables that describe personnel characteristics and PT scores. Peddecord concluded that qualified laboratory personnel are an important component for higher performance on proficiency tests and noted higher PT results were usually associated with higher personnel qualifications. The associations were statistically significant, but correlation coefficients were typically low ($r<0.5$); and independent

variables explained very little of the overall variance in PT scores. Other factors to consider that contributed to the variation in PT performance included the area of concentration of clinical expertise, experience, direction and supervision, technology, and the size of the laboratory.

A limited number of suitable studies that accurately analyzed the relationship between credentials of testing personnel and laboratory quality exist (Peddecord, 1996). Most of the studies focused on hospital and independent laboratories, and rarely included physician office laboratories. The studies reviewed were limited in that all were cross-sectional and no causal inferences could be made. Furthermore, extremely diverse groups of laboratories were included such that testing personnel were not consistently defined across those laboratories included in Peddecord's review. A further limitation was that the studies were conducted prior to CLIA'88 and the associated regulatory changes in testing personnel could not be evaluated.

Of note in Peddecord's review was his observation that individuals outside of the mainstream laboratory practice community conducted many of the studies evaluating laboratory personnel and performance. Although some laboratory professionals contributed to and participated in some of these studies, there was little research dedicated to laboratory related health services. This lack of professionalism and contribution to clinical research remains a concern today as health care systems constrained costs in response to DRG/PPS in 1983. Peddecord expressed a need for laboratorians to demonstrate the benefit of their professionalism and qualifications to medical care. However, there has been little research to support this concept that the

clinical laboratory professional contributes more to the quality of medical care compared to an individual who performs laboratory testing without formal clinical laboratory science education and/or national certification. Peddecord also noted that laboratory supervisors had no uniform definition of competency but did seem to recognize technical abilities, productivity, and professionalism as essential skills.

CLIA'88 regulations also require that laboratories evaluate and assure the competency of all personnel who perform competency tests. In the study of Christian, et al. (1997) that included 20 diversified laboratory types, no single definition of "competent staff" emerged among the participant laboratories that had completed an extensive open-ended 40-question survey. While all laboratorians stated that they wanted competent staff and 75% of the respondents saw some benefits to having a competency assessment program, a variety of definitions of competency were noted. The two most frequently (60% each) stated characteristics of competent staff members reported by the respondents were the production of accurate results in a timely manner and the recognition and resolution of problems and errors. Additional characteristics of competent staff included the ability to make no or few errors (50%), education, training, and continuing education (45%), the ability to follow policy and procedures and to correctly perform analysis (35%), understanding of the principle and purpose of the analysis, (25%), and appropriate communication and interpersonal skills (25%). The most frequently noted assessment method reported from the survey was the performance on proficiency surveys by the testing personnel and documentation of the performance (85%). Other assessment methods included direct observation by supervisor of test with

documentation (80%); pencil and paper quizzes of policy procedures, troubleshooting, problem solving (70%); internal blind samples with performance documented (65%); and performance deficiencies or incident reports in employee's file (60%). It was concluded that competency assessment is in the early phases of development with no consensus as to what should become the model for the assessment of clinical laboratorians.

The importance of credentials, licenses, and certification cannot be minimized; these are essential for a minimal level of training, yet do not totally guarantee competency (Christian, et al., 1997). Regardless of all credentials, each individual has strengths, weaknesses, and lapses of knowledge. Thus, the importance of continuing education, retraining, and periodic assessments may contribute to the competency of laboratorians and the quality of the work that they produce.

As the scope of laboratory analysis becomes increasingly diverse, the value of qualified testing personnel remains a significant healthcare quality issue. There is a focus in the healthcare community on the need to reduce medical errors in the managed care system where concern regarding increasing cost exists. Errors must be evaluated for preventability and classified as cognitive, non-cognitive, or both (Astion, 2003). Cognitive errors are due to a lack of knowledge or poor judgment and may be attributed to inadequate training or supervision and thus, directly linked to the level of education, training, and clinical experience. Noncognitive errors are due to disruptions in processes that are relatively automatic and include data entry errors, mislabeling, and errors in calculations. Noncognitive errors are reduced through simplifying procedures, incorporating automation, using checklists, and improving staffing. Because cognitive

errors are linked to learning and training, appropriate education in a clinical laboratory program may directly influence the incidence of cognitive errors.

There are shortages in qualified laboratory testing personnel with vacancy rates for some positions in excess of 10%. (Ward-Cook, Chapman, & Tannar, 2003). Laboratories that operate with an inadequate number of qualified personnel may adversely impact the accuracy of results. Demographic data from the ASCP member database indicates that over 72% of the current laboratory workforce is greater than 40 years of age with a median age of laboratorians of 49 years (Ehrhardt, 2002). Further, the Bureau of Labor Statistics estimates that between 2002 and 2010, there will be a need for 12,200 new MT/CLS and MLT/CLT graduates each year to meet the demand of laboratory services as the American population ages. (Ward-Cook, et al., 2003). The staffing shortage is further compounded by the national decline in the number of CLS/MT and CLT/MLT training programs and a decreasing number of students entering the laboratory profession.

A variety of tools to measure laboratory quality exist and include competency testing, proficiency testing, turn-around-time, physician and patient satisfaction, and patient outcomes. Many of these measurement tools are subjective and evaluation methods differ based on the type of laboratory setting. Proficiency testing provides an objective, consistent measurement tool for laboratory quality and is a required component in the evaluation of total quality management in the laboratory. Laboratory regulations, including those of CLIA`88 require PT as a component of the laboratory accreditation process and have been enacted to ensure that quality analysis are performed in all laboratory settings. Although studies exist which relate proficiency test results to specific

types of laboratories and certification credentials, no single study has investigated the contributions of education, certification, and years of laboratory experience to success in proficiency test performance.

This study will investigate the hypothesis that laboratory quality as measured by the accuracy score of performance on proficiency tests is related to the level of education, years of experience of the testing personnel, and personnel certification credentials. The unit of study is the individual testing personnel; the test sites include a variety of laboratories located in Virginia, northeastern Ohio and western Pennsylvania, which represent diverse demographics for the testing personnel. Chapter III will discuss the methodology used to test the hypothesis. Chapter IV and Chapter V will discuss the pilot study and results of the expanded study, respectively.

CHAPTER III – METHODOLOGY

The purpose of this study was to determine if a relationship exists between the quality of laboratory services as defined by successful events in proficiency testing (PT) and the credentials of laboratory testing personnel, including the level of education, certifying credentials, and number of years of clinical experience. This design was a retrospective, cross-sectional, nonexperimental study that reviews one year of PT performance in databases existing in participating clinical laboratories.

This study was differentiated from prior similar studies because the study analyzes proficiency testing using the individual and not the laboratory as the unit of analysis. Further, a demographic survey ensured that laboratories meet requirements for test and personnel diversity. Additionally, the demographic survey from each participant laboratory was used to analyze other relationships between personnel mix and laboratory performance on PT surveys. Indeed, Hamlin (1992) noted the lack of laboratory demographics as a weakness in the previous studies of Lunz, et al., (1987, 1992). Whereas, prior studies of Lunz, et al., (1987, 1992) reviewed performance of only bachelor level medical technologists with ASCP certification, this study analyzed diverse levels of laboratory professionals with varying certification credentials. Further, additional personnel credentials collected for this study included degree, major, years of clinical experience, certification type and level. The data analyzed was post-CLIA'88

such that effects on regulations can be evaluated, after personnel standards have been universally implemented. The data were comprised of survey results collected from private, physician office, reference, and traditional hospital laboratories to provide a diverse mix of testing sites and personnel from northeastern Ohio and western Pennsylvania. The data collection plan provided diverse personnel credentials needed to fulfill the goals of the study.

Sample

Existing proficiency testing data was reviewed retrospectively for the year 2003 in several institutions with diverse clinical laboratory testing settings in one geographic area. There were six laboratory facilities included in the study, of which three were traditional hospital laboratories. Two of the hospital laboratories were from northeast Ohio and one was from western Pennsylvania. There was also one commercial reference laboratory from northeast Ohio and two physician office laboratories, one each from northeastern Ohio and western Pennsylvania. The sample for the pilot study was obtained from a single institution, Virginia Commonwealth University Health System (VCUHS) and was comprised of results from the 2002 proficiency surveys. A collection procedure and consent to participate form (Appendix B) was provided to and discussed with the laboratory management at each participant site.

Using the data and proficiency test error rate from the pilot study, the power analysis was performed by G. H. Chang, a dissertation committee member, to determine sample size for the statistical analyses. Based on an error rate of 0.01, alpha of 0.05, and power

of 0.9, the minimal sample size was calculated to be 3210 PT results. The ascertainment of six laboratory facilities provided 11,689 PT results for the year 2003.

Graded proficiency reports are maintained within the laboratory record system and are thus, available for review. Each participant laboratory completed one demographic survey and a table of personnel credentials with unique identifier codes ("tech codes") to maintain the anonymity of the individual persons.

The laboratory manager or designated individual at each of the six participant laboratories coordinated the data collection. Each participant laboratory was given a set or range of code numbers for their facility. Next, each section or department (i.e., hematology and coagulations, transfusion medicine, chemistry, clinical microbiology and immunology) of each laboratory were assigned unique codes within their assigned ranges. The managers reported the personnel credentials for each individual to whom a "tech code" was assigned. The required information included: highest degree attained, major area of study (i.e., Medical Technology/Clinical Laboratory Science, Biology, as noted in Table 10), Certification Agency (ASCP, NCA, AMT) and type or level of certification (MLT/CLT, MT/CLS, Categorical, specialist), and years of experience as laboratory testing personnel. For partial years, the managers rounded up to the next year for over six months and rounded down to the previous year for less than six months. For six months, managers indicated one-half year of clinical experience. Personnel data was directly recorded into a table labeled, "Grid for Collection of Personnel Credentials" which is found in the Data Collection Plan in Appendix B.

One demographic survey which included information of the numbers and types of testing personnel and volume and scope of laboratory testing was completed by a representative at each facility. Type of laboratory and level of analysis were also included in the demographic survey. Proficiency testing survey result forms were copied by a representative at each facility. Next, the corresponding tech code was written on the PT survey result forms to indicate the testing personnel for each PT event.

Data Collection

The data collection period of one year provided ample data for analysis. Proficiency testing typically involves three cycles per year; review of one year of survey data provided 11,689 PT results to be included in the study for demographic frequencies, logistic regression analysis, and odds ratio analysis. Evaluation of a complete annual survey minimized any bias created by changes in testing personnel influenced by unusual staffing patterns or extraneous variables associated with unusually difficult or simplistic PT survey events that have occurred during any of the three survey testing periods. The Institutional Review Board (IRB) at Virginia Commonwealth University (VCU) approved the study (IRB # 03131) under the exempt status.

Independent and Dependent Variables

The independent variables in the study were the credentials of the testing personnel, summarized in Table 3. The independent variables included degree, college major, years of clinical experience, certification agency and certification level. The dependent variable, measured as a categorical variable, is the number of PT survey event results recorded as acceptable or unacceptable from the existing PT database for 2003.

Table 3.

Measurement and Categories of Independent Variables

Independent Variable	Measurement	Categories
Degree	Levels based on years of post secondary education	No post secondary education
		Associate Degree
		Baccalaureate Degree in MT/CLS
		Baccalaureate Degree in Biology or Chemistry
		Other Baccalaureate Degree
		Master of Science in CLS or Pathology
		Other Master Degree
		Doctoral or Medical Degree
Major	Record all degree types, then collapse into those with highest frequencies	
Clinical Experience	Years recorded as a continuous variable and then grouped into 8 categories	
Certification Agency	5 levels based on type	None
		ASCP
		NCA
		Both ASCP and NCA
		Other (Military)
Certification Level	5 levels based on category of certification examination	None
		CLA
		MLT/CLT
		Categorical (H, M, C, BB)
		MT/CLS
		Specialist (SH, SM, SC, SBB)

Statistical Analysis

Frequencies of all independent variables for personnel demographics and the number and frequency of PT results completed by each demographic category were calculated.

PT errors were also categorized by type and summarized according to degree, college major, certification agency and type, and years of clinical experience.

Logistic regression analysis was used to assess the relationship between the predictor variables (educational level as measured through degree and major, years of clinical experience, and certification agency and level) and the outcome variable, performance accuracy on proficiency test surveys. More specifically, logistic regression may be used to predict the likelihood of an event, for example the probability of an acceptable or unacceptable result. Logistic regression also determines the degree to which independent variables affect the probability of a particular outcome. One dependent variable, the success or failure of the PT event and five independent variables were reported as categorical variables. Binary logistic regression permits the analysis of a dependent variable with two outcomes. Some results of PT are not graded or there may be no consensus or peer group result. In such cases, the responses are not graded as either acceptable or unacceptable. Years of clinical experience, an independent variable, was recorded as a continuous variable, then grouped into categories.

The goal of logistic regression is to create a linear combination of the log of the odds of being in one group, which is accomplished by assessing the contribution of each predictor variable. Logistic regression is a suitable statistical tool in this study because the predictors do not have to follow a normal distribution, be linearly related, or be of equal variance within each group (Tabichnick & Fidell, 1996). Specifically, personnel credentials or the independent variables (X) are college major, educational degree, certification, level of certification, and years of clinical experience. The estimated

coefficients for each independent variable represent the amount of the total variance of the dependent variable attributed to the independent variables. The logistic regression model is expressed as:

$$\ln [P/(1-P)] = \alpha + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \ldots \beta_k X_k + \varepsilon$$

Where:

P = the probability of the dependent variable being present
α is the regression constant
$\beta_1, \beta_2, \beta_3 \ldots \beta_k$ are estimations of the regression coefficients
$X_1, X_2, X_3 \ldots X_k$ are the independent variables
ε is the variance that is due to chance or error

Pairs and trios of independent variables were also included in the logistic regression analysis to elucidate the effects of these factors on the outcome variable. Logistic regression using the full model of the predictor variables was also performed.

Odds ratio analysis predicts the strength of the relationship between the dependent variable, success on proficiency testing, and the independent variables, personnel credentials. It is generally more useful to interpret logistic regression using odds ratio than probability (Portney & Watkins, 2000). Odds ratio indicates how likely it is thatan event belongs in the target group. An odds ratio is the probability of occurrence divided by the probability of nonoccurrence (Munro, 2001). In statistical programs, the odds ratio is expressed as the Exponential Beta (EXP β). If the odds ratio is greater than 1.00, then the event is more likely to occur than if the odds ratio is less than one. Conversely, for odds ratios less than 1.00, the event is less likely to occur when compared to events with

odds ratios greater than 1.00. The odd ratio of a successful PT event based on the credentials of the testing personnel was evaluated.

The goodness of fit statistic is a measure of how well the data fit the model and compares the observed probabilities to those predicted by the model. The Homer-Lemeshow goodness of fit statistic is based on grouping cases into deciles and compares the observed probabilities with the expected probabilities within each decile and was used to determine if the data fit the model (Tabachnick & Fidell, 1996).

Chapter IV presents the methods and results of the pilot study.

CHAPTER IV – PILOT STUDY

The pilot study was conducted at Virginia Commonwealth University Health System (VCUHS) Laboratories under the direction of Greg Miller, Ph.D., Professor of Pathology, VCU School of Medicine in June and July of 2003.

Purpose

The purpose of the pilot study was to assess the adequacy of the data collection plan and to determine the required sample size. Further, the pilot study afforded the investigator the opportunity to scrutinize the data once collected and to evaluate various methods of collecting and recording data. The data collection plan was revised based on experiences in the pilot study.

Methods

The laboratory managers of each of four laboratory departments at VCUHS provided information concerning the credentials of the personnel performing proficiency testing as described in the Chapter III. The managers completed the personnel credentials for each individual to whom a tech code was assigned and a tech code was provided for the PT survey results.

Results

The data collected from the pilot study was analyzed in two phases, the frequencies of the demographics and analysis of the PT results and the laboratory's performance.

Summary of Pilot Study Demographics

The first part of the analysis included personnel information reported by the VCUHS laboratory managers onto the Grid for Collection of Personnel Credentials. The data was entered into SPSS as four individual laboratory sections (Microbiology/Immunology, Hematology/ Coagulations, Transfusion Medicine, and Clinical Chemistry). Next, the data were merged into one output for the entire laboratory. At this point, several categories in "Major" and "Degree" needed to be collapsed into fewer categories, because frequencies were small in several of the original categories.

There were 179 laboratory practitioners whose credentials were provided by the laboratory managers included in the pilot study. These included 174 practitioners in the core hospital laboratory and five nonlaboratorians who performed laboratory analysis in the satellite VCUHS laboratories in the EXCEL PT program. Additionally, there was one chemistry/toxicology laboratory practitioner and five health care personnel from the satellite laboratories who had no credentials provided. The demographic information for the 179 practitioners whose credentials were provided is summarized in subsequent tables. Those six individuals whose personnel credentials were not provided were not included in the demographic summaries nor were the PT results include that had been performed by these persons.

The degree frequencies are summarized in Table 4. There were 102 practitioners with the Bachelor of Science (B.S.) in Medical Technology or Clinical Laboratory Science (MT/CLS), which represented 57.0% of the participants. There were 38 participants (21.2%) with a BS in Biology or Chemistry. Four participants (2.2%)

Table 4.

Laboratory Personnel by Degree Type

Degree	Number	Percentage
None (High School Diploma)	6	3.4%
Associate Degree	4	2.2%
Bachelor of Science in Medical Technology (MT)/ Clinical Laboratory Science (CLS)	102	57.0%
Bachelor of Science in Biology or Chemistry	38	21.2%
Other Bachelor of Arts or Bachelor of Science	10	5.6%
Master of Science in Clinical Laboratory Science or Pathology	5	2.8%
Other Master Degree	12	6.7%
Medical Degree/Ph.D	2	1.1%
Total	179	100.0%

possessed an associate degree (AD); of these, two majored in medical laboratory technology (MLT). There were 21 participants with dual or multiple degrees at various levels. Most often, these individuals held two undergraduate degrees, a B.S. in MT/CLS and a B.S. in another field and were classified in the BS, MT/CLS category for statistical purposes. When the second degree was at the graduate level, the participants were categorized in the master degree category within the appropriate degree designation.

Table 5 is a summary of the major field of the study for the participants in the study. There were 104 participants (58.1%) with a MT/CLS major at the BS level, three

Table 5.

Laboratory Personnel by College Major

Major	Number	Percentage
None	6	3.4%
MLT/CLT	2	1.1%
MT/CLS	104	58.1%
Biology/Microbiology/Animal Science	40	22.3%
Chemistry/Biochemistry	5	2.8%
Forensics/Criminal Justice	4	2.2%
Clinical Laboratory Specialty/Pathology	3	1.7%
Medicine	1	0.6%
Other	14	7.8%
Total	179	100.0%

participants (1.7%) with a CLS/Pathology major at the master degree level, and two participants (1.1%) with a MLT/CLT major for a total of 109 (60.9%) of participants with a clinical laboratory major. There were 40 (22.3%) subjects with a biology major, five (2.8%) with a chemistry major, and four (2.2%) with a criminal justice major.

Table 6 shows the certification credentials for the participants. Of the participants, 114 (63.7%) had obtained certification through ASCP while 55 (30.7%) were not certified through any agency. Four subjects (2.2%) held certification through both NCA).

Table 6.
Laboratory Personnel by Certification Agency

Agency	Number	Percentage
None	55	30.7%
ASCP	114	63.7%
NCA	4	2.2%
Military	1	0.6%
Multiple (Both ASCP & NCA)	4	2.2%
Other (NRCC)	1	0.6%
Total	179	100.0%

and ASCP. There was one individual certified through the military and one who had received certification through the NRCC (the National Registry of Clinical Chemists

Table 7 is a summary of the level of certification for the laboratory personnel. The most frequent level of certification was at the MT/CLS level with 98 (54.7%) of the participants. There were six participants (3.4%) certified at the MLT/CLT level, one (0.6%) at the CLA level, 14 (7.8%) categorical certifications, and five (2.8%) specialist certifications. Those individuals who held multiple certifications were assigned into the highest level. Of the participants, 55 or 30.7% were not certified at any level.

Years of experience is shown in Table 8. Forty-five participants (25.1%) had two years or less of clinical experience. There were 48 (26.8%) subjects with over 20 years of clinical experience. The remaining participants showed between 3 and 20 years of experience.

Table 7.

Laboratory Personnel by Level of Certification

Level	Number	Percent
None	55	30.7%
Clinical Laboratory Assistant (CLA)	1	0.6%
MLT/CLT	6	3.4%
Categorical (H, M, C, BB)	14	7.8%
MT/CLS	98	54.7%
Specialist (SH, SM, SBB)	5	2.8%
Total	179	100.0%

Table 8.

Laboratory Personnel by Years of Experience

Years of Experience	Number	Percent
Less than 1	12	6.7%
1 – 2	33	18.4%
3 – 5	20	11.2%
6 – 10	20	11.2%
11 – 15	28	15.6%
16 – 20	18	10.1%
21 – 25	16	8.9%
Over 25	32	17.9%
Total	179	100.0%

Demographics for those participants with a clinical laboratory major were further evaluated. There were 109 participants with a clinical laboratory major that included 104 (95.4%) with a MT/CLS major, two (1.8%) with a MLT/CLT major, and three (2.8%) with a clinical pathology/laboratory specialist major. Of these 109 participants, 104 (95.4%) held certification through one of the certification agencies with 98 (89.9%) certified through ASCP, four (3.7%) certified through both ASCP and NCA, and one each certified through NRCC (0.9%) and the military (0.9%). There were five (4.6%) laboratory majors who were not certified through any agency. For those 104 who held certification, the level of certification was 95 (87.1%) at the MT/CLS level, three categorical (2.8%), and four at the specialist level (3.7%), and two (1.8%) at the MLT/CLT level. The years of clinical experience for clinical laboratory majors showed five (4.6%) with less than one year, 23 (21.1%) with 1 -2 years, 14(12.8%) with 3- 5 years, 16 (14.7%) with 6 – 10 years, 20 (18.3%) with 11-15 years, nine (8.3%) with 16 – 20 years, four (3.7%) with 21 to 25 years, and 18 (16.5%) with over 25 years experience.

Correlations

A cross-tabulation was performed to determine if a correlation existed between possession of a MT/CLS degree and holding certification from any of the agencies. The Pearson Chi-Square analysis indicated a statistical significance that degree and certification not independent events($\chi^2 = 81.861$, df= 1, $p < 0.001$). Further, certification and degree were correlated, when using laboratory degree to predict for certification ($\lambda = 0.561$). Additionally, cross-tabulation revealed a correlation between clinical laboratory major and certification when using laboratory major to predict for

certification (λ=0.587). The Pearson Chi-Square analysis indicated a statistical significance (χ^2=87.118, df=1, p<0.001) that laboratory major and certification are not independent events.

Odds Ratio Analysis

Finally, using odds ratio analysis, the odds of certification with a clinical laboratory major versus without a clinical laboratory major were analyzed. There were 124 individuals who were certified and 55 who were not certified by any agency. The probability of certification (0.94) with a laboratory degree was found by dividing the number of certified personnel with a laboratory degree (104) by the total number of personnel with a laboratory degree (111). The odds of certification with a clinical laboratory degree were found by dividing the probability of the occurrence (0.94) by the probability of a nonoccurrence (0.06) and were determined to be 16. Thus, it is 16 times more likely for an individual with a clinical laboratory degree to attain certification than it is for such an individual not to attain certification.

The probability of certification without a clinical laboratory degree (0.37) was found by dividing the number of certified laboratory personnel who did not hold a laboratory degree (20) by the total number of personnel who did not hold a clinical laboratory degree (68). The odds of certification without a clinical laboratory degree were found by dividing the probability of the occurrence (0.29) by the probability of the nonoccurrence (0.71) and were found to be 0.40. Next, the odds ratio was found by finding the ratio of the probability of one event to the other (16/0.40) or 40. Thus, it is 40 times more likely

that an individual with a clinical laboratory degree will be certified when compared to an individual without a laboratory degree for all levels of degree in the study.

Analysis of Pilot Study PT Data

The number of PT results completed by the laboratory practitioners was determined. Because multiple practitioners contributed to 123 of the PT results in Transfusion Medicine and Microbiology, the total number of valid PT challenges performed by the laboratorians was reduced from 3299 by 123 to 3266. Table 9 is a summary of PT performance by type of degree. Those practitioners with a BS in MT/CLS performed 50.2% of the PT results followed by those practitioners with a BS in Biology or Chemistry who performed 26.4% of the results. Of the 185 practitioners who were included in the study, 104 or 56.2% participated in the proficiency test program.

Table 10 is a summary of the number of PT results completed by laboratory personnel who studied within a particular college major. Of the 3266 PT results completed, 1672 (51.2%) were completed by practitioners with a MT or CLS major. There were 791 (24.2%) of the results completed by those with a degree in biology, microbiology or animal science major. Additionally, in the Excel Surveys, registered nurses and nurse practitioners completed 56 (1.7%) of the PT results and operating room or cardiac care technicians completed 66 (2.0%) of the PT results.

Table 11 is a summary of certification agency by number of PT results. Of the results completed, 1653 (50.6%) were performed by individuals certified by ASCP while 1267 (38.8%) were completed by practitioners who were not certified by any agency.

Table 9.

PT Results Completed by Educational Degree of Laboratory Personnel

Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None (High School Diploma)	6	24	0.7%	2
Associate Degree	4	30	0.9%	3
Bachelor of Science in Medical Technology (MT)/ Clinical Laboratory Science (CLS)	102	1638	50.2%	58
Bachelor of Science in Biology or Chemistry	38	862	26.4%	20
Other Bachelor of Arts or Bachelor of Science	10	185	5.7%	4
Master of Science in Clinical Laboratory Science or Pathology	5	114	3.5%	3
Other Master Degree	12	259	7.9%	7
Medical Degree/Ph.D	2	39	1.2%	2
Degree Not Given	6	115	3.5%	5
Total	185	3266	100.0%	104

Table 10.

PT Results Completed by College Major of Laboratory Personnel

Major	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	6	24	0.7%	3
MLT/CLT	2	24	0.7%	1
MT/CLS	103	1672	51.2%	59
Biology/Microbiology/ Animal Science	40	791	24.2%	24
Chemistry/Biochemistry	5	215	6.6%	1
Forensics/Criminal Justice	4	68	2.1%	2
Clinical Laboratory Specialty/Pathology	3	84	2.6%	1
Medicine	1	15	0.5%	1
Other	14	257	7.9 %	6
Major Not Given	7	116	3.5%	6
Total	185	3266	100.0%	104

Table 11.

PT Results Completed by Certification Agency of Laboratory Personnel

Certification Level	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	57	1267	38.8%	33
ASCP	114	1653	50.6%	62
NCA	4	10	0.3%	2
Military	1	24	0.7%	1
Multiple (Both ASCP & NCA)	4	105	3.2%	3
Other (NRCC)	1	155	4.8%	1
Certification Not Given	4	52	1.6%	2
Total	185	3266	100.0%	104

Table 12 is a summary of certification level by number of PT results. Of the 3266 valid results completed, 1503 (46.0%) were completed by those certified as MT/CLS and 1267 (38.8%) were completed by those who were not certified at any level.

Table 13 is a summary of results completed by years of laboratory experience. Of the 3266 surveys completed, 618 (18.9%) were performed by those with 1 - 2 years experience and 688 (21.1%) were performed by those with 3 - 5 years of experience. Also, 431 (13.2%) were performed by practitioners with over 25 years of laboratory experience.

Table 12.

PT Results Completed by Certification Level of Laboratory Personnel

Certification Type	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	57	1267	38.8%	33
Clinical Laboratory Assistant (CLA)	1	2	0.1%	1
MLT/CLT	6	24	0.7%	1
Categorical (H, M, C, BB)	14	274	8.4%	7
MT/CLS	98	1503	46.0%	57
Specialist (SH, SM, SBB)	5	144	4.4%	3
Type Not Given	4	52	1.6%	2
Total	185	3266	100.0%	104

Table 13.

PT Results Completed by Years of Experience of Laboratory Personnel

Years of Experience	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
Less than 1	13	22	0.7%	3
1 -- 2	32	618	18.9%	20
3 -- 5	20	688	21.1%	15
6 – 10	20	425	13.0%	14
11 -- 15	28	338	10.3%	20
16 – 20	18	115	3.5%	7
21 – 25	15	499	15.3%	7
Over 25	33	431	13.2%	15
Years Not Given	6	130	4.0%	3
Total	185	3266	100.0	104

There were 3306 successful PT events reported (97.6%) and 36 unsuccessful events (1.1%) for the entire laboratory. There were also 47 (1.4%) testing events, which

were graded as 'no consensus value', or 'response was not graded.' Testing personnel and type of error in Table 14 summarizes the unsuccessful events and errors reported in the PT data evaluation. Of the 36 unacceptable PT results, 15 were performed by personnel credentialed as MT(ASCP). There were three MT(ASCP) personnel who had each performed two unacceptable PT results. There were 15 unacceptable PT results performed by personnel with other majors, including biology, chemistry, forensics, nursing, and radiation sciences; of these a practitioner who majored in biology performed four unacceptable PT results and a second individual with the same college major performed two unacceptable PT results. Two personnel who did not have college degrees performed three unacceptable results and two personnel whose majors were not provided had performed two unacceptable PT results. Individuals with a degree in MT/CLS performed 50.2% of the PT results while those with a BS in either chemistry or biology performed 26.4% of the results. Because three practitioners with varying credentials performed Item 22, the error was not categorized with respect to degree, major, or certification.

Of particular note were the EXCEL surveys, which are designed by CAP primarily for smaller hospital laboratories and physician office laboratories and utilized as external quality assurance for the satellite laboratories at VCUHS. Nonlaboratory personnel, including nurse practitioners, patient care technicians and physicians, generally staff these satellite laboratories. Ten individuals participated in the EXCEL PT surveys. There were 105 PT results (3.2% of total results reported) at the satellite laboratories with six unacceptable results noted, producing an error rate of 5.7%. The remaining 30 errors

Table 14.
PT Error Summary by Credentials of Testing Personnel

Error Item	Tech Code	Degree	Major	Certification	Years	Error Type
1	1543	BS	MT	ASCP	16	6
2	1527	BS	BIOL	NONE	2	1
3	1542	BS	MT	ASCP	3	6
4	1503	BS	BIO	NONE	25	2
5	1540	BS	MT	ASCP	2	2
6	1547	BS	BIO	NONE	2	2
7	1547	BS	BIO	NONE	2	2
8	1547	BS	BIO	NONE	2	2
9	1547	BS	BIO	NONE	2	2
10	1521	BS	CHEM	NRCC	22	6
11	1592	NONE	NONE	NONE	6 months	6
12	1514	BS	MT	ASCP	1	1
13	1058	BS	MT	ASCP	4	1
14	1058	BS	MT	ASCP	4	1
15	1518	BS	MT	ASCP/NCA	1	1
16	1327	BS	MT	ASCP	6	2
17	1327	BS	MT	ASCP	6	2
18	1324	BS	MT	ASCP	1	4
19	1508	BS	MT	ASCP	2	3
20	1512	BS	BIO	NONE	7	1
21	1005	BS/MS	BIO/ FORENSICS	NONE	22	2
22*	1309	BS/MS	BIO/MICRO	NONE	30	6
	1311	BS	MT	ASCP	15	
	1319	BS	MT	ASCP	13	
23	1544	BS	AN SCI	NONE	32	2
24	1512	BS	BIO	NONE	7	2
25	1512	BS	BIO	NONE	7	2
26	1504	MS	FORENSICS	NONE	5	6
27	1518	BS	MT	ASCP/NCA	1	1
28	1518	BS	MT	ASCP/NCA	1	5
29	1324	BS	MT	ASCP	1	6
30	1409	BS	MT	ASCP	8	1
31	1903	MD	XX	NONE	XX	3
32	1903	MD	XX	NONE	XX	3
33	1900	NURSE PRACTIONER	NURSING	NONE	24	1
34	1907	NONE	PATIENT CARE TECH	NONE	4	5
35	1907	NONE	PATIENT CARE TECH	NONE	4	5
36	1905	CARDIAC CARE TECH	RADIATION SCIENCE	NONE	18	6

Note: XX= NOT KNOWN;
Item 22 result was performed by three practitioners (not included in discussion)

were found in the 3161 results performed by laboratory personnel at the core VCUHS laboratory and produced an error rate of 0.95%. Because specific demographic data was not available on some of the nonlaboratory personnel, the reason for this large discrepancy cannot be concluded. However, one might postulate that the use of nonlaboratory personnel in the satellite laboratories might be associated with a higher error rate. Thus, in order to obtain a diverse sample, a variety of laboratories is required, including hospital core laboratories, satellite laboratories and physician office laboratories that represent all types of personnel who are performing laboratory testing and proficiency testing.

The types of exception codes or error types are described and summarized in Table 15. Technical problems comprised 30.6% of the exception codes and occurred with 11 of the cases. There were eight cases of errors (22.2%) due to methodologic problems, seven cases of clerical errors (19.4%) and six cases of "Other" (16.7%); but specific descriptions were not given in the exception reports.

Table 16 is a summary of the years of experience of those personnel performing unsatisfactorily on the surveys. The years of experience with the greatest number of errors (14) representing 38.9% of the error were those practitioners with 1 - 2 years of experience. Those practitioners with 1 – 2 years of experience performed 18.9% of the PT analysis, but accounted for 38.9% of the error. Those practitioners with 11-15 years of experience showed no errors and performed 10.3% of the results. Those practitioners with less than one year of experience performed 22 (0.7%) of the results and accounted for one (2.8%) of the errors.

Table 15.

Exception (Error) Code Summary

Exception Code	Error Description	Number	Percentage
1	Methodologic Problem	8	22.2%
2	Technical Problem	11	30.6%
3	Clerical Problem	7	19.4%
4	Problem with Survey Materials	1	2.8%
5	No explanation after investigation	3	8.3%
6	Other (specify)	6	16.7%
	Total	36	100.0%

Table 16.

Years of Laboratory Experience by Number of Errors

Years of Experience	Number of Errors	Percentage of Errors
Less than 1	1	2.8%
1 - 2	14	38.9%
3 - 5	6	16.6%
6 - 10	6	16.6%
11 - 15	0	0.0%
16 - 20	2	5.6%
21 - 25	4	11.1%
Over 25	1	2.8%
Unknown (not provided)	2	5.6%
TOTAL	36	100.0%

Multivariate Analyses

Multivariate analysis was performed on the data set. First, the data were screened for missing values and multiple practitioners contributions to a single result and also to determine if sufficient cases were present in each level for each dependent variable. After screening, the data set contained 3093 PT events. The original data collection categories were then collapsed into meaningful groups as shown in Table 17. Level of certification was found to be redundant with certification agency and was not included in the multivariate analysis. Those cases with result values of 1 (successful) or 2 (not successful) were selected for analysis, and those cases with result values of 3 (lack of consensus) were not included in the analysis, which resulted in 3093 total cases.

Table 17.

Final Groups of Independent Variables

Independent Variable	Original Groups	Final Groups
Degree	8 levels	3 levels: Associate Degree or lower Bachelors Degree Master Degree or higher
Major	9 levels	2 levels: Clinical Laboratory Major Non- Clinical Laboratory Major
Certification Agency	5 levels	2 levels: Certified Not Certified
Clinical Experience	8 levels	4 levels: 2 years or less 3 to 10 years 11 to 20 years Greater than 20 years

Tables 18 through 21 show the valid cases for each level of each independent variable. Of the cases, 56.4% held clinical laboratory major and 43.6% held a non-clinical laboratory major (Table 18). There were 1.6% of the participants with an associate degree or lower, 85.8% of the participants with a bachelor's degree, and 12.6% of the participants with a master's degree or higher (Table 19). Of the cases (Table 20), certified personnel completed 61.9% of the results and 38.1% were completed by not certified personnel. Years of clinical experience (Table 21) showed 20.7% of the cases with less than two years of laboratory experience, 35.6 % of the cases with 3 to 10 years of laboratory experience, 14.5% of the cases with 11 to 20 years of laboratory experience, and 29.2% of the cases with over 20 years of laboratory experience. There were 3060 (98.9%) acceptable cases and 33 (1.1%) unacceptable in the analysis.

Table 18.

Number of PT Results by Major

Major	Number of PT Results	Percent
Clinical Laboratory Major	1744	56.4%
Non Clinical Laboratory Major	1349	43.6%
Total	3093	100.0%

Table 19.

Number of PT Results by Degree

Degree	Number of PT Results	Percent
Associate Degree or Lower	50	1.6%
Bachelor Degree	2653	85.8%
Master Degree or Higher	390	12.6%
Total	3093	100.0%

Table 20.

Number of PT Results by Certification

Certification	Number of PT Results	Percent
Certified	1914	61.9%
Not Certified	1179	38.1%
Total	3093	100.0%

Table 21.

Number of PT Results by Years of Experience

Years of Experience	Number of PT Results	Percent
2 years or less	639	20.7%
3– 10	1100	35.6%
11—20	450	14.5%
Over 20 years	904	29.2%
Total	3093	100.0%

Using the 'Enter' method, the logistic regression analysis was performed using SPSS. The four predictor variables (degree, major, certification, and clinical experience) were entered as single categorical variables against the dichotomous dependent variable, result accepted or result not accepted (Table 22). The model using years as the predictor variable was significant (N = 3093, χ^2= 10.731, p = 0.017) with significance noted for 2 years or less experience (p=0.008). Further, the model using degree as the predictor variable was also statistically significant (N=3093, χ^2 =5.755, p=0.012) with significance

Table 22.

Logistic Regression: Single Independent Variables

IV	df	χ^2	-2LL	p	EXP (β)	R^2
Major	1	1.603	363.709	0.207	1.559	0.001-0.003
Certified	1	2.460	362.852	0.116	1.735	0.001-0.007
Years	3	10.731	354.581	0.017*		0.003 -0.031
2 years or less				0.008*	4.028	
3 - 10 years				0.200	1.983	
11 - 20 years				0.793	0.803	
Degree	2	5.755	359.557	0.012*		0.002-0.017
Associate or less				0.020*	6.160	
Bachelor				0.932	0.955	

Note: N = 3093

* indicates model is statistically significant at the 0.05 level.

noted for those with an associate degree or less (p=0.020). None of the other predictor variables were found to show statistical significance.

Next, the logistic regression was performed running pairs of independent variables (Table 23). Those models that included predictor pairs with the variable years and/or degree showed statistical significance. These included major and years (N=3093. χ^2=13.254, p=0.010); certified and years (N=3093, χ^2=12.408, p=0.015); and degree and years (N=3093, χ^2=17.273, p=0.004). In each case, two years or less of experience was statistically significant (p<0.05). Additionally, the models with major and degree (N=3093, χ^2=7.200, p=0.015) and certification and degree (N=3093, χ^2=8.016, p=0.046) showed statistical significance. In each case, associate degree or less was statistically significant (p<0.05).

Table 23.

Logistic Regression: Pairs of Independent Variables

IV Pairs	df	χ^2	-2LL	P	EXP (β)	R^2
Major & Certified	2	2.476	362.837	0.290		0.001-0.007
Major	1			0.901	1.070	
Certified	1			0.358	1.648	
Major & Years	4	13.254	352.058	0.010*		0.004-0.038
Major	1			0.112	1.797	
Years	3			0.014*		
2 years or less				0.004*	4.641	
3 - 10 years				0.091	2.563	
11 - 20 years				0.956	1.048	
Major & Degree	3	7.200	358.113	0.066		0.002-0.021
Major	1			0.230	1.538	
Degree	2			0.014*		
Associate or less				0.015*	6.648	
Bachelor				0.881	1.085	
Certified & Years	4	12.408	352.904	0.015*		0.004-0.036
Certified	1			0.195	1.583	
Years	3			0.024*		
2 years or less				0.008*	3.971	
3 - 10 years				0.183	2.038	
11 - 20 years				0.887	0.888	
Certified & Degree	3	8.016	357.297	0.046*		0.003-0.023
Certified	1			0.131	1.722	
Degree	2			0.015*		
Associate or less				0.014*	6.870	
Bachelor				0.799	1.151	
Years & Degree	5	17.273	348.039	0.004*		0.006-0.050
Years	3			0.020*		
2 years or less				0.011*	4.336	
3 - 10 years				0.131	2.317	
11 - 20 years				0.619	0.655	
Degree	2			0.012*		
Associate or less				0.190	3.081	
Bachelor				0.222	0.485	

Note: N = 3093

*indicates model is statistically significant at the 0.05 level.

Using trios of independent variables (Table 24), logistic regression revealed statistical significance for all models, which contained years and degree as one of the predictor variables. These included major, years, and certified (N=3093, χ^2=13.275, p=0.021) degree, certified, and years (N=3093, χ^2=17.804, p=0.007); and degree, major, and years (N=3093, χ^2=18.433, p=0.005). The model containing degree, major, and certified as the predictor variables ((N=3093, χ^2=8.027, p=0.091) failed to show statistical significance, although the predictor variable, degree, was statistically significant (p=0.015).

Statistical analysis of the complete model is shown in Table 25. The nonsignificant goodness of fit (p=0.899) indicated that the data fit the model. The model χ^2 refers to thedifference between the –2 Log Likelihood (-2LL) for the model with only a constant andthe –2LL for the complete model, indicates the explanatory power of the independent variables. A test of the full model with all four predictors against a constant only model. was statistically reliable (N = 3093, χ^2 =18.581, p =0.010, df =7), indicating that the predictors, as a set, distinguish successful results from nonsuccessful results.

Using the complete model (Table 25), statistical significance was not noted with major (p=0.384) or certification (p=0.702). However, years of clinical experience (p=0.029) and degree (p=0.033) were found to be statistically significant. Those cases with 2 years or less of clinical experience also showed statistical significance with p = 0.010. Further, those practitioners with less than two years of clinical experience were over five times more likely (Exp β = 5.153) to commit an error in proficiency testing than those practitioners with 20 years of clinical experience or more. In addition, those practitioners

Table 24.
Logistic Regression: Trios of Independent Variables

IV Trios	df	χ^2	-2LL	p	EXP (β)	R^2
Major, Certified, & Years	5	13.275	352.037	0.021*		0.004-0.038
Major	1			0.359	1.972	
Certified	1			0.884	0.902	
Years	3			0.020*		
2 years or less				0.007	4.797	
3 - 10 years				0.114	2.665	
11 - 20 years				0.934	1.075	
Degree, Certified, & Years	6	17.804	347.509	0.007*		0.006-0.052
Degree	2			0.030*		
Associate or less				0.195	3.067	
Bachelor				0.323	0.544	
Certified	1			0.465	1.318	
Years	3			0.035		
2 years or less				0.014*	4.220	
3 - 10 years				0.131	2.330	
11 - 20 years				0.719	0.733	
Degree, Major, & Years	6	18.433	346.879	0.005*		0.006-0.053
Degree	2			0.036*		
Associate or less				0.214	2.923	
Bachelor				0.321	0.550	
Major	1			0.279	1.524	
Years	3			0.023*		
2 years or less				0.008*	4.676	
3 - 10 years				0.081	2.726	
11 - 20 years				0.851	0.848	
Degree, Major, & Certified	4	8.027	357.286	0.091		0.003-0.023
Degree	2			0.015*		
Associate or less				0.014*	6.880	
Bachelor				0.794	1.155	
Major	1			0.916	1.060	
Certified	1			0.369	0.007	

Note: N = 3093
* indicates model is statistically significant at the 0.05 level.

Table 25.

Logistic Regression: Full Model

IVs	df	χ^2	-2LL	p	EXP (β)	R^2
Degree, Major, Years, & Certified	7	18.581	346.731	0.010*		0.006-0.054
Degree	2			0.033*		
Associate or less				0.234	2.808	
Bachelor				0.291	0.523	
Major	1			0.384	1.974	
Years	3			0.029*		
2 years or less				0.010*	5.153	
3 - 10 years				0.084	3.029	
11 - 20 years				0.904	0.898	
Certified	1			0.702	0.748	

Note: N = 3093

* indicates model is statistically significant at the 0.05 level.

with an associate degree or less were almost three times (Exp β = 2.808) more likely to commit an error than those with a master degree or higher.

Limitations

The pilot study was limited by lack of demographic data for some of the participants. This is a particular concern in the Excel surveys where two (5.5%) of the errors occurred yet had to be deleted from the logistic regression analysis due to missing information for personnel credentials. Further, those proficiency surveys performed by more than one practitioner were eliminated from the study. The lack of a demographic survey for the pilot study site further limited any correlational studies between the individual practitioner and the institution. There were no demographic data available on the five individuals who performed PT at the satellite laboratories in the EXCEL PT program. In addition, demographic data for one individual who performed clinical chemistry PT was

not available. One cycle of surveys in immunology did not have the practitioner noted for any of the tests performed.

The pilot study was limited in that only one year of survey data from a single institution was examined. A concern with lengthening the collection period was the difficulty in collecting the demographic data and PT results from the participant sites, and possible increase for missing data. Employee turnover was one reason for lacking demographic data for some participants. A prospective study may have enhanced the success in collection of demographics as would a feedback mechanism to follow up on any missing information. An additional concern associated with a longer collection period was the fear of nonparticipation from the laboratory managers due to competing priorities.

Further, not all practitioners included in the demographic survey performed proficiency testing. There were 185 laboratory personnel included, but only 104 (56.2%) performed PT testing. While those performing the analysis represented a wide range of degrees and majors, most of the PT analysis was performed by those with either a MT/CLS degree (50.2%) or BS in Chemistry or Biology (26.4%). Only one MLT/CLT participated in the PT surveys. In order to attain a diverse personnel sample, a variety of laboratory settings was included in the full study.

These limitations were addressed in the data collection of the full study. Complete demographic data was obtained for all but two practitioners and a complete demographic survey for each participant site was obtained.

Adjustments to the data collection plan based on the pilot study included the need to ensure collection of all demographic data on those individuals who have performed PT. Also, the demographic survey for the entire laboratory must be completed thoroughly and accurately; thus, more attention was given to survey completion. Additionally, it was decided that the laboratory managers would place the unique identifying code of the personnel directly onto the PT survey result, instead of onto the Data Collection Table. The principal investigator then completed the data collection table in order to facilitate the data collection process.

The pilot study provided an opportunity to analyze and revise the data collection plan and to determine the suitability of the proposed statistical analysis. Adaptations made in the study plan facilitated data collection, recording, and analysis during the full study.

CHAPTER V – RESULTS

The study was conducted at six clinical laboratories from the Northeastern Ohio and Western Pennsylvania region. There were three hospital laboratories (HL-1, HL-2, HL-3), two physician office laboratories (POL-1, POL-2), and one commercial reference laboratory (CRL-1). Using the Data Collection Plan found in Appendix B a designated individual at each laboratory site completed one demographic survey for the laboratory and demographic information for each individual testing personnel. The demographics of the laboratories are summarized in Table 26.

Summary of Study Demographics

The data collected from the study was analyzed in two phases. The first part of the analysis included personnel information reported by the laboratory managers onto the Grid for Collection of Personnel Credentials. Based on the findings in the pilot study (Chapter 4)), several categories for the demographic predictor variables were collapsed into smaller categories. Frequencies for each predictor variable at each laboratory site were determined as was a complete demographic analysis for the six laboratories in the study. Demographics of the individual laboratories are found in Appendix D: Tables D1 through D5.

This study included 174 laboratory practitioners in the combined laboratories of which 105 (60.3%) held a B.S. degree in MT/CLS, 33 (19.0%) held an associate level. There

Table 26.

Demographics of Participating Laboratories

Laboratory	Annual Lab Tests (2003)	Level of Testing	Testing Personnel By Employment Titles		
			MT/CLS	MLT/CLT	OTHER
HL-1	1,553,443	Moderate and High Complexity Waived	53	6	0
HL-2	788,000	Moderate and High Complexity, Waived	20	10	2 CLA
HL-3	685,045	Moderate and High Complexity	36	8	0
POL-1	255,385	Moderate and High Complexity	1	4	0
POL-2	183,885	Moderate and High Complexity Waived	1	3	2 MAT 3 OTHER
CRL-1	600,700	Moderate and High Complexity	12	0	0

Note: HL = Hospital Laboratory, POL = Physician Office Laboratory, CRL = Commercial Reference Laboratory, MAT = Medical Assisting Technician

were eight (4.6%) who held no college degree and two (1.1%) who had earned a master level degree (Table 27). Approximately 79% of the participants majored in clinical laboratory sciences at the associate or Bachelor of Science degree level (Table 28). There were 159 (91.4%) who held certification and 15 (8.6%) who held no certification (Table 29). As shown in Table 30, the majority of the practitioners were certified at the

Table 27.

Laboratory Personnel by Degree Type: Combined Laboratories

Degree	Number	Percentage
None (High School Diploma)	8	4.6%
Associate Degree	33	19.0%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	105	60.3%
Bachelor of Science in Biology or Chemistry	12	7.0%
Other Bachelor of Arts or Bachelor of Science	14	8.0%
Master Degree	2	1.1%
Total	174	100.0%

Table 28.

Laboratory Personnel by College Major – Combined Laboratories

Major	Number	Percentage
None	5	2.9%
MLT/CLT	29	16.6%
MT/CLS	108	62.0%
Biology/Microbiology/Animal Science	17	9.8%
Chemistry/Biochemistry	3	1.7%
Other	12	7.0%
Total	174	100.0%

Table 29.

Laboratory Personnel by Certification Agency: Combined Laboratories

Certification Agency	Number	Percentage
None	15	8.6%
ASCP	153	87.9%
Multiple (Both ASCP & NCA)	6	3.5%
Total	174	100.0%

Table 30. Laboratory Personnel by Certification Level: Combined Laboratories

Level	Number	Percent
None	15	8.6%
Clinical Laboratory Assistant (CLA)	3	1.7%
MLT/CLT	27	15.5%
MT/CLS	122	70.2%
Specialist (SH, SM, SBB)	7	4.0%
Total	174	100.0%

MT/CLS level (122, 70.0%). Six practitioners (3.4%) were cited as having less than two years of experience in the laboratory while there were 82 (47.2%) practitioners with over 20 years of experience (Table 31).

Table 31.

Laboratory Personnel by Years of Experience: Combined Laboratories

Years of Experience	Number	Percent
Less than 1	2	1.1%
1 – 2	4	2.3%
3 – 5	9	5.2%
6 – 10	24	13.8%
11 – 15	29	16.7%
16 – 20	22	12.6%
21 – 25	29	16.7%
Over 25	55	31.6%
Total	174	100.0%

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Summary of Acceptable and Unacceptable Results

Table 32 summarizes the total PT results from 2003 including the number and percentage of acceptable and unacceptable results. There were 11,689 PT results in the

Table 32.

Acceptable and Unacceptable PT Results by Laboratory

Laboratory	Total PT Results	Not Graded or No Consensus Results	Valid PT Results	Acceptable PT Results		Unacceptable PT Results	
				Number	**Percent**	**Number**	**Percent**
HL—1	3760	88	3672	3642	99.2%	30	0.8%
HL—2	1720	75	1645	1629	99.0%	16	1.0%
HL—3	3253	124[a]	3129	3080	98.4%	49	1.6%
POL—1	633	35	598	598	100.0%	0	0.0%
POL—2	822	32	790	785	99.4%	5	0.6%
CRL—1	1501	102	1399	1386	99.1%	13	0.9%
TOTAL	11689	456	11233	11120	99.0%	113	1.0%

**Note*: Valid PT Results = Total PT Results – Not Graded/No Consensus Results
[a]Includes 73 results that were not submitted & not graded

study of which 456 were not graded or no consensus results. Included in the not graded category was a single survey of 74 PT events, which had not been submitted by the testing personnel to the PT survey agency. The omission of this single survey that led to the failure to submit 74 results occurred in a satellite laboratory associated with one of the study sites. Testing at the satellite laboratory was entirely performed by nonlaboratory personnel who did not hold clinical laboratory major, held bachelor level degrees, who were not certified, and who had over twenty years of experience. This omission was

counted as a single unacceptable result. Although this omission may be considered a postanalytical error, none of the analytes were tested and the survey was not submitted or graded. This omission was assigned to one of the individuals in the satellite laboratory. Both of these individuals had identical credentials when categorized into the final groups of independent variables. The remaining 73-nonsubmitted results were included in the "not-graded" category.

The number of valid PT results (11,233) was found by subtracting the not graded/no consensus results from the total PT results. There were 11,120 (99.0%) successful PT results and 113(1.0%) unsuccessful PT results for the combined laboratories.

Those cases with unacceptable results or errors were further analyzed and categorized according to the type of error and demographics of the testing personnel (Table 33). Of the 113 unacceptable results, the most frequent error type noted was technical problem (N= 35, 31.0%) followed by clerical problem (N = 31, 27.4%).

Table 33.

Exception (Error) Code Summary

Exception Code	Error Description	Number	Percentage
1	Methodologic Problem	24	21.2%
2	Technical Problem	35	31.0%
3	Clerical Problem	31	27.4%
4	Problem with Survey Materials	3	2.7%
5	No explanation after investigation	13	11.5%
6	Other (specify)	7	6.2%
	Total	113	100.0%

Tables 34 and 35 summarize the educational demographics for unacceptable results. The majority of PT results were completed by practitioners whose college major was in clinical laboratory sciences (77.9%) with a bachelor degree (73.7%), who were certified (91.5%) and who had over 20 years of experience (56.9%). There were 73 errors (64.6%) performed by those with a clinical laboratory major and 40 errors (35.4%) performed by those who did not possess a clinical laboratory major. Those with an associate degree or less performed 3003 (25.7%) of the results and accounted for 32 (28.3%) of the unacceptable results. Those with a bachelor level degree completed 8619 (73.7%) of the PT results and produced 81 (71.7%) of the errors.

Table 34.

Errors (Unacceptable Results) by Laboratory Major

Major	PT Results Completed		Errors	
	Number	**Percent**	**Number**	**Percent**
Clinical Laboratory Major	9106	77.9%	73	64.6%
Nonlaboratory Major	2583	22.1%	40	35.4%
TOTAL	11,689	100.0%	113	100.0%

Table 35.

Errors (Unacceptable Results) by Degree

Degree	PT Results Completed		Errors	
	Number	**Percent**	**Number**	**Percent**
Associate Degree or Lower	3003	25.7%	32	28.3%
Bachelor Degree	8619	73.7%	81	71.7%
Master Degree or Higher	67	0.6%	0	0.0%
TOTAL	11689	100.0%	113	100.0%

The relationship between certification and errors (Table 36) produced was also determined. Of the 113 errors, 93 (82.3%) were committed by those who were certified and 20 (17.7%) by those who were not certified. Table 37 summarizes errors as related to years of experience. Those with over 20 years of clinical experience completed over 50% (58.7%) of the unacceptable results and those with 20 years or less of clinical experience completed less than 50% (42.5%).

Table 36.

Errors (Unacceptable Results) by Certification

Certification	PT Results		Errors	
	Number	**Percent**	**Number**	**Percent**
Certified	10691	91.5%	93	82.3%
Noncertified	998	8.5%	20	17.7%
TOTAL	11689	100.0%	113	100.0

Table 37.

Errors (Unacceptable Results) by Years of Experience

Years of Experience	PT Results		Errors	
	Number	**Percent**	**Number**	**Percent**
2 or less	33	0.3%	0	0.0%
3—10	1766	15.1%	25	22.1%
11—20	3026	25.9%	23	20.4%
Over 20	6864	58.7%	65	57.5%
TOTAL	11689	100.0%	113	100.0%

Table 38 summarizes the number of PT results and errors by the tech code and demographics of the testing personnel. Of the 144 testing personnel who performed proficiency testing, 51 (35.4%) produced erroneous results. Multiple errors in PT testing were performed by 25 (49.0%) of those who had performed erroneous testing. The remaining 26 practitioners each produced one error. Three practitioners produced eight errors, the greatest number of errors by any single practitioners. Two of the three practitioners were personnel without a clinical laboratory major and who worked in a satellite laboratory.

Table 38:

Errors (Unacceptable Results) by Tech Codes and Demographics

Code	Number of Errors	Number of Results	Degree	Major	Certified	Years
101	6	177	Bachelor	Nonlab	Yes	Over 20
109	3	115	Associate or lower	Lab	Yes	11-20
115	1	50	Bachelor	Lab	Yes	Over 20
116	1	29	Bachelor	Nonlab	Yes	3-10
303	1	28	Bachelor	Lab	Yes	11-20
500	1	186	Bachelor	Nonlab	Yes	Over 20
502	3	223	Bachelor	Lab	Yes	3-10
1802	1	149	Associate or lower	Lab	Yes	11-20
1803	2	65	Associate or lower	Lab	Yes	3-10
1804	1	51	Associate or lower	Lab	No	3-10
1805	1	208	Associate or lower	Nonlab	No	11-20
1821	2	328	Bachelor	Lab	Yes	Over 20
1823	2	179	Bachelor	Lab	Yes	Over 20
1824	2	350	Bachelor	Lab	Yes	Over 20

table continues

Code	Number of Errors	Number of Results	Degree	Major	Certified	Years
1825	5	93	Bachelor	Lab	Yes	11-20
1827	1	107	Bachelor	Lab	Yes	Over 20
1828	1	79	Bachelor	Lab	Yes	Over 20
2002	8	99	Bachelor	Nonlab	No	Over 20
2003	8	111	Bachelor	Nonlab	No	Over 20
2100	6	192	Bachelor	Nonlab	Yes	11-20
2102	1	161	Bachelor	Nonlab	Yes	11-20
2106	1	48	Bachelor	Lab	Yes	Over 20
2200	8	111	Bachelor	Lab	Yes	11-20
2201	3	66	Bachelor	Lab	Yes	Over 20
2202	2	14	Bachelor	Lab	Yes	11-20
2203	1	54	Associate or lower	Lab	Yes	Over 20
2301	1	25	Bachelor	Nonlab	Yes	11-20
2503	3	227	Bachelor	Lab	Yes	Over 20
2504	1	275	Bachelor	Lab	Yes	Over 20
2505	1	191	Associate or lower	Nonlab	Yes	Over 20
2506	1	197	Bachelor	Lab	Yes	11-20
2508	2	260	Associate or lower	Nonlab	Yes	Over 20
2801	2	16	Bachelor	Nonlab	Yes	3-10
4205	1	4	Bachelor	Lab	Yes	Over 20
4300	1	31	Bachelor	Lab	Yes	Over 20
4301	3	47	Bachelor	Lab	Yes	Over 20
4305	2	69	Bachelor	Lab	Yes	Over 20
4306	1	12	Bachelor	Lab	Yes	Over 20
4307	1	81	Bachelor	Lab	Yes	Over 20
4502	3	159	Bachelor	Lab	Yes	Over 20
4504	2	60	Bachelor	Lab	Yes	Over 20
4505	3	81	Bachelor	Lab	Yes	Over 20
4509	2	382	Bachelor	Lab	Yes	Over 20
4511	1	393	Bachelor	Lab	Yes	Over 20
4514	1	178	Bachelor	Lab	Yes	Over 20
4515	1	43	Bachelor	Lab	Yes	Over 20
4517	3	89	Bachelor	Lab	Yes	Over 20
4518	1	46	Bachelor	Lab	Yes	Over 20
4519	1	189	Bachelor	Lab	Yes	11-20
4802	1	102	Bachelor	Lab	Yes	Over 20
4803	2	32	Associate or lower	Lab	Yes	3-10

Demographics of Personnel Performing Proficiency Testing

The number of PT results completed by laboratory personnel at each laboratory, categorized by type of credential, was determined and summarized in Appendix E. With the exception of one participating facility, more than 96% of the laboratory personnel were utilized in proficiency testing. The degree and major of the demographics of the number and percent of the testing personnel who performed PT testing for the combined laboratories are summarized in Tables 39-40.

Table 39.

Proficiency Test Results by Post-Secondary Degree of Laboratory Personnel

Post-Secondary Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None (High School Diploma)	8	541	3.5%	7
Associate Degree	33	2462	21.1%	29
Bachelor of Science in Medical Technology (MT)/ Clinical Laboratory Science (CLS)	105	7140	61.1%	85
Bachelor of Science in Biology or Chemistry	12	521	4.5%	8
Other Bachelor of Arts or Bachelor of Science	14	958	8.2%	13
Other Master Degree	2	67	0.6%	2
Total	174	11,689	100.0%	144 (82.8%)

Of the 11,689 PT results, there were 7140 (61.1%) completed by personnel with a BS degree in MT/CLS; 1479 (12.7%) of the results were completed by those with a

bachelor's degree in a different field (see table 39). Two practitioners with a graduate degree completed 67 (0.6%) of the PT results. Personnel who held an associate degree reported approximately 21% of the PT results and 3.5% of the testing was completed by high school graduates. As shown in Table 40, the majority of the results (7201, 61.6%) were completed by those that majored in MT/CLS; 1905 results (16.3%) were completed by those with a MLT/CLT major.

Table 40.

PT Results Completed by College Major of Laboratory Personnel

Major	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	5	268	1.7%	5
MLT/CLT	29	1905	16.3%	25
MT/CLS	108	7201	61.6%	86
Biology/Microbiology/ Animal Science	17	818	7.0%	14
Chemistry/Biochemistry	3	428	3.7%	3
Other	12	1069	9.1%	11
Total	174	11,689	100.0%	144 (82.8%)

Tables 41 and 42 summarize the certification credentials of the testing personnel. Certified personnel accounted for 10691 (91.5%) of the results with those certified at the MT/CLS level performing 8486 (72.6%) of the results. Although only seven practitioners held specialist certification, all were utilized in the PT testing, reporting approximately 2% of the results.

Table 41.

PT Results by Certification Agency of Laboratory Personnel

Certification Level	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	15	998	8.5%	14
ASCP	153	10438	89.3%	124
Multiple (Both ASCP & NCA)	6	253	2.2%	6
Total	174	11,689	100.0%	144 (82.8%)

Table 42.

PT Results Completed by Certification Level of Laboratory Personnel

Certification Type	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
None	15	998	8.5%	14
Clinical Laboratory Assistant (CLA)	3	322	2.8%	3
MLT/CLT	27	1661	14.2%	21
Categorical (H, M, C, BB)	0	0	0.0%	0
MT/CLS	122	8486	72.6%	99
Specialist (SH, SM, SBB)	7	221	1.9%	7
Total	174	11,689	100.0%	144 (82.8%)

Only 33 (0.3%) of the results (see Table 43) were completed by a practitioner with two years or less of experience. There were 6864 (58.7%) results completed by personnel with over 20 years of experience. Of the 174 practitioners in the study, 144 (82.8%) performed proficiency testing.

Table 43. PT Results by Years of Laboratory Experience of Laboratory Personnel

Years	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
Less than 1	2	0	0.0%	0
1 – 2	4	33	0.3%	2
3 – 5	9	707	6.0%	9
6 – 10	24	1059	9.1%	19
11 – 15	29	1145	9.8%	22
16 – 20	22	1881	16.1%	20
21 – 25	29	2177	18.6%	25
Over 25	55	4687	40.1%	47
Total	174	11,689	100.0	144

Multivariate Analysis

Multivariate analysis was subsequently performed on the data set to determine if the data were suitable for binary logistic regression analysis. First, the data were screened for missing values and multiple practitioners and to determine if sufficient cases were present in each level for each dependent variable. The original data collection categories were then collapsed into meaningful groups as shown in Table 44. There was multicollinearity between certification agency and level of certification. For example, the same fifteen individuals who were not certified by any agency were likewise not certified at any level. These variables were thus found to be redundant and were not included in the multivariate analysis. There were insufficient cases in the "Master Degree or Higher" category for degree. Thus, degree was divided into two categories which were associate degree or lower and bachelor degree or higher. Even though the screening resulted in fewer categories for each variable, the data set remained at 11,689 PT events.

Table 44.

Independent Variables Used in the Multivariate Analysis

Independent Variable	Original Groups	Final Groups
Degree	8 levels	2 levels: Associate Degree or lower Bachelors Degree or higher
Major	9 levels	2 levels: Clinical Laboratory Major Non Clinical Laboratory Major
Certification Agency	5 levels	2 levels: Certified Not Certified
Clinical Experience	8 levels	4 levels: 2 years or less 3 to 10 years 11 to 20 years Greater than 20 years

The demographics for major and degree of the combined data sets using the revised categories are shown in Tables 45-46. There were 137 individuals (78.7%) in the study with a clinical laboratory major and 133 (76.4 %) held a bachelor or graduate degree, four of which completed a master degree or higher. These were reclassified into the bachelor or graduate degree category.

Table 45.

Multivariate Analysis: Laboratory Personnel by Clinical Laboratory Major

Major	Number of Individuals in Study	Percent
Clinical Laboratory Major	137	78.7%
Non Clinical Laboratory Major	37	21.3%
Total	174	100.0%

Table 46.

Multivariate Analysis: Laboratory Personnel by Degree Level

Degree	Number of Individuals in Study	Percent
Associate Degree or Lower	41	23.6%
Bachelor or Graduate Degree*	133	76.4%
Total	174	100.0%

Note: Includes 4 practitioners at master or higher level

Table 47 summarizes the certification characteristics of the testing personnel. There were 159 (91.4%) certified personnel included in the multivariate analysis. Years of experience for the personnel are found in Table 48. Only six (3.4%) individuals had two years or less of clinical experience while 84 (48.3%) had over 20 years of clinical experience.

Table 47.

Multivariate Analysis: Laboratory Personnel by Certification

Certification	Number of Individuals in Study	Percent
Certified	159	91.4%
Not Certified	15	8.6%
Total	174	100.0%

Table 48.

Multivariate Analysis: Laboratory Personnel by Years of Experience

Years of Clinical Experience	Number of Individuals in Study	Percent
2 years or less	6	3.4%
3– 10	33	19.2%
11—20	51	29.7%
Over 20 years	84	47.7%
Total	174	100.0%

Table 49 contains the number of PT results for the combined laboratories completed by those with a clinical laboratory major and without a clinical laboratory major. Of the 11,689 PT results, 9106 (77.9%) were completed by personnel with a clinical laboratory

Table 49.

Multivariate Analysis: Number of PT Results by Laboratory Major

Major	Number of PT Results	Percent
Clinical Laboratory Major	9106	77.9%
Non Clinical Laboratory Major	2583	22.1%
Total	11689	100.0%

major. The number of PT results completed by degree of the personnel is found in Table 50. There were 8686 (74.3%) results completed by those with a bachelor degree or higher. Certified personnel (Table 51) completed 10,691 (91.5%) of the results.

Table 50.

Multivariate Analysis: Number of PT Results by Degree

Degree	Number of PT Results	Percent
Associate Degree or Lower	3003	25.7%
Bachelor Degree or Higher	8686	74.3%
Total	11689	100.0%

Table 51.

Multivariate Analysis: Number of PT Results by Certification

Certification	Number of PT Results	Percent
Certified	10691	91.5%
Not Certified	998	8.5%
Total	11689	100.0%

The number of PT results completed by years of clinical experience is shown in Table 52. Only 33 results (0.3%) were completed by practitioners with less than two years of clinical experience and 6864 (58.7%) of the results were completed by personnel with more than 20 years of clinical experience.

Using the 'Enter' method, the logistic regression analysis was performed using SPSS. The four predictor variables (degree, major, certification, and clinical experience) were entered as single categorical variables against the dichotomous dependent variable, result acceptable or not acceptable (Table 53). Those results that were 'not-graded' or reported

Table 52.

Multivariate Analysis: Number of PT Results by Years of Clinical Experience

Years of Clinical Experience	Number of PT Results	Percent
2 years or less	33	0.3%
3– 10	1766	15.1%
11—20	3026	25.9%
Over 20 years	6864	58.7%
Total	11689	100.0%

Table 53.

Logistic Regression: Single Independent Variables (N=11,233)

IV	df	χ^2	-2LL	p	EXP (β)	R^2
Major	1	11.040	1253.223	0.001*	1.983	0.001-0.009
Certified	1	10.781	1253.503	<0.001**	2.460	0.001-0.009
Years	3	5.507	1227.776	0.165		0.000-0.007
2 years or less				0.998	0.000	
3 - 10 years				0.083	1.508	
11 - 20 years				0.356	1.040	
Degree	1	0.459	1263.865	0.494	0.799	0.000-0.000

Note: N=11,233
*indicates model is statistically significant at the 0.05 level.
**indicates model is statistically significant at the 0.001 level

as 'no consensus' were not included in the study. This resulted in a final data set of

11,233 cases.

The models using college major (χ^2= 11.040, p=0.001) and certification (χ^2= 10.781, p<0.001) as the predictor variables were statistically significant. The models using degree (χ^2 = 0.459, p =0.494) and years of experience (χ^2= 5.507, p =0.1165) as predictor variables were not found to show statistical significance. Additionally, those without a clinical laboratory major were almost twice (EXP β = 1.983) as likely to perform an unacceptable result as those with a clinical laboratory major. Noncertified personnel were over twice (EXP β = 2.460) as likely to perform an unacceptable result when compared to certified personnel (Table 53).

Next, the logistic regression (N= 11,233) was performed running pairs of independent variables (Table 54). Statistical significance was found for the following models: major and certification (χ^2= 14.001, p=0.001); major and years (χ^2=17.838, p = 0.001); major and degree (χ^2= 11.230, p=0.004); certification and years (χ^2= 15.033, p=0.005); and certification and degree (χ^2= 11.059, p=0.004). The model using the predictor pair, degree and years of experience (χ^2= 5.913, p=0.206) was not statistically significant.

Using trios of independent variables, logistic regression revealed statistical significance for all of the models analyzed. These models (Table 55) were major, years of experience, and certification (χ^2=19.587, p=0.001); degree, certification, and years (χ^2=12.278, p=0.009); degree, major, and years (χ^2=18.318, p=0.003); and degree, major, and certification (χ^2=14.822, p=0.002).

Logistic regression of the complete model is shown in Table 56. The data were determined to fit by model as evidenced by the nonsignificant goodness of fit (p=0.691)

Table 54.

Logistic Regression: Pairs of Independent Variables (N=11,233)

IV Pairs	df	χ^2	-2LL	P	EXP (β)	R^2
Major & Certification	2	14.001	1250.163	0.001*		0.010-0.012
Major	1			0.058	1.590	
Certified	1			0.076	1.726	
Major & Years	4	17.838	1246.425	0.001*		0.002 -0.018
Major	1			<0.001**	2.072	
Years	3			0.099		
2 years or less				0.998	0.000	
3 - 10 years				0.063	1.555	
11 - 20 years				0.262	0.761	
Major & Degree	2	11.230	1253.034	0.004*		0.001-0.009
Major	1			0.001*	2.047	
Degree	1			0.665	0.908	
Certification & Years	4	15.033	1249.251	0.005*		0.001-0.013
Certified	1			0.001*	2.350	
Years	3			0.354		
2 years or less				0.998	1.330	
3 - 10 years				0.239	2.111	
11 - 20 years				0.318	0.784	
Certification & Degree	2	11.059	1253.225	0.004*		0.001-0.009
Certified	1			<0.001**	2.615	
Degree	1			0.601	0.866	
Years & Degree	4	5.913	1258.371	0.206		0.001-0.005
Years	3			0.181		
2 years or less				0.998	0.000	
3 - 10 years				0.112	1.467	
11 - 20 years				0.313	0.780	
Degree	1			0.521	1.148	

Note: N=11,233

*indicates model is statistically significant at the 0.05 level.

**indicates model is statistically significant at the 0.001 level

Table 55.

Logistic Regression: Trios of Predictor Variables

IV Trios	df	χ^2	-2LL	p	EXP (β)	R^2
Major, Certification, & Years	5	19.587	1244.677	0.001*		0.002-0.016
Major	1			0.026*	1.734	
Certified	1			0.182	1.525	
Years	3			0.208		
2 years or less				0.998	0.000	
3 - 10 years				0.139	1.437	
11 - 20 years				0.268	0.764	
Degree, Certification, & Years	5	15.278	1249.011	0.009*		0.001-0.013
Degree	1			0.627	0.890	
Certified	1			0.001*	2.485	
Years	3			0.347		
2 years or less				0.998	0.000	
3 - 10 years				0.210	1.361	
11 - 20 years				0.374	0.802	
Degree, Major, & Years	5	18.318	1246.046	0.003*		0.002-0.015
Degree	1			0.541	0.869	
Major	1			<0.001**	2.175	
Years	3			0.099		
2 years or less				0.998	0.000	
3 - 10 years				0.051	1.603	
11 - 20 years				0.292	0.772	
Degree, Major, & Certification	3	14.822	1249.442	0.002*		0.001-0.012
Degree	1			0.401	0.822	
Major	1			0.044*	1.655	
Certified	1			0.055	1.840	

Note: N= 11,233

*indicates model is statistically significant at the 0.05 level.

**indicates model is statistically significant at the 0.001 level.

Table 56.

Logistic Regression: Full Model – Expanded Study

IVs	df	χ^2	-2LL	p	EXP (β)	R^2
Degree, Major, Years, & Certification	6	20.416	1243.848	0.002*		0.002-0.017
Degree	1			0.368	0.806	
Major	1			0.018*	1.820	
Years	3			0.185		
2 years or less				0.998	0.000	
3 - 10 years				0.102	1.501	
11 - 20 years				0.335	0.788	
Certified	1			0.134	1.624	

Note: N=11,233
*indicates model is statistically significant at the 0.05 level.

statistic. The model χ^2 indicates the explanatory power of the independent variables when the –2 Log Likelihood (-2LL) for the complete model is compared with a constant only model. The predictors, as a set, distinguish acceptable results from nonacceptable results as determined by a test of the full model which was statistically reliable with all four predictors included in the analysis (χ^2 =20.416, p =0.002, df =6).

Using the complete model (Table 56), statistical significance was noted with the predictor variable, major (p=0.018). The predictor variables degree (p = 0.368), certification (p=0.134) and years of experience (p=0.185 failed to show statistical significance. Using beta weights, it was found that those without a clinical laboratory major were almost twice as likely (Exp β= 1.820) to produce an unacceptable result when compared to those with a clinical laboratory major.

The best fitting model is one that has a high likelihood of observed results as indicated by a small -2LL (Munro, 2001). For those models testing single predictor variables, the best fitting model was that using years (-2LL = 1253.233, p = 0.001). For the analysis of pairs of predictor variables, the best fitting model was the model that used major and years (2LL = 1246.425, p = 0.001). For trios of predictor variables, the best fitting model was that using major, certification, and years (-2LL = 1244.677, p = 0.001). Of the models tested, the full model, which included all four parameters, had the lowest -2LL (1243.848). Thus, all predictor variables contributed to the outcome. Goodness of fit is tested for by the Homer-Lemeshow statistic. For the full model, the Homer-Lemeshow statistic was 3.059, which is less than the χ^2 of the model (20.416); this indicates that the model does fit the data. Additionally, a nonsignificant result for the goodness of fit statistic (p=0.691) indicates that the null hypothesis is not rejected and that the model fits (Munro, 2001).

The data from the pilot study and the expanded study were merged. There was similar statistical significance for the outcomes both studies. In both studies, the full model best predicted the outcome and were found to show statistical significance, p= 0.002 for the expanded study and p=0.010 for the pilot study. The percentage of unacceptable results in the expanded and pilot study was also similar, 1.0% & 1.1%, respectively. Merging the data in the studies provided a more diverse demographic sample and also yielded a sampling of two different geographic regions. However, the PT data analyzed in the pilot study was collected from surveys performed in 2002 while that analyzed in the expanded study was collected in 2003 survey data.

There were 14,709 PT results in the merged data set with 14,326 valid results after deleting those cases that were either performed by multiple practitioners or which had no target value and were, thus, not graded by the PT provider. There were 14,177 (99.0%) acceptable and 149 (1.0%) unacceptable results. The merged data set contained 359 practitioners of which 245 (68.2%) held a clinical laboratory major and of which 114 (32.8%) held a non clinical laboratory major. There were 51 (14.2%) individuals who held an associate degree or lower, 279 (77.7%) who held a bachelor degree and 29 (8.1%) who held a master degree or higher. There were 283 (78.8%) certified personnel and 76 (21.2%) who did not hold certification. Of the practitioners, 132 (36.8%) had over 20 years of experience; 97 (27.0%) held 11-20 years of experience, 73 (20.4%) held 3-10 years of experience and 51 (14.2%) held two years or less of experience.

The full model with all predictors added was determined to be the best fitting model. This model is summarized in Table 57. The Homer and Lemeshow statistic ($p= 0.318$) indicated that the independent variables predicted for the outcome. Statistical significance was noted for the predictor variables clinical laboratory major ($p = 0.035$) and years of experience ($p=0.042$). Statistical significance was also noted for those individuals with two years or less of experience ($p=0.043$) and those individuals with two years or less of experience were almost twice as likely ($Exp\ \beta = 1.849$) to produce an error when compared to those individuals with over twenty years of experience.

Additionally, those practitioners without a clinical laboratory major were almost two times as likely ($Exp\ \beta = 1.638$) to produce unacceptable PT results when compared to

Table 57.

Logistic Regression: Full Model – Merged Data

IVs	df	χ^2	-2LL	p	EXP (β)	R^2
Degree, Major, Years, & Certified	7	23.796	1454.492	0.001*		0.002-0.015
Degree	2			0.683		
Associate or less	1			0.427	0.683	
Bachelor	1			0.549	0.427	
Major	1			0.035*	1.638	
Years	3			0.042*		
2 years or less	1			0.043*	1.849	
3 - 10 years	1			0.111	1.410	
11 - 20 years	1			0.305	0.785	
Certified	1			0.548	1.182	

Note, N = 14,326

* Indicates model is statistically significant at 0.05 level

those with a clinical laboratory major. The predictors, degree (p=0.683) and certified (p=0.548) did not show statistical significance.

Logistic regression of the interactive effects of the predictor variables was performed. No statistically significant interactive effects were found in the merged data set.

Because of the small percentage of unacceptable results (1.0%), a logistic regression analysis of a 2% (265 cases) random sampling of the acceptable cases and all of the unacceptable cases was performed. This subset of the merged data contained 411 cases and the logistic regression analysis of the complete model is found in Table 58. Statistical significance was found with the full model (χ^2= 26.600, p=0.001) and the predictors major (p=0.015) and years (p=0.001) showed statistical significance. The predictors degree (p=0.539) and certification (p=0.821) did not show statistical significance. Thus, using randomly selected cases, statistical significance was found for the same predictors

Table 58.

Logistic Regression: Full Model – Randomly Selected Acceptable Cases of Merged Data

IVs	df	χ^2	-2LL	p	EXP (β)	R^2
Degree, Major, Years, & Certified	7	26.600	508.214	0.001*		0.063-0.086
Degree	2			0.539		
Associate or less	1			0.556	0.641	
Bachelor	1			0.367	0.511	
Major	1			0.015*	2.124	
Years	3			0.001*		
2 years or less	1			0.065	2.233	
3 - 10 years	1			0.062	1.678	
11 - 20 years	1			0.016*	0.585	
Certified	1			0.821	0.918	

Note: N= 411

as when performing logistic regression on the entire merged data set. However, those with 11-20 years of experience showed statistical significance (p=0.016) in the randomly selected data but not in the entire merged data set. There was no statistical significance noted for those practitioners with two years or less of experience (p = 0.086) as was shown in the entire merged data set.

A discussion of the study results is found in Chapter VI.

CHAPTER VI– DISCUSSION

Conclusions

Key conclusions of this study include the significance of a clinical laboratory education and experience in prediction of successful PT performance in both the expanded and pilot studies. In the pilot study, educational degree and years of experience were statistically significant in predicting an acceptable PT outcome while the expanded study revealed statistical significance for one predictor, college major. By merging the data from the pilot study and expanded study, the final data set provided demographics that were more diverse and incorporated data from two different regions of the United States. Merging of the pilot and expanded studies also revealed that the presence of a clinical laboratory major and experience were statistically significant predictors of acceptable PT results. In addition, satellite laboratories staffed by nonlaboratorians in both the expanded and pilot studies consistently produced a higher percentage of PT errors.

Specifically, the presence of a clinical laboratory major and years of experience were statistically significant in the prediction of acceptable PT results in the merged data. These findings supported the hiring of personnel who have completed a formal clinical laboratory education program. Notably, the results of this study indicate that training in a clinical laboratory program as indicated by college major of the practitioner favorably affected the outcome of the PT surveys. Practitioners with a clinical laboratory major

produced 9106 results of which 9033 (99.2%) were acceptable and 73 (0.8%) were not acceptable. By contrast those with a nonclinical laboratory major completed 2583 results of which 2543 (98.4%) were acceptable and 40 (1.6%) were not acceptable. Thus, those with a clinical laboratory major produced a significantly higher percentage of acceptable results than those without a clinical laboratory major (χ^2=11.348, $p<0.05$). Qualified personnel are needed to provide accurate results. This study identified the quality indicators of clinical laboratory major, certification, degree and years of clinical experience as predictors for acceptable performance on PT surveys. Although PT is only one aspect of quality laboratory testing, it provides a consistent and objective approach to the measure of quality laboratory performance.

The study also provides laboratory management with some guidance for staffing benchmarks. According to Valenstein, Souers and Wilkinsen (2005), the quality of laboratory testing may be affected by under skilled or inadequate staffing. Alternatively, increasing cost of analysis and inefficient laboratory operations may occur due to excessive staffing numbers. Because laboratory personnel comprise 50 – 70% (Valenstein, Souers, & Wilkinsen, 2005) of direct clinical laboratory cost, there is a need to determine the appropriate mix of laboratory personnel to ensure laboratory quality and productivity. Data related to staffing in the clinical laboratory are limited and most are proprietary data that are not available to the public. Although current shortages have stabilized for some clinical laboratory disciplines and regions in the country, staffing concerns remain (Ward-Cook, Chapman, & Tannar, 2003).

The laboratories included in the expanded study employed fewer laboratory practitioners when compared to the pilot study laboratory. Additionally, the pilot study was performed in a clinical laboratory affiliated with an academic medical center while none of the sites in the expanded study were affiliated with an academic medical center. This may account for the more diverse laboratory personnel demographics in the pilot study. Also, because the pilot study site is affiliated with a CLS/MT program, perhaps continuing education is more strongly emphasized when compared to those laboratories in the expanded study. Limited research is performed in the facilities included in the expanded study as compared to the research performed at VCUHS. In addition, VCUHS laboratory personnel participate in the clinical laboratory science education of bachelor and graduate level students that may continue to improve laboratory quality. Continuing education is required for all laboratory personnel involved in the clinical education of students enrolled in accredited clinical laboratory education programs. The practitioners included in the pilot study may participate in additional professional activities when contrasted with those in the expanded study. Jones (2001) has reported that benefits of facilities that serve as clinical sites include improved work quality of staff, ability to maintain and upgrade staff skills and knowledge. None of the sites utilized in the expanded study participate in a hospital based clinical laboratory education program.

Clinical laboratory education programs must graduate sufficient students to replace the large number of professionals who are predicted to retire in the next five years. While numbers of accredited MLT/CLT programs have remained consistent over the past five years, accredited MT/CLS programs continue to close (National Accrediting Agency for

Clinical Laboratory Sciences, 2004). For example, in 1996, there were 352 accredited CLS/MT programs; today there are 232 programs. During this period, the CLS/MT has assumed an expanded role in healthcare with more diverse responsibilities, including consultation on laboratory testing and services, supervision of testing, oversight of point of care testing, quality assurance, education, marketing , information systems, management and reimbursement issues (NAACLS, 1999). Inadequate numbers of graduates from accredited and structured CLS/MT programs may certainly influence laboratory efficiency and quality as these positions may be filled by individuals who do not hold a clinical laboratory major. Laboratory departments with more experienced staff often develop efficient procedures that lead to increased productivity.

The study also suggests that health care facilities should reexamine the costs and benefits of clinical education. There are tangible and intangible benefits of clinical education. Studies (Jones, 2001) have shown that quality of care and productivity remain consistent and a net monetary benefit can be realized (Holland, 1997) while training students. Students may contribute to the work output and by virtue of the accreditation process. Those practitioners involved in education must participate in pertinent continuing education relevant to the discipline as well as to education methodologies. Furthermore, health care facilities may financially benefit through serving as a clinical affiliate. One study has shown that hiring a student trained in a health care facility resulted in $20,000 savings when costs of advertising, interviewing, training, recruitment, and overtime for covering the vacancy were all considered (Snyder, 1992).

retirements predicted in next five years.

Additionally, the number of years of experience of the testing personnel influenced the results of the PT surveys. Those with over 20 years of experience produced a 6864 (58.7%) of the results of which 6799(99.1%) were acceptable and 65 (0.9%) were not acceptable. Those with ten years or less of experience produced 1799 (15.4%) or the results of which 1774 (98.6%) were acceptable and 25 (1.4%) were not acceptable. Nearly half (48.3%) of the laboratory testing personnel in the expanded study had 20 years or more of experience and approaching retirement. These retirements will contribute to the shortage of laboratory personnel in the region included in the study. Insufficient staff is entering the workforce to replace the laboratory staff expected to retire in the next three to five years (Steward, Ward-Cook, & Tannar, 2005). Certainly, the skills and experience of a new employee as compared to a veteran laboratorian who has developed the ability to perform accurate and efficient analysis presents a concern.

The results for the variable, years, are more evenly distributed in the pilot study and thus, may be more reliable in the pilot study as compared to the expanded study. Analysis in the pilot study consistently revealed that those with two years or less of experience were more likely to produce errors in PT when compared to those with over 20 years of experience.

The findings in the expanded study support the hiring of certified personnel who have completed formal clinical laboratory education program. The presence of at least one certified MT/CLS at each participating site may have contributed to similar unacceptable or error rates for the various types of laboratories in this current study. Error rates ranged from 0.0% for one POL to 1.6% for a hospital laboratory. The overall error rate for the

combined laboratories was 1.0%; thus, the combined laboratories produced 99.0% acceptable results. Hoeltge, Phillips, and Mockrige (2005) reported 14,085 errors in 3,500,000 PT results or an error rate of 0.4% in a retrospective analysis of CAP proficiency testing in 2002-2003.

The similar performance for the various laboratory types contrasts with the results reported in prior studies, including that of Stull, Hearn, Hancock, Handsfield, & Collins (1997) who reported higher successful rates for hospital and independent laboratories as compared to other testing sites, such as POLs. An additional contribution to the high rate of acceptable PT results in the current study is the presence of at least one certified MT/CLS at each testing site. The presence of a MT/CLS has previously been associated with successful performance in PT by St. John, et al. (2002).

The study also found that a commercial reference laboratory employed 100% ASCP certified medical technologists produced 99.1% acceptable results which is lower when compared to other testing sites performing similar PT testing that employed a mixture of laboratory practitioners. This finding contrasted with the earlier studies of Lunz, Castleberry, James, & Stahl (1987) and Lunz, Castleberry, & James (1992) who reported that those laboratories that employ all ASCP certified medical technologists produced higher accuracy scores when compared to those laboratories employing no ASCP certified medical technologists.

Further, ASCP certified personnel from all six of the testing sites performed 10,691 (91.5%) of the results with 10,598 acceptable results (99.1%). By contrast, noncertified personnel produced 998 (0.09%) of the results with acceptable 978 (98.0%) results. Thus,

certified personnel produced statistically significant fewer unacceptable results when compared to noncertified personnel (χ^2 =11.083, p< 0.05).

Future studies with a more even distribution of certified and noncertified personnel are needed to determine if certification predicts for an acceptable PT result. A high correlation between certification and major in the pilot study may have suppressed the significance of certification. In addition, certification primarily measures didactic and not psychomotor skills, and may not predict performance in PT analysis.

Because both the expanded (Ohio and Pennsylvania) and pilot studies (Virginia) were performed in states that do not require licensure of laboratory testing personnel, the relationship of the study to licensure cannot be ascertained. Licensure requires continuing education and periodic assessment to ensure the continued competence of testing personnel. An expanded sample that incorporates practitioners from those states that require licensure is needed to determine if a statistically significant difference exists for licensed and nonlicensed laboratory personnel.

In both the pilot study and expanded study, satellite laboratories performed some of the PT analysis. In both cases, noncertified practitioners who did not hold laboratory majors staffed the satellite laboratories. The personnel in these satellite laboratories accounted for a large proportion of the unacceptable results. In the pilot study, the satellite laboratories performed 105 (3.2%) of the 3266 results reported and accounted for six of the 36 errors that resulted in an error rate of 5.7%. The remaining 30 errors were found in the 3161 results produced by the core laboratory producing an error rate of 0.95%. In the expanded study, the personnel in the satellite laboratory performed 132

(1.1%) of the 11,689 results and accounted for 16 (14.2%) of the 113 errors. The remaining 97 errors were found in the 11,577 results produced by the main laboratories producing an error rate of 0.84%. Additionally, the same satellite laboratory failed to submit an entire PT survey, an omission that may lead to probationary status for a laboratory. These examples highlight the importance of the presence of certified practitioners with a clinical laboratory major personnel in all laboratory settings and the impact of personnel who have not been educated in the clinical laboratory discipline. As laboratory testing moves from the traditional core laboratory to satellite and other alternative testing sites, quality laboratory testing must be maintained through qualified laboratory personnel.

The hospital laboratories and commercial reference laboratory utilized a greater percentage of personnel with a bachelor degree or higher when compared to the physician office laboratories. Personnel with a bachelor degree or higher personnel ranged from 62.5% to 100.0% for the hospital and commercial reference laboratory and 16.7% to 21.2% for the physician office laboratories. In each POL, there was one ASCP certified medical technologist. This medical technologist would have an expanded role with increased responsibility when compared to the hospital laboratories that employed several bachelor degreed or higher personnel in positions at the managerial and bench level.

Although not all practitioners participated in PT testing, a greater percentage of personnel were more likely to be utilized in the smaller laboratories that had lower numbers of testing personnel. For example, the POLs and CRL both had 100.0% of personnel who participated in PT while the rate for the hospital laboratories ranged from

65.2% to 96.9%. The hospital with the largest number of testing personnel and annual laboratory tests had the lowest percentage of participation in PT. Perhaps there are insufficient PT surveys available to include all practitioners in those facilities with the largest number of testing personnel. Alternatively, perhaps the laboratory managers assign PT analysis to the more experienced personnel in order to obtain more satisfactory results. Because this study did not survey the laboratory managers as to the process of assigning PT, this determination cannot be made. One laboratory manger indicated that a conscious effort is made to circulate PT surveys to all laboratory personnel involved in patient testing. At this site, all but one practitioner participated in the PT process.

The distinction between the effects of the two variables, major in CLS/MT and degree in CLS/MT is difficult to separate. Additionally, a high degree of correlation between major and degree may have affected the statistical significance of the outcome. Although not multicollinear, the correlation between major and degree was statistically significant at the 0.01 level for the pilot (p= -0.180), expanded (p=0.311) and merged (0.137) studies. A high correlation between independent variables may influence the variances in parameter estimates that may lead to the lack of statistical significance of individual independent variables while the overall model may be strongly significant (University of Kentucky Computing Center, 2005). Perhaps this is an explanation for the statistical significance of predictors, such as degree and certification in the nested models as compared to the nonsignificant result obtained while running the full model. Of note is the correlation between certification and major in the pilot study (p=0.749).

Some individuals while not attaining a degree in CLS/MT did indeed major in CLS/MT as indicated in the demographic information. However, these results strongly suggest that completion of a clinical laboratory sciences program is a qualification that laboratory managers should seek in their employees. The use of a single variable that indicates formal MT/CLS training from an accredited program may provide a clearer differentiation of the effects of clinical laboratory education for future studies.

Limitations

Limitations of the study included the use of a single year of PT data for the pilot study (2002) and for the expanded study (2003). Unique variation in the composition or characteristics of PT materials may have altered the suitability of the materials for analysis and the accuracy of the results. For example, in one survey for a bacterial antigen, the survey material could not be accurately analyzed by a particular commercial method. Reported as a methodological error, the results were graded as unacceptable by the survey provider, which falsely increased the number of unacceptable results.

An additional limitation is the small number of institutions utilized in the study. Though personnel from a mixture of laboratory types were ascertained for this study, the study sites were limited in number and geographical region, which restricts the ability to generalize the findings of the study. In addition, there was a high percentage (91.5%) of certified practitioners in the expanded study, which may not be typical for other regions of the country. The corresponding low percentage of noncertified personnel (8.5%) may not typify laboratorians in other regions. Also, the majority of nonlaboratory majors were employed in the nonhospital sites in the expanded study; a sample including a more

diverse mix of majors in all testing sites would be recommended for future studies. Years of experience was unevenly distributed in the expanded study with almost half of the participants held over 20 years of experience.

Although every attempt was made to obtain complete demographics on all study participants, this was not possible. Laboratory managers did not have access to the personal demographics of the testing personnel in some of the satellite laboratories in the pilot study. Perhaps a prospective study in which demographic data is collected prior to PT analysis would enable the investigator to obtain complete and thorough demographic information. A prospective study would also enhance the ability to obtain a more demographically diverse sample.

Additionally, not all laboratory practitioners participated in the PT, even though CLIA'88 mandates such participation for all testing personnel who perform patient testing. Therefore, the performance of those who did not participate in the study or who had missing demographic information could not be included in the logistic regression analysis and limits the interpretation of the results from this analysis.

Each PT result in the data set was treated as one case although the difficulty if performing the various analyses differs. Also, the effects of a practitioner who performs multiple errors may confound the analysis with repetition. The low percentage of unacceptable results may have affected the ability of some models to arrive at a solution. For example, no final solution could be found for some of the analysis using interactive variables after numerous iterations. However, a random selection of acceptable cases combined with all of the acceptable cases produced similar statistical significance for the

predictor variables, major and years of experience. Future studies might include a larger variety of laboratories and testing personnel to ascertain if the unacceptable performance rate is typically this low. However, laboratories with higher rates of unacceptable performance may be reluctant to participate in such a study.

Future studies would ideally include a larger and more diverse sample from laboratories that represent all of the geographic regions in the country. Increasing the sample size might afford the opportunity to investigate a larger number of unacceptable results.

The study revealed that a large percentage of the practitioners held over 20 years of experience and who participated extensively with high degrees of accuracy in the PT analysis. The process to replace veteran laboratorians with newly hired personnel may be more efficient if there is an opportunity to mentor students and new employees. As retirements continue to reduce the number of experienced laboratorians, health care facilities must seize this opportunity to establish or re-establish clinical laboratory education programs. Currently, the laboratory work force is well skilled and a unique opportunity exists to mentor prospective laboratorians. This prospect will be lost when the effects of retirements are realized in the upcoming years. The increased accuracy associated with clinical laboratory majors combined with expertise that may be garnered through a mentoring process with experienced personnel are needed to ensure quality laboratory analysis in the future.

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Appendix A:

Glossary of Key Terms

Glossary of Key Terms

Accreditation: A voluntary process where an agency or organization evaluates and recognizes a program of study or a facility as meeting certain predetermined qualifications or standards; The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) accredits hospitals. The process of external peer review whereby an agency grants public recognition to a program of study of in institution that meets established qualifications and educational standards; the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accredits clinical laboratory science programs

Accuracy: closeness of the agreement between the measured value of an analyte and its "true" value. (Koch and Peters in Tietz, p 234, 2001) of the measurement (NCCLS, 1996). Primary mechanism for assessment is PT.

Bias (systemic error) : systematic deviation of test results from the accepted reference value; relative difference between the mean number of measurements and the value expected on the basis of the result from the comparative method.

Certification: process whereby a nongovernmental agency or association grants recognition, usually to an individual who has met pertinent qualifications specified by

that agency or association, such as passing a national certification examination. Examples of agencies that certify laboratory personnel are the National Credentialing Agency for Laboratory Personnel (NCA) and the Board of Registry (BOR) of the American Society of Clinical Pathologists (ASCP). Laboratories may also be awarded certification, through achieving the requirements of a recognized laboratory accrediting agency, such as the College of American Pathologists (CAP) (Waller, 2003).

Commutability: ability of a test material to show interassay changes comparable to those in human sera; property of a stabilized material to produce results that show the same relationship between two different analytical procedures as to patient sera.

External Quality Assessment: quality program where specimens are submitted to laboratories for analysis and the results of the laboratory are compared with the results for the group of peer participating laboratories; sometimes used interchangeably with proficiency testing.

Inaccuracy: percent difference between a singled measured result and the value expected value expected on the basis of the result from the comparison method.

Licensure: Process where a state or local government recognizes an individual or institution through legislation enacted to protect the public by either controlling entrance into the profession through testing of by enforcing standards of practice.

Precision: closeness of agreement between a series of independent test results under specified conditions (NCCLS, 1996); not typically expressed as a numerical value, but quantitatively in terms of imprecision –the standard deviation (SD) or coefficient of variation (CV). Koch and Peters in Tietz, p 235, 2001. Primary mechanism for assessment is internal quality control.

Proficiency Testing: process where simulated patient specimens made from a common pool are analyzed by laboratories with the results submitted to an external agency who evaluates the results of the procedures to determine the quality of the laboratory's performance.

Quality control: laboratory's primary surveillance system for precision; QC materials are tested as patient samples, compared to established acceptable ranges as a measure of the degree to which the test system (equipment, reagents, operator) are within control limits. An unacceptable QC should lead to corrective action by the testing personnel.

Appendix B.

Data Collection Plan

Appendix B. Data Collection Plan

DATE

Dear XXXXXX

As per our recent discussions, I am seeking your participation as a test site for my dissertation research study to assess laboratory quality. The purpose of the study is to determine if laboratory quality as measured by performance on proficiency challenges is related to the credentials of the testing personnel. The study is being undertaken to fulfill my dissertation requirement for a doctoral degree, the Ph.D. Program in Health Related Sciences at Virginia Commonwealth University. The proposed study is a nonexperimental, retrospective review of existing proficiency testing scores in your clinical laboratory.

Demographic data that will be collected include degree, major, certification, and years of clinical experience. Laboratory quality will be measured by a review of existing proficiency test surveys and analysis of the number of successful and unsuccessful proficiency testing events in a one-year period. All participant sites and testing personnel will be assigned a unique code to ensure confidentiality.

I have enclosed the data collection plan and participant survey for your laboratory that will assist me in my research design and proposal. This participant form will permit me to review your facility's PT results and will also provide valuable information on your laboratory's demographics.

I will eagerly discuss this proposal in more detail with yourself, pathologists, and your laboratory staff. Please contact me if you wish to set up an appointment. Thank you, for your consideration of this project. Please don't hesitate to contact me if you have any questions. I look forward to working with you and your staff.

Please feel free to contact myself or my advisor, Teresa Nadder, Ph.D. for further clarification. Thank you for your participation.

Sincerely,

Maria E. Delost, MS, MT(ASCP), CLS(NCA)
Professor of Clinical Laboratory Programs, Youngstown State University
Doctoral Candidate --Virginia Commonwealth University --School of Allied Health Professions
[redacted]

Teresa Nadder, Ph.D., CLS(NCA), MT(ASCP)
Associate Professor and Assistant Chair, Dept. of Clinical Laboratory Sciences
Virginia Commonwealth University --School of Allied Health Professions
[redacted]

Consent to Participate

_____ (Laboratory Facility) located in _____ is willing to participate in "*Quality Laboratory Services - Is it Related to Personnel Credentials*", the dissertation proposal of Maria Delost. As the representative of this facility, I have read and comprehend the data collection procedure. Further, it is understood that all personnel credentials and survey results will remain confidential through a unique coding system.

_____

Signature Date

_____

Name Title

Demographic Survey

Laboratory Facility:_____
Contact Person:_____Position_____
Phone:_____ Email_____

1. Approximate Number of Clinical Procedures Annually:

Bacteriology _____ Chemistry _____
Mycology _____ Hematology _____
Parasitology _____ Coagulations _____
Mycobacteriology _____ Urinalysis _____
Blood Banking _____
Transfusions _____
Other (please specify type and number)

_____ _____
_____ _____
_____ _____

Total:_____

2. Type of Laboratory

Hospital Laboratory ____
Commercial Reference Laboratory ____
Private Laboratory ____
University Laboratory ____
Physician Office Laboratory ____
Other ____ Please specify type _____

3. Level(s) of testing performed

Waived _____
PPMP _____
Moderate Complexity _____
High Complexity _____

4. Testing Personnel Currently Employed:

Number of certified medical technologists/clinical laboratory scientists ___
Number of noncertified medical technologists/clinical laboratory scientists___
Number of certified medical laboratory technicians/clinical laboratory technicians___
Number of noncertified medical laboratory technicians/clinical laboratory technicians___
Number of certificate or diploma level clinical laboratory assistants_____
Other testing personnel:
Description_____ Number_____
Description_____ Number_____

Data Collection Method

Summary and General Directions

Existing Proficiency data for one year (2003) will be reviewed by each laboratory section manager and recorded on Tables 1 and 2. Data will be directly entered into Excel tables. The tables, provide in Excel and the demographic survey in Word will be furnished on a floppy disk. The disk can either be mailed or the tables sent as email attachments.

Using Table 1, create an anonymization table as detailed below to identify each testing personnel. Each individual laboratory testing personnel will be given a unique identifier (tech code) to maintain anonymity.

Record all PT events, using Table 2. Results of each PT event and the identification number of the testing personnel who performed each PT result are also recorded as detailed below. Alternatively, you may write the unique tech code on the actual proficiency test survey result sheets and mail them to me. As the investigator, I can then transfer the tech codes and information to Table 2 to facilitate data collection.

In addition, one demographic survey should be completed for each participant laboratory.

Examples of Table 1 and Table 2 are provided.

Table 1: Credentials of Testing Personnel

Directions for Completing Table I:

Assign a unique identifier (tech code) to each member of your section who performs proficiency testing. Each individual must receive a specific, unique number.

Codes may be assigned based on laboratory section. For example,

Hematology	1000 to 1099
Coagulations	1100 to 1199
Blood Banking/Transfusions	1200 to 1299
Microbiology	1300 to 1399
Immunology/Virology	1400 to 1499
Chemistry	1500 to 1599
Toxicology	1600 to 1699
Molecular Diagnostics	1700 to 1799
Generalist	1800 to 1899
EXCEL	1900 to 1999

1. Complete the personnel credentials for each individual to whom you have assigned a tech code. The following information is required:

    a. Highest Degree attained
    b. Major area of study (Medical Technology/Clinical Laboratory Science, Biology, Chemistry, etc.)
    c. Certification
        - Agency (ASCP, NCA, AMT)
        - Type or Level of certification: MLT/CLS, MT/CLT, Categorical (H,C, M), or specialist (SBB, SH, SM). For categorical and specialist, specify type.
    d. Years of experience as laboratory testing personnel
        - For partial years, round up to the next year for over six months and round down to the previous year for less than six months. For six months, indicate one-half year

Table 1A is provided to assist laboratory managers in data recording. It contains the same information as Table 1 with the addition of the tech name.

Table 1: Credentials of Testing Personnel

Tech Code	Highest Degree Attained	Major Area of Study (CLS/MT, Biology, Chemistry, etc.)	Certification		Years of Laboratory Experience
			*Agency	**Type or Level	

* Agency: ASCP, NCA, AMT

** **Type or Level: MT/CLS, MLT/CLT, Categorical (specify category)**

Table 1A: Credentials of Testing Personnel (Managers only; not to be revealed to investigators)

Tech Name	Tech Code	Highest Degree Attained	Major Area of Study (CLS/MT, Biology, Chemistry, etc.)	Certification		Years of Laboratory Experience
				*Agency	**Type or Level	

* Agency: ASCP, NCA, AMT

** Type or Level: MT, MLT, Categorical (specify category)

This form is for laboratory manager use only and will not be made available to the investigators for purposes of confidentiality.

Table 2: PT Data Collection Directions:

Directions for Completing Table 2

Record all PT events and the name of all tests for which a result was reported for an event. Note the actual numeric or alpha result is not necessary, only that a result was reported.

Indicate beside each result name if it was acceptable or not according to the criteria used for evaluation by the PT provider.

Record the following information:

1. PT Provider: CAP, COLA, AABB, Other (please specify)
   There may be a variety of PT providers depending on the analyte or group.

2. Survey Cycle/Year: Indicate Cycle such as A, B, or C and year

3. Survey Code/Name: Indicate group, such as Bacteriology, Hematology and Code, such as C-6, C-7.

4. Analyte Name: Indicate name of test or analyte, such as Albumin, ALT, WBC, RBC. Each analyte measured for a particular challenge would be noted as a row in the table for that specific code.

5. Response (results) accepted? Please indicate yes if the result was accepted and no if the result was not accepted. If the response is no, please indicate the type of error or exception code. These are located at the end of the table. For response #6 (other), indicate type of error when possible. If the response is yes, no further explanation is required.

6. Tech Code: Enter the unique identifier assigned to each individual testing personnel.

NOTE: Alternatively, you may write the unique tech code on the actual proficiency test survey result sheets. As the investigator, I can then transfer the tech codes and information to Table 2 to facilitate data collection.

Table 2: PT Data Collection

PT Provider:	Survey/Cycle:	Survey Code/Name:	
Analyte Name	Response Accepted: Yes or No If No, specify type of error or exception code		Tech Code
	Yes/No	Error Type or Exception Code*	

*Error Codes for Unacceptable Result:

1: Methodologic Problem **2:** Technical Problem **3:** Clerical Error

4: Problem with Survey Materials **5**:No Explanation after investigation **6:** Other (specify)

Appendix C: IRB

VCU

Virginia Commonwealth University

MCV Campus

Office of Research
Subjects Protection

DATE: April 3, 2003

TO: [redacted]

FROM: [redacted]

RE: **VCU IRB #: 03131**
Title: Proficiency Test Performance: It is related to Personnel Credentials?

On April 1, 2003 the following research study ***qualified for exemption*** according to 45 CFR 46.101(b) Category 4. This determination includes the following items reviewed by this Panel:

RESEARCH APPLICATION/PROPOSAL: None

PROTOCOL: Proficiency Test Performance: It is related to Personnel Credentials?

ADDITIONAL DOCUMENTS:

- Sample Informational Letter, received March 13, 2003

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable)*:

1) Conduct the research as described in and required by the approved protocol.

2) Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved).

3) Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent Documentation is specifically approved).

MCV Campus

Virginia Commonwealth University

Office of Research
Subjects Protection

DATE: January 24, 2005

TO: [redacted]

FROM: [redacted]

RE: **VCU IRB #: 03131**
Title: Proficiency Test Performance: It is related to Personnel Credentials?

On January 23, 2005 the following **change(s)** to your research study have ***qualified for exemption*** according to 45 CFR 46.101(b) Category 4. This determination reflects the revisions received in the Office of Research Subjects Protection on January 6, 2005. This determination includes the following items reviewed by this Panel:

PROTOCOL:

- **Proficiency Test Performance: It is related to Personnel Credentials?**
  - **Tri State Medical Group Laboratory – Beaver Falls, PA**

This Institutional Review Board is in compliance with good clinical practices (GCP) as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonization (ICH) guidelines. Virginia Commonwealth University is approved by DHHS to conduct human subjects research under a Federal Wide Assurance #FWA00005287. **All correspondence related to this research study must include the IRB protocol number and the investigator's name(s) to assist us in locating your file. Please note that the CCHR number is no longer valid, if applicable.**

The Primary Reviewer assigned to your research study is Dennis Hoban, ED. If you have any questions, please contact Dr. Hoban at [redacted] or you may contact Brenda Innis, IRB Coordinator, VCU Office of Research Subjects Protection, at [redacted]

Appendix D:

Demographics of Laboratory Personnel of Individual Laboratories

Table D1,

Laboratory Personnel by College Degree

College Degree	Number	Percentage
HL-1		
Associate Degree	6	8.7%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	60	88.4%
Bachelor of Science in Biology or Chemistry	2	2.9%
Other Master Degree	1	0.0%
Total HL-1	69	100.0%
HL-2		
None (High School Diploma)	5	15.6%
Associate Degree	7	21.9%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	15	46.9%
Bachelor of Science in Biology or Chemistry	3	9.4%
Other Bachelor of Arts or Bachelor of Science	2	6.2%
Total HL-2	32	100.0%
HL-3		
None (High School Diploma)	3	6.4%
Associate Degree	8	17.0%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	16	34.0%
Bachelor of Science in Biology or Chemistry	7	14.9%
Other Bachelor of Arts or Bachelor of Science	12	25.5%
Other Master Degree	1	2.1%
Total HL-3	47	100.0%
POL-1		
Associate Degree	5	83.3%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	1	16.7%
Total POL-1	6	100.0%
POL-2		
Associate Degree	7	77.8%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	2	21.2%
Total POL-2	9	100.0%

(table continues)

College Degree	Number	Percentage
CRL-1		
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	11	100.0%
Total CRL-1	11	100.0%
Combined Laboratories		
None (High School Diploma)	8	4.6%
Associate Degree	33	19.0%
Bachelor of Science in Medical Technology (MT)/Clinical Laboratory Science (CLS)	105	60.3%
Bachelor of Science in Biology or Chemistry	12	7.0%
Other Bachelor of Arts or Bachelor of Science	14	8.0%
Master Degree	2	1.1%
Total Combined Laboratories	174	100.0%

Table D2.

Laboratory Personnel by College Major

College Major	Number	Percentage
HL-1		
MLT/CLT	6	8.7%
MT/CLS	63	91.3%
Total HL-1	69	100.0%
HL-2		
None	4	12.5%
MLT/CLT	8	25.0%
MT/CLS	15	46.9%
Biology/Microbiology/Animal Science	4	12.5%
Other	1	3.1%
Total HL:2	32	100.0%
HL-3		
None	1	2.1%
MLT/CLT	8	17.0%
MT/CLS	17	36.2%
Biology/Microbiology/Animal Science	13	27.7%
Chemistry/Biochemistry	3	6.4%
Other	5	10.6%
Total HL-3	47	100.0%
POL-1		
MLT/CLT	4	66.6%
MT/CLS	1	16.7%
Other	1	16.7%
Total POL-1	6	100.0%
POL-2		
MLT/CLT	3	33.3%
MT/CLS	1	11.1%
Other	5	55.6%
Total POL-2	9	100.0%
CRL-1		
MT/CLS	11	100.0%
Total CRL-1	11	100.0%

(table continues)

College Major	Number	Percentage
Combined Laboratories		
None	5	2.9%
MLT/CLT	29	16.6%
MT/CLS	108	62.0%
Biology/Microbiology/Animal Science	17	9.8%
Chemistry/Biochemistry	3	1.7%
Other	12	7.0%
Total	174	100.0%

Table D3.

Laboratory Personnel by Certification Agency

Certification Agency	Number	Percentage
HL-1		
None	0	0.0%
ASCP	69	100.0%
Total HL-1	69	100.0%
HL-2		
None	3	9.4%
ASCP	25	78.1%
Multiple (Both ASCP & NCA)	4	12.5%
Total HL-2	32	100.0%
HL-3		
None	7	14.9%
ASCP	38	80.0%
Multiple (Both ASCP & NCA)	2	4.3%
Total HL-3	47	100.0%
POL-1		
None	0	0%
ASCP	6	100.0%
Total POL-1	6	100.0%
POL-2		
None	5	55.6%
ASCP	4	44.4%
Total POL-2	9	100.0%
CRL-1		
None	0	100.0%
ASCP	11	100.05
Total CRL-1	11	100.0%
Combined Laboratories		
None	15	8.6%
ASCP	153	87.9%
Multiple (Both ASCP & NCA)	6	3.5%
Total Combined Laboratories	174	100.0%

Table D4.
Laboratory Personnel by Certification Level

Certification Level	Number	Percentage
HL-1		
None	0	0.0%
MLT/CLT	6	8.7%
MT/CLS	59	85.5%
Specialist (SH, SM, SBB)	4	5.8%
Total HL-1	69	100.0%
HL-2		
None	3	9.4%
Clinical Laboratory Assistant (CLA)	2	6.2%
MLT/CLT	7	21.9%
MT/CLS	20	62.5%
Total HL-2	32	100.0%
HL-3		
None	7	14.9%
Clinical Laboratory Assistant (CLA)	1	2.1%
MLT/CLT	6	12.8%
MT/CLS	30	63.8%
Specialist (SH, SM, SBB)	3	6.4%
Total HL-3	47	100.0%
POL-1		
MLT/CLT	5	83.3%
MT/CLS	1	16.7%
Total POL-1	6	100.0%
POL-2		
None	5	55.6%
MLT/CLT	3	33.3%
MT/CLS	1	11.1%
Total POL-2	9	100.0%
CRL-1		
MT/CLS	11	100.0%
Total CRL-1	11	100.0%
Combined Laboratories		
None	15	8.6%
Clinical Laboratory Assistant (CLA)	3	1.7%
MLT/CLT	27	15.5%
MT/CLS	122	70.2%
Specialist (SH, SM, SBB)	7	4.0%
Total Combined Laboratories	174	100.0%

Table D5.
Laboratory Personnel by Years of Experience

Years	Number	Percentage
HL-1		
Less than 1	1	1.4%
1 -- 2	1	1.4%
3 -- 5	1	1.4%
6 -- 10	3	4.3%
11 -- 15	10	14.5%
16 – 20	10	14.5%
21 – 25	14	20.3%
Over 25	29	42.0%
Total HL-1	69	100.0%
HL-2		
Less than 1	1	3.1%
1 -- 2	2	6.2%
3 -- 5	1	3.1%
6 -- 10	7	21.9%
11 -- 15	6	18.8%
16 – 20	4	12.5%
21 – 25	2	6.2%
Over 25	9	28.2%
Total HL-2	32	100.0%
HL-3		
1 -- 2	1	2.1%
3 -- 5	1	2.1%
6 -- 10	9	19.1%
11 -- 15	8	17.0%
16 – 20	6	12.8%
21 – 25	11	23.4%
Over 25	9	19.1%
Years not given	2	4.3%
Total HL-3	47	100.0%
POL-1		
11 -- 15	3	50.0%
Over 25	3	50.0%
Total POL-1	6	100.0%

(table continues)

Years	Number	Percentage
POL-2		
3 -- 5	3	33.3%
6 -- 10	3	33.3%
11 -- 15	1	11.1%
16 – 20	1	11.1%
Over 25	1	11.1%
Total POL-2	9	100.0%
CRL-1		
3 -- 5	3	27.3%
6 -- 10	2	18.2%
11 -- 15	1	9.1%
16 – 20	1	9.1%
Over 25	4	36.4%
Total CRL-1	11	100.0%
Combined Laboratories		
Less than 1	2	1.1%
1 -- 2	4	2.3%
3 -- 5	9	5.2%
6 -- 10	24	13.8%
11 -- 15	29	16.7%
16 – 20	22	12.6%
21 – 25	27	15.6%
Over 25	55	31.6%
Years not known	2	1.1%
Total Combined Laboratories	**174**	**100.0%**

Appendix E: PT Results by Demographics

Table E1.
PT Results by Educational Degree of Laboratory Personnel

Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
HL-1				
Associate Degree	6	354	9.4%	2
Bachelor of Science in MT/ CLS	62	3342	88.9%	42
Master Degree	1	64	1.7%	1
Total HL-1	69	3760	100.0%	45 (65.2%)
HL-2				
None (High School Diploma)	5	140	8.2%	4
Associate Degree	7	322	18.7%	7
Bachelor of Science in MT/CLS	15	769	44.7%	15
Bachelor of Science in Biology or Chemistry	3	264	15.3%	3
Other Bachelor of Arts or Bachelor of Science	2	225	13.1%	2
Total HL-2	32	1720	100.0%	31 (96.9%)
HL-3				
None (High School Diploma)	3	401	12.3%	3
Associate Degree	8	567	17.4%	8
Bachelor of Science in MT/CLS	16	1394	14.8%	16
Bachelor of Science in Biology or Chemistry	7	257	7.9%	5
Other Bachelor of Arts or Bachelor of Science	12	632	19.4%	11
Other Master Degree	1	3	0.1	1
Total HL-3	47	3254	100.0%	44 (93.6%)

(table continues)

Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
POL-1				
Associate Degree	5	418	66.0%	5
Bachelor of Science in MT/CLS	1	114	18.0%	1
Other Bachelor of Arts or Bachelor of Science	1	101	16.0%	0
Total POL-1	6	633	100.0%	6 (100%)
POL-2				
Associate Degree	7	801	97.4%	7
Bachelor of Science in MT/CLS	2	21	2.6%	2
Total POL-2	9	822	100.0%	9 (100%)
CRL-1				
Bachelor of Science in MT/CLS	11	1501	100.0%	11
Total CRL-1	11	1501	100.0%	11 (100%)
Combined Laboratories				
None (High School Diploma)	8	541	3.5%	7
Associate Degree	33	2462	21.1%	29
Bachelor of Science in MT/CLS	105	7140	61.1%	85
Bachelor of Science in Biology or Chemistry	12	521	4.5%	8
Other Bachelor of Arts or Bachelor of Science	14	958	8.2%	13
Other Master Degree	2	67	0.6%	2
Total	174	11,689	100.0%	144

Table E2.

PT Results by College Major of Laboratory Personnel

Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
HL-1				
MLT/CLT	6	354	9.4%	2
MT/CLS	63	3406	90.6%	43
Total HL-1	69	3760	100.0%	45 (65.2%)
HL-2				
None	4	77	4.5%	4
MLT/CLT	8	385	22.4%	8
MT/CLS	15	769	44.7%	15
Biology/Microbiology/ Animal Science	4	489	28.4%	4
Other	1	0	0.0%	0
Total HL-2	32	1720	100.0%	31 (96.9%)
HL-3				
None	1	191	5.9%	1
MLT/CLT	8	284	8.7%	8
MT/CLS	17	1397	42.9%	17
Biology/Microbiology/ Animal Science	13	329	10.1%	10
Chemistry/Biochemistry	3	428	13.2	3
Other	5	625	19.2%	5
Total HL-3	47	3254	100.0%	44 (93.6%)
POL-1				
MLT/CLT	4	519	82.0%	4
MT/CLS	1	114	18.0%	1
Other	1	0	0.0%	1
Total POL-1	6	633	100.0%	6 (100%)
POL-2				
MLT/CLT	3	363	44.2%	3
MT/CLS	1	15	1.8%	1
Other	5	444	54.0%	5
Total POL-2	9	822	100.0%	9 (100%)
CRL-1				
MT/CLS	11	1501	100.0%	11
Total CRL-1	11	1501	100.0%	11 (100 %)

(table continues)

Degree	Number in Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
Combined Laboratories				
None	5	268	1.7%	5
MLT/CLT	29	1905	16.3%	25
MT/CLS	108	7201	61.6%	86
Biology/Microbiology/ Animal Science	17	818	7.0%	14
Chemistry/Biochemistry	3	428	3.7%	3
Other	12	1069	9.1%	11
Total Combined Laboratories	174	11,689	100.0%	144 (82.8%)

Table E3.

PT Results by Certification Agency of Laboratory Personnel

Certification Level	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
HL-1				
None	0	0	0.0%	0
ASCP	69	3760	100.0%	45
Total HL-1	69	3760	100.0%	45 (65.2%)
HL-2				
None	3	32	1.0%	2
ASCP	25	1464	85.1%	25
Multiple (Both ASCP & NCA)	4	224	13.0%	4
Total HL-2	32	1720	100.0%	31 (96.9%)
HL-3				
None	7	471	14.5%	6
ASCP	38	2754	84.6%	36
Multiple (Both ASCP & NCA)	2	29	0.9%	2
Total HL-3	47	3254	100.0%	44 (93.6%)
POL-1				
None	0	0	0.0%	0
ASCP	6	633	100.0%	6
Total POL-1	6	633	100.0%	6 (100%)
POL-2				
None	6	495	60.2%	6
ASCP	3	327	39.8%	3
Total POL-2	9	822	100.0%	9 (100%)
CRL-1				
MT/CLS	11	1501	0.0%	11
Total CRL-1	11	1501	100.0%	11 (100%)
None	15	998	8.5%	14
ASCP	153	10438	89.3%	124
Multiple (Both ASCP & NCA)	6	253	2.2%	6
Total Combined Laboratories	174	11,689	100.0%	144

Table E4.
PT Results Completed by Certification Level of Laboratory Personnel

Certification Type	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
HL-1				
MLT/CLT	6	354	9.4%	2
MT/CLS	59	3266	86.9%	39
Specialist (SH, SM, SBB)	4	140	3.7%	4
Total HL-1	69	3760	100.0%	45 (65.2%)
HL-2				
None	3	34	2.0%	2
Clinical Laboratory Assistant (CLA)	2	131	7.6%	2
MLT/CLT	7	267	15.5%	7
MT/CLS	20	1288	74.9%	20
Total HL-2	32	1720	100.0%	31 (96.9%)
HL-3				
None	7	471	14.5%	6
Clinical Laboratory Assistant (CLA)	1	191	4.9%	1
MLT/CLT	6	209	6.4%	5
MT/CLS	30	2312	71.0%	29
Specialist (SH, SM, SBB)	3	71	2.2%	3
Total HL-3	47	3254	100.0%	44
POL-1				
MLT/CLT	5	519	82.0%	5
MT/CLS	1	114	18.0%	1
Total POL-1	6	633	100.0%	6 (100%)
POL-2				
None	6	495	60.2%	6
MLT/CLT	2	312	38.0%	2
MT/CLS	1	15	1.8%	1
Total POL-2	9	822	100.0%	9 (100%)
CRL-1				
MT/CLS	11	1501	0.0%	11
Total CRL-1	11	1501	100.0%	11 (100%)

(table continues)

Certification Type	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
Total Combined Laboratories				
None	15	998	8.5%	14
Clinical Laboratory Assistant (CLA)	3	322	2.8%	3
MLT/CLT	27	1661	14.2%	21
Categorical (H, M, C, BB)	0	0	0.0%	0
MT/CLS	122	8486	72.6%	99
Specialist (SH, SM, SBB)	7	221	1.9%	7
Total Combined Laboratories	174	11,689	100.0%	144

Table E5.
PT Results by Years of Experience of Laboratory Personnel

Years	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
HL-1				
Less than 1	1	0	0	0
1 -- 2	1	0	0	0
3 -- 5	1	32	0.9	1
6 – 10	3	0	0.0%	0
11 -- 15	10	91	2.4%	3
16 – 20	10	614	16.3%	8
21 – 25	14	867	23.1%	10
Over 25	29	2156	57.3%	23
Total HL-1	69	3760	100.0	45 (65.2%)
HL-2				
Less than 1	1	0	0.0%	0
1 -- 2	2	33	1.9%	2
3 -- 5	1	89	5.2%	1
6 – 10	7	424	24.7%	7
11 -- 15	6	123	7.2%	6
16 – 20	4	172	10.0%	4
21 – 25	2	118	6.9%	2
Over 25	9	761	44.2%	9
Total HL-2	32	1720	100.0	31 (96.9%)
HL-3				
Less than 1	0	0	0.0%	0
1 -- 2	1	0	0.0%	0
3 -- 5	1	9	0.3%	1
6 -- 10	9	357	11.0%	7
11 -- 15	8	131	4.0%	8
16 – 20	6	556	17.1%	6
21 – 25	11	982	30.2%	11
Over 25	9	1008	31.0%	9
Years Not Given	2	211	6.5%	2
Total HL-3	47	3254	100.0	44
POL-1				
11 -- 15	3	304	50.0%	3
Over 25	3	329	50.0%	3
Total POL-1	6	633	100.0%	6(100.0%)

(table continues)

Years	Number of Individuals in Study	Number of Results Completed	Percentage of Results Completed	Number of Individuals Performing PT
POL-2				
3 -- 5	3	343	41.7%	3
6 – 10	3	107	13.0%	3
11 -- 15	1	147	17.9%	1
16 – 20	1	210	25.5%	1
Over 25	1	15	1.8%	1
Total POL-2	9	822	100.0%	9 (100%)
CRL-1				
3 -- 5	3	234	15.7%	3
6 – 10	2	171	11/5%	2
11 -- 15	1	349	23.5%	1
16 – 20	1	329	21.7%	1
Over 25	4	418	27.0%	4
Total CRL-1	11	1501	100.0%	11 (100%)
Combined Laboratories				
Less than 1	2	0	0.0%	0
1 -- 2	4	33	0.3%	2
3 -- 5	9	707	6.0%	9
6 – 10	24	1059	9.1%	19
11 -- 15	29	1145	9.8%	22
16 – 20	22	1881	16.1%	20
21 – 25	27	1967	16.8%	23
Over 25	55	4687	40.1%	47
Years Not Given	2	210	1.8%	2
Total Combined Laboratories	174	11,689	100.0	144

Vita