Assessment of technical competence of candidates within a Clinical Pathology discipline

By

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DECLARATION

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material that has been accepted for the award of any other degree or diploma of the university or other institute of higher learning, except where due acknowledgment has been made in the text.

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DEDICATION

"Give thanks to the Lord, for He is good; His love endures forever" Psalm 108:1

This master's thesis is dedicated to my parents, my late father, Gopaul, and my mother, Mathilda, my sister Rosemary and brothers Gerard and, the late Kevin Govender.

Last but not least, my loving and supportive husband, Vinesh Baruth for graciously allowing me time and space to complete this dissertation and motivating and encouraging me on this journey. I am truly blessed to have him in my life.

ABSTRACT

Background

Medical laboratories play a crucial role in patient care and require a competent skilled workforce to deliver this essential service. The current process of Medical Technologist training is a summative assessment consisting of two written 3 hour papers that correlates theoretical knowledge acquired at a tertiary level with the practical internship. Currently there is no assessment of technical competence of Intern Medical Technologists (candidates) by the HPCSA.

Aim: This study aims to determine how technical competence was assessed for Intern Medical Technologists who are eligible to write the National Board Examination in the Clinical Pathology discipline.

Methods: A quantitative design was used for assessing the technical competence of the candidates that were eligible to write the National Board Examination by using an adapted SANAS witnessing tool across ten Clinical Pathology test procedures by direct observation as well as to determine how technical competence is assessed in HPCSA registered training laboratories using a survey administered to Laboratory managers and trainers. The data was collected and analysed using the statistical software SPSS version 24.0.

Results:

Some candidates that were directly observed in each of the Clinical Pathology test procedures were deemed not yet competent in compliance and adherence to SOP's, acceptability of results, internal quality control procedures and the acceptability of the outcome and availability of signed training and competency records on the direct observation checklist. These results of the assessment of technical competence were compared to the results of the National Board examination that candidates wrote and there was no correlation between the two except for the Microbiology sub-discipline and the general section.

Results of operations of competency assessment in 9 HPCSA registered Training Laboratories revealed that 100% of respondents have a technical competence laboratory policy, 90% identified the Laboratory Manager as having responsibility for ensuring assessment of staff competency, 100% stated that frequency of competency testing was upon initial employment and once in two years thereafter, 90% had clear criteria to define competency assessment and 100% indicated that the remedial process used in their laboratories was documented corrective action which included re-training and re-assessment.

Conclusion:

From this study it can be concluded that assessment of technical competency for Intern Medical Technologists in the Clinical Pathology could augment current assessment systems of Intern Medical Technologists for conferment of professional designation and a policy review is recommended.

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LIST OF ABBREVIATIONS AND ACRONYMS

ABBREVIATION	DESCRIPTION
HPCSA	Health Professions Council of South Africa
SMLTSA	Society of Medical Technologists of South Africa
SAQA	South African Qualifications Authority
ISO	International Standards Organization
SANAS	South African National Accreditation System
ETDP SETA	Education Training and Development Practices Sector Education and Training Authority
OSCE	Objective Structured Clinical Examinations
CBME	Competency-Based Medical Education
CLSI	Clinical and Laboratory Standards Institute
QC	Quality Control
CAP	College of American Pathologists
JACHO	Joint Commission on Accreditation of Healthcare Organisation
SLMTA	Strengthening Laboratory Management Toward Accreditation
WHO	World Health Organisation
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
WHO AFRO	World Health Organisation's Regional Office for Africa
CSF	Cerebrospinal Fluid
UK	United Kingdom
HCPC	Health and Care Professions Council
IBMS	Institute of Biomedical Science
mcq	multiple choice question

EPBS	European Association for Professions in Biomedical Sciences
KZN	KwaZulu-Natal
NHLS	National Health Laboratory Services
TB	Tuberculosis
MCS	Microscopy, Culture and Antimicrobial Sensitivities
RPR	Rapid plasma regain
FBC	Full Blood count
ESR	Erythrocyte sedimentation rate
DIFF	Slide differential count
PT	Proficiency testing
EQA	External Quality Assurance
CHEM PATH	Chemical Pathology
vs	versus
LIS	laboratory information system
Clin Path	Clinical Pathology
Micro Exam	Microbiology National Board Examination
Chem Exam	Chemical Pathology National Board Examination
Haem Exam	Haematology National Board Examination
Gen Exam	General examination National Board Examination
PoE	Portfolio of Evidence
DHET	Department of Higher Education and Training

CHAPTER ONE: INTRODUCTION AND BACKGROUND TO THE STUDY

1.1. INTRODUCTION

Medical laboratories play a crucial role in patient care and require a competent skilled workforce to deliver this essential service. Medical laboratories consist of the technical and non-technical staff members. The technical staff categories are made up of Pathologists, Medical Technologists, Medical Technicians, and Medical Laboratory Assistants. Medical Technologists are the backbone of the laboratory service because they are mainly responsible for all acts performed during the analysis of pathological samples and support medical practitioners in the diagnosis and treatment of patients (HPCSA, 2005). The training of a Medical Technologist consists of a three (3) year national diploma qualification from a University of Technology followed by an internship period of twelve (12) months in a Health Professions Council of South Africa (HPCSA) registered training laboratory (HPCSA, 2008).

The current process of Medical Technologist training is a summative assessment which consists of two written 3 hour papers correlating theoretical knowledge that was acquired at the University of Technology with the practical internship. The examinations are conducted by the Society of Medical Technologists of South Africa (SMLTSA) as recognized by the Professional Board for Medical Technology. The Professional Board for Medical Technology is a statutory body that promotes healthcare of the population, determines standards of education and training and setting and maintaining excellent standards of ethical and professional practice.

Once an intern technologist passes this National Board Examination and satisfies all other rules, registration as a qualified Medical Technologist with HPCSA for independent practice follows as the professional body confers the professional designation. The Health Professions Act 56 of 1974, rules for the registration of Medical Technologists section 1, subsection 3 states that the council may register a Medical Technologist if he shall have passed an examination recognized by the Professional Board for Medical Technology and the council for registration purposes.

The purpose of this Board Examination is to confer professional designation. A professional designation means a title or status conferred by a professional body in recognition of a person's expertise and /or right to practice in an occupational field according to South African Qualifications Authority (SAQA) National policy and criteria for designing and implementing assessment in South Africa (SAQA, 2008).

1.2. ADEQUACY OF INTERN MEDICAL TECHNOLOGIST ASSESSMENTS

Currently there is no stipulated requirement for technical competence assessment for Intern Medical Technologists (candidates) by the HPCSA. The lack of the technical competence assessments makes this important aspect of training to be an optional activity for some laboratories. The missing practical assessment is according to some studies what drives learning (Carr, 2004; Holmboe et al, 2010). The assessment methods and tools used for competence need to meet the minimum requirements for quality as determined by the International Standards Organization (ISO) standard 15189:2012 for medical laboratories. According to the South African National Accreditation System (SANAS) 15189 standard (2012) the laboratory must follow appropriate training and must assess technical competency according to established criteria.

There has also been a paradigm shift from structure and process based to competency–based education and measurements of outcomes (Carraccio et al, 2002). A single assessment method is not optimal for medical professionals (Baartman et al, 2007; Epstein, 2007; Miller, 1990).

According to Holmboe et al (2010), medical education has suffered from too much variability in the choice and use of assessment tools, akin to the variability seen in the delivery and quality of healthcare. The success of competency based medical education does not only depend on the combination of better assessment tools but a more skilled faculty and other assessors who will use them (Holmboe et al, 2010).
Desjardins and Fleming (2014), suggest that competency evaluation of candidates should include measures of determination of what the individual knows what the individual can do, and if the individual actually follows policies and procedures

prescribed. A distinction should be made between the use of formative versus summative assessments and it is vital when selecting a method for evaluating competence of high stake assessments such as licensing and certification exams (Epstein, 2007). Most authors advocate for an integrated assessment that involves the use of all the different types of assessment tasks required for a professional designation such as written tests and practical demonstration of competence. Integrated assessment should assess the ability to combine key foundational practical and reflexive competencies and apply these in a practical context for a defined purpose (DHET, 2010).

Kruger, Eagleton and Maule (2016) have stated that high failure rates of Intern Medical Technologists in the National Board examinations have been a serious continuing concern over the last ten years and the majority of students who successfully attain the National Diploma find it very challenging to pass their National Board examination on first attempt.

Personal communication using emails on the 2 December 2015 with Ms Bukiswa Bungane and 14 November 2016 with Ms Roshini Bridgemohan, Laboratory Managers have revealed concerns regarding the current situation where candidates who are technically competent have failed the written Board Examination and, also those candidates that have passed the Board Examination in Clinical Pathology but are not yet technically competent in some laboratory processes. This is a challenge as these candidates are hired on the premise that they are “qualified” and have an HPCSA registration for independent practice.

It is thus unclear if the current written Board Examination alone is an adequate means of assessing technical competence of an Intern Medical Technologist or an integrated assessment approach using a practical element of assessing technical competence by direct observation should be included.

This study aims to determine how technical competence was assessed for Intern Medical Technologists who are eligible to write the National Board Examination in Clinical Pathology discipline and to further assess their technical competencies

The goal of the study is to make policy recommendations for a possible augmentation of the regulations and rules of training and assessment of Intern Medical Technologists for conferment of professional designation.

1.3. OBJECTIVES AND KEY QUESTIONS

The aim of the research is:

1. To determine how technical competence is assessed in HPCSA registered training laboratory by using a questionnaire adapted from Desjardins and Fleming (2014) study.
2. To assess the technical competencies of Intern Medical Technologists who are eligible to write the National Board Examination by direct observation.

The objectives are:

- To observe the most common Clinical Pathology processes used to deem a Medical Technologist technically competent in the medical laboratories using a modified validated SANAS F15 - Witnessing tool for direct observation.
- To identify possible factors that may lead to candidates not achieving technical competence levels – this will be established by the questionnaire that will be administered to Laboratory Managers as well as from the direct observation.
- To compare the technical competence assessment results from the direct observation with the National Board Examination results.
- To determine how technical competence is assessed in HPCSA registered training laboratories with the use of a questionnaire

1.4. CONCLUSION

This chapter presented a background on the current assessment of competency for conferring professional designation and competency based medical education. This study aimed at assessing technical competence of candidates eligible to write the next Board Examination by direct observation in a Clinical Pathology discipline. It further aimed to determine how technical competence is assessed in HPCSA

registered training laboratories. The following chapter covers the literature regarding assessment, competence, competency based medical education and laboratory standards in a medical laboratory.

CHAPTER TWO: LITERATURE REVIEW

2.1. INTRODUCTION

In this chapter the researcher conducts a literature review on competency based assessment in medical education and in particular Biomedical Technology, the field of the current study. The following databases: Google scholar and PUBMED were consulted to perform a literature search. The search terms used were assessment, competence, technical competence, and clinical competence, assessment of competence, competency, biomedical science, medical laboratory, pathology laboratory and competency-based medical education.

Machi (2009), emphasises that literature review is a practical and theoretical imperative of every health care practitioner who has the responsibility of evidence-based medicine. Performing a literature review allows one to explore different types of reasoning about a particular topic. Machi (2009), confirms that conducting a literature review empowers one with a sound knowledge base on the selected topic. The review has some limitation of using assessment of competence studies from so-called first world countries (mostly United Kingdom, Canada, United States of America) as no published literature from South Africa or within Africa is available in this area of study yet. Further to this competency assessment literature was used mostly from other health care professionals mainly medical doctors as limited literature was available for Medical Technologists or Biomedical Laboratory Scientists.

2.2 ASSESSMENT AND ASSESSMENT PRINCIPLES

South African Qualifications Authority (SAQA 2008), defines assessment as “the process used to gather and interpret information and evidence against the required competencies in a qualification or professional designation in order to make a judgment about a learner’s achievement.”

It is essential to adhere to the assessment principles provided by SAQA when conducting assessments and designing assessment methods. The assessment principles include validity, reliability, integrity, transparency, accountability, fairness,

absence of bias, sensitivity to language, credibility in the form of supportive administration procedures and assessment range (SAQA 2008). Validity refers to the congruence between what the assessment sets out to measure with that which is actually measured. Validity relates mainly to the assessment design and the assessment method must be fit for purpose. Reliability is when similar results are achieved even though different measures are used under consistent conditions. These assessment principles must be built into the direct observation instruments being designed for the study on technical assessment of competence. Five criteria for determining the usefulness of a particular method of assessment according to Van Vleuten and cited by Epstein (2007) include reliability, validity, impact on future learning and practice, acceptability to learners and faculty and costs (to the individual trainee, the institution, and society at large).

2.3 IMPLEMENTING ASSESSMENT FOR DIFFERENT PURPOSES

2.3.1 Formative assessment

Formative assessments include demonstrations, feedback on partly and completed work, interaction with trainers either individually or in small groups. These formative assessments may be regarded as formal when the results are recorded and count towards promotion marks (SAQA 2008).

2.3.2 Summative assessment

Summative assessment is performed following whole learning programme to evaluate learning related to that qualification or professional designation (SAQA, 2008). The Education Training and Development Practices Sector Education and Training Authority (DHET 2010), states that summative assessment should be made up of evidence collected through a variety of assessment methods and through activities that are part of current or previous work or life experience.

2.3.3 External assessment

External assessment means that this is developed by a qualified and competent person or body not directly involved in the development and/or delivery of the learning being assessed (SAQA 2008).

2.3.4 Integrated assessment

Integrated assessment involves all the different types of assessment tasks required for a professional designation such as written tests and practical demonstration of competence. Integrated assessment should assess the ability to combine key foundational, practical and reflexive competencies and apply these in a practical context for a defined purpose (DHET 2010). It is vital to assess learners in modes in which they are expected to display competencies.

2.3.5 Assessment for conferment of professional designation in Biomedical Technology

Currently the assessment being implemented to confer professional designation to Intern Medical Technologists is an external summative written Board Examination. This study will seek to investigate the suitability of a competency-based approach of assessment in Medical Technology and possibly provide a more integrated assessment to display full competence for conferring a professional designation into Medical Technology.

2.3.6 Strengths and limitations of assessment methods for board certification and licensure examination

According to Epstein (2007), distinction should be made between the use of formative versus summative assessments and it is vital when selecting a method for evaluating competence of high stake assessments such as licensing and certification examinations. The strengths and limitations of assessment methods for board certification and licensure examinations are outlined in Table 1.

Table 1: Assessment methods for Board certification and licensure examination application including strengths and limitations Epstein (2007).

Written exercises		
ASSESSMENT METHOD	**STRENGTHS**	**LIMITATIONS**
Multiple-choice questions either in single best answer or extended matching format	Can assess many content areas in relatively little time, have high reliability, can be graded by computer	Difficult to write, especially in certain content areas, can result in cueing, can seem artificial and removed from real situations
Key feature and script concordance questions	Assess clinical problem solving ability, avoid cueing, can be graded by computer	Not yet proven to transfer to real life situations that require clinical reasoning
Assessments by supervisors		
ASSESSMENT METHOD	**STRENGTHS**	**LIMITATIONS**
Structured direct observation checklists with ratings	Feedback provided by credible experts	Selective rather than habitual behaviors observed, relatively time consuming
Oral examinations	Feedback provided by credible experts	Subjective, sex and race bias has been reported, time-consuming, require training of examiners, summative assessments need two or more examiners
Clinical simulations		
ASSESSMENT METHOD	**STRENGTHS**	**LIMITATIONS**
Objective structured clinical examinations (OSCE)	Tailored to educational goals, reliable, consistent case presentation and ratings, can be observed by faculty, realistic	Timing and setting may seem artificial, require suspension of disbelief, checklists may penalize examinees who use shortcuts, expensive
Multisource(‘360 degree”) assessments		
ASSESSMENT METHOD	**STRENGTHS**	**LIMITATIONS**
Portfolios	Displays projects for review, foster reflection and development of learning plans	Learner selects best case material, time consuming to prepare and review

2.4 COMPETENCE

2.4.1 Competence definitions and concepts

According to the ISO guideline 10015 (1999), “competence is the application of knowledge, skills and behavior in performance.” “It is the quality of being functionally adequate, or having sufficient knowledge, judgement, skill, or strength for a particular duty” is the definition from the Merriam Webster dictionary (2016). Proposed definitions of Competency-based medical education (CBME) and related terms by International CBME Collaborators (Frank et al. 2010a) are described in Table 2.

Table 2: Proposed definitions of Competency-based medical education (CBME) and related terms by the International CBME Collaborators (Frank et al., 2010a).

Competence - The array of abilities across multiple domains or aspects of health professional's performance in a certain context. Statements about competence require descriptive qualifiers to define the relevant abilities, context and stage of training. Competence is multi-dimensional and dynamic. It changes with time, experience and setting.
Competency - An observable ability of a health professional, integrating multiple components such as knowledge, skills, values and attitudes. Since competencies are observable, they can be measured and assessed to ensure their acquisition. Competencies can be assembled like building blocks to facilitate progressive development.
Competency-based medical education - An outcomes-based approach to the design, implementation, assessment, and evaluation of medical education programs, using an organizing framework of competencies.
Competent - Possessing the required abilities in all domains in a certain context at a defined stage of medical education or practice.
Dyscompetence - Possessing relatively less ability in one or more domains of a health professional competence in a certain context and at a defined stage of medical education or practice.
Incompetent - Lacking the required abilities in all domains in a certain context at a defined stage of medical education or practice.
Progression of competence - For each aspect or domain of competence, the spectrum of ability from novice to mastery. The goal of medical education is to facilitate the development of a health professional to the level of ability required for optimal practice in each domain. At any given time, and in a given context, an individual health professional will reflect greater or lesser ability in each domain.

2.4.2 Paradigm shift

There has been a paradigm shift from structure and process based to competency – based education and measurements of outcomes (Carraccio et al, 2002). Work-based assessment is an essential component of competency based medical education, especially given the greater need for formative assessment and feedback (Holmboe et al, 2010). There are currently no published studies that provide a practical sense into how to accomplish implementation of the competency-based paradigm shift within medical technology in a South African context.

2.4.3 Competence models in medical education

2.4.3.1 Introduction

Educational theorists have published numerous models to describe the development of knowledge and the educational processes involved in achieving competence (Carr, 2004). More than thirty years ago Rasmussen (1983) suggested as cited by Carr (2004) that the first step in practical learning is the gaining of skills and that one can be competent in these skills before the full knowledge relating to that skill is acquired. He also theorises that with time the practical skill is improved with knowledge and the learner moves to the highest level of “knowledge based practice” (Carr, 2004).

2.4.3.2 Dreyfus and Dreyfus model

Dreyfus and Dreyfus established a five stage model initially to describe the development of knowledge and skills of a pilot and thereafter extended the model to cover the acquisition of clinical skills in medicine as represented in Table 3 (Carr, 2004).

Table 3: Dreyfus stages as applied to clinical medicine (Carr, 2004).

Dreyfus Stage	Description
Stage 1- novice	Learns basics
Stage 2- advanced beginner	Learns to apply skills in situations which enables learning through experience
Stage 3- competent	Learns to plan approach to each patients situation and consequences of actions and pattern recognition
Stage 4- proficient	Develops routines to streamline patient care and integrates skills
Stage 5- expert	Recognises patterns and able to identify distorted patterns and slow down when things don't fit the expected pattern

The Dreyfus stages as tabulated above is applied to clinical medicine and the stages from one to five have been modified in order to be applied to a pathology laboratory context for the current study.

There are five stages of competency that is also suggested by Chambers and Glassman (1997) and cited by Carraccio et al (2002), which begins with novice; progressing through beginner, competent, proficient and the highest and ends with the expert stage. These clearly defined stages of competency were utilized when adapting the witnessing instrument developed to assess the technical competence of Intern Medical Technologists.

2.4.3.3 Millers Model of Clinical Competence

A more useful model of clinical competence was proposed by Miller (1990) in his well-known triangle in Figure 1.

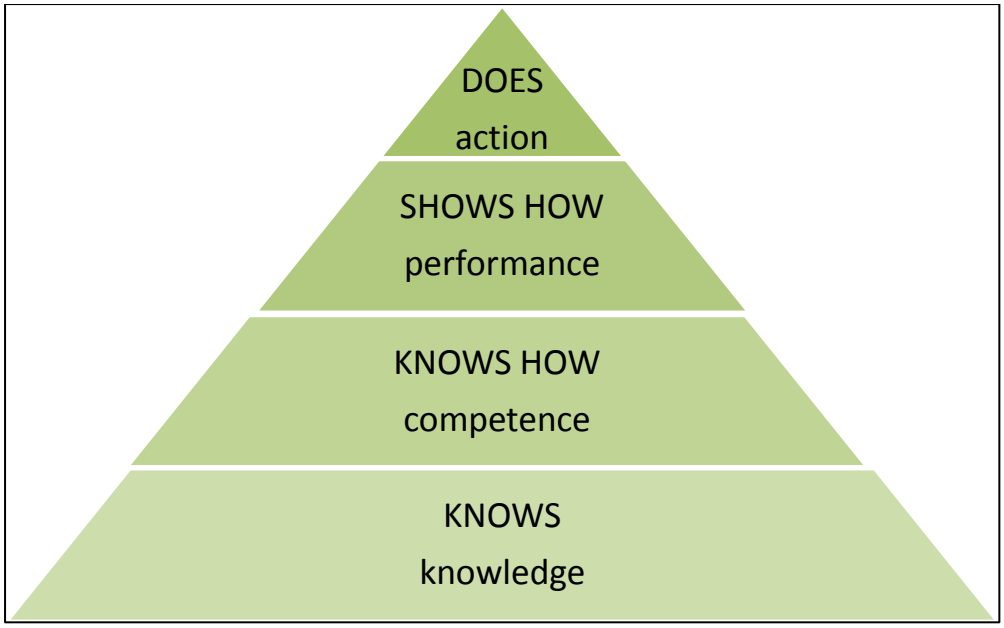


Figure 1: Millers Triangle of clinical competence

At the lowest level of the triangle is knowledge (knows) followed by competence (knows how), performance (shows how), and action (does) (Norcini, 2003). In this framework Miller differentiates between lower levels and "action". "Action" focuses on what occurs in practice rather than a simulated testing situation (Norcini, 2003). Norcini (2003), further explains that work based methods of assessments target this highest level of the triangle and collect information about the staff member in their normal practice. Assessment of knowledge is dominant in institutions and most Board Examination systems (Miller, 1990). Assessment of knowledge, as defined in stages one and two of Miller's pyramid, is generally performed using written and oral tests, whilst stages three and four, proves more challenging. In medical specialties, practical clinical examinations and objective structured clinical examinations (OSCE) is currently assessed (Carr, 2004).

The importance of direct observation of trainee health professionals to ensure effective assessment of clinical skills is also emphasized by Carr, (2004). Therefore, in the current study direct observation is the methodology used to assess technical competence of Intern Medical Technologists. A limitation of Millers triangle is that competence predicts performance which is not always true.

2.4.3.4 Cambridge Model

Another model, the “Cambridge model”, was proposed by Rethan’s and colleagues in 2002 and cited by Carr (2004), as a modification to Millers model to address the concerns regarding “knowing and showing does not mean that a doctor will perform in a certain way in real practice” (Carr, 2004). Cambridge model is a modified triangle (Figure 2).

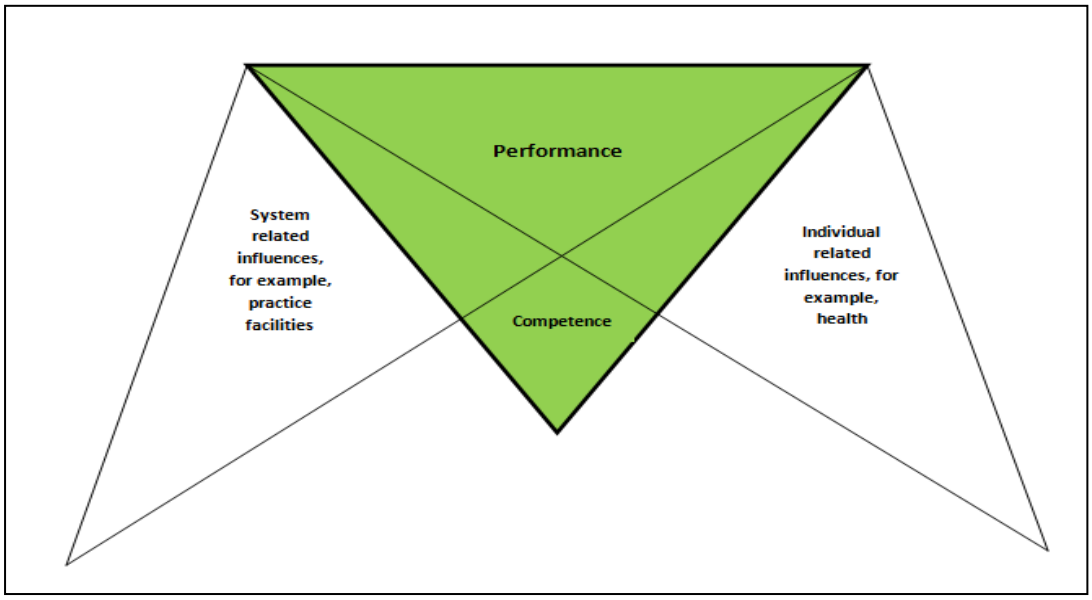


Figure 2: Cambridge model for delineating performance and competence (Rethan et al. 2002)

Carr (2004), describes that the Cambridge model acknowledges that in addition to assessing knowledge and practical skill, the global competence or performance of interns in training need to be assessed in as realistic a way as possible. He further states that performance builds upon competence but also encompasses other influences on one’s eventual performance, including system related influences, e.g., guidelines or Standard Operating Procedures (SOP’s) and individual related influences, e.g., relationship with others including peers, knowledge and skills of trainers. Mbhele, Genis and Du Toit (2011) also confirm that resources in some workstations as well as inconsistency in the quality of work stations, causes students of the same cohort in a qualification to have variable levels of work experiences which is another example of system related influence on competence.

2.5 COMPARING EDUCATION, TRAINING AND COMPETENCE

The Clinical Laboratory Standards Institute (CLSI) (2009), guidelines for training and competence states that a " distinction must be made between the education that one receives in an academic setting for the purposes of gaining knowledge and being trained in a set of skills for the purpose of being able to put the knowledge to practical use. From Table 4 below, it is evident that the evaluation or assessment methods for education will differ with that of training and it can be inferred that both would be integrated to demonstrate competence. 'In professional training the intern is allowed to develop and practice skills in a setting similar to the work environment" (CLSI, 2009).

Table 4: Journey from knowledge to competence (CLSI, 2009)

SEQUENCE	MANIFESTED BY	EVALUATED BY
Education	Knowing it	Written/oral assessments
Training	Knowing how it's done	Competence assessment
Practice	Showing how it's done	Performance
Experience	Doing it	Actions
Competence	Correctness and completion of actions	Written and oral assessments of knowledge and observation of actions

The CLSI guidelines (2009), display that there is a gap in the current assessment practices of Intern Medical Technologists and that the Board Examination addresses education optimally, however, it is evident from Table 4 that competence is best evaluated by written assessments of knowledge and observation of actions.

2.6 THE ROLE OF ASSESSMENT IN COMPETENCY-BASED MEDICAL EDUCATION

Competency-based medical education (CBME) by definition necessitates a multi-faceted robust assessment system (Norcini 2003). ISO 15189 standards (2012) and CLSI guidelines (2009) provide a variety of approaches to assessing competency in a pathology laboratory.

Various excerpts from literature confirm that a single assessment method is not optimal. Miller (1990) states that no single assessment method can provide all the data required for judgment of anything so complex as the delivery of professional services. The use of traditional tests alone is not sufficient in competence-based education (Baartman et al, 2007). Epstein (2007), also states that “although summative assessments are intended to provide professional self regulation and accountability, they may also act as a barrier to further practice or training.” He further states that “the use of multiple observations and several different methods over time can partially compensate for flaws in any one method” (Epstein, 2007). Swing and his colleagues (2009) confirm that “no single individual should make judgments about the competence of a trainee in isolation, especially for summative decisions.”

According to Holmboe and colleagues (2010), medical education has suffered from too much variability in the choice and use of assessment tools, akin to the variability seen in the delivery and quality of healthcare. The success of competency based medical education does not only depend on the combination of better assessment tools but a more skilled faculty and other assessors who will use them (Holmboe et al, 2010).

From the literature cited above, one can deduce why a single method of assessment, the National Board Examination for Intern Medical Technologists is not the most appropriate system and a more integrated assessment will be more advantageous for conferring professional designation. This forms a basis for the

current study where another approach of assessment will be investigated and possibly used to augment the current system.

An advantage of competency based medical education is the opportunity to regain public trust by using resources efficiently, ensuring that all trainees attain high standards of knowledge, skills and attitudes (Holmboe et al, 2010).

2.7 HPCSA RULES FOR REGISTRATION OF MEDICAL TECHNOLOGISTS

In terms of the HPCSA Act 56 of 1974, the rules for the registration of Medical Technologists within council are as follows:

The council may register as a Medical Technologist in one or more category or discipline any person who satisfies the council that he complies with the requirements as set out in sub rules 1-4 of this rule:

1 The person should hold a qualification in Medical Technology (National Diploma)
2 He shall have completed a structured practical training in an approved laboratory for a further period of at least twelve (12) months as prescribed by the Professional Board for Medical Technology and the Council.
3 He shall have passed an examination recognized by the Professional Board for Medical Technology and the Council for registration purposes.
4 No person shall be eligible for registration as a Medical Technologist until a period of four years shall have elapsed since the date of registration as a student Medical Technologist.

It must be noted that the subrule 3 indicates the requirement for passing an examination but does not prescribe the assessment methods. Further investigations are necessary on the most appropriate and effective assessment method for conferring a professional designation and this study aims to provide some input into this.

2.8 STANDARDS OF TRAINING AND COMPETENCE WITHIN A PATHOLOGY LABORATORY

South African National Accreditation System (SANAS) is the body responsible for the accreditation of medical laboratories for quality and competence. The ISO 15189:2012, an internationally recognised standard defines competence as "demonstrated ability to apply knowledge and skills". In order to prove its competence and become accredited, a laboratory must prove its' staff are competent (Stajdohar-Paden, 2008). CLSI guidelines for training and competence (2009) states that, "competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly".

2.8.1 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLSI)

In the United States of America, governmental mandates compel medical laboratories to assess the competency of all laboratory workers who handle patient specimens (Sharp and Elder, 2004; CLSI, 2009). Competence of laboratory staff can be assessed by using any combination or all of the approaches under the same conditions as the general working environment. Implementation of competency allows for flexibility at a laboratory level, however, what must be assessed is stipulated in the governmental mandates as stated above. These approaches will be incorporated into the current study.

2.8.2 COLLEGE OF AMERICAN PATHOLOGISTS (CAP) & JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANISATIONS (JACHO)

College of American Pathologists (CAP) guidelines request that each person performing any duty in the laboratory is competent and if an employee fails to demonstrate acceptable performance there is a plan of corrective action for retraining and reassessment of that individual's competency (Sharp and Elder, 2004). JACHO also has standards regarding competency assessment similar to CAP and holds the laboratory director responsible for the competence of laboratory staff (Sharp and Elder, 2004).

2.8.3 SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM (SANAS)

In the current South African context, the ISO 15189 (2012) standard states “following appropriate training, the laboratory shall assess the competence of each person to perform technical tasks according to established criteria. Reassessment shall take place at regular intervals. Retraining shall occur when necessary.” SANAS (2013) provides a Form 15-08 a witnessing of activity tool or instrument that is used for direct observation of pathology laboratory processes. This tool will be adapted and used to assess technical or practical competencies of candidates in this current study within a South African context.

2.8.4 STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION (SLMTA)

Strengthening Laboratory Management Toward Accreditation (SLMTA) is a competency-based laboratory management training programme that was launched by the World Health Organisation (WHO) in 2009 to improve quality and strive for accreditation (Yao, 2014).

2.8.5 STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARDS ACCREDITATION (SLIPTA)

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) is World Health Organisation’s Regional Office for Africa (WHO AFRO) five –stage accreditation-preparedness scheme (Yao, 2014). Laboratories are audited against a SLIPTA checklist to determine the level of compliance with the ISO 15189 standard and are also based on the 12 quality system essentials from the CLSI (Yao, 2014).

According to Yao (2014), there is a close association between SLMTA and SLIPTA, “as the SLIPTA checklist provides the SLMTA programme with a means to identify gaps and benchmark progress whereas SLMTA enables Laboratory Managers to implement quality management systems to improve their SLIPTA scale and eventually achieve formal SANAS accreditation status.”

2.9 ELEMENTS THAT MUST BE INCLUDED IN A COMPETENCY ASSESSMENT PROGRAM

There are six key areas that must be incorporated into a laboratory competency assessment program and these are:

- Direct observation of routine patient test performance
- Monitoring the recording and reporting of test results
- Review of intermediate test results, QC records, proficiency testing results and preventative maintenance records
- Direct observation of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously analyzed samples, internal blind testing samples, or external proficiency testing samples
- Assessment of problem solving skills

It must be noted that all elements that are described above is included on the validated SANAS form 15 witnessing tool that was modified for this study
(CLSI, 2009 ; SANAS 2013; Sharp and Elder, 2004).

TABLE 5: Elements of a competency assessment program according to the six items of CLSI requirements, a description of requirement and examples (Sharp, 2004).

ITEM INCLUDED IN A COMPETENCY ASSESSMENT PROGRAM	DESCRIPTION OF THE ITEM	EXAMPLES OF EACH ITEM
Direct observation of routine patient test performance	This is the actual observation of work as it is being performed by the laboratory staff. All processes from specimen preparation to patient's results.	Positive cerebrospinal fluid (CSF) specimen, following appropriate work instructions, accurate interpretation of test reactions, susceptibility testing
Monitoring the recording and reporting of test results	Review of patient results for the proper and correct recording and reporting.	Documentation of observation of an employee writing or entering patient test results on report forms or into the computer
Review of intermediate test results, QC records , proficiency testing results and preventative maintenance records	This is as it is implied that one must view intermediate patient results, QC records, proficiency testing results and preventative maintenance records	This can be accomplished by review of worksheets or computer entries for accurate recording of patient results, review of QC worksheets for acceptable results and for review of preventative maintenance records for the appropriate and timely checks and documentation.
Direct observation of performance of instrument maintenance and function checks	Direct observation must be used when employees are performing maintenance procedures and check of instruments.	One must directly observe an employee when performing maintenance procedures and function checks on instruments in the laboratory such as Chemical Pathology analyser.
Assessment of test performance through testing previously analyzed samples, internal blind testing samples, or external proficiency testing samples	One must assess employee competence by giving them unknown samples.	This can be accomplished by split sample analysis, previously analysed specimens or external proficiency testing.
Assessment of problem solving skills	One must assess the ability of employees to solve problems that arise during their practice.	This can be accomplished by asking the employees write up a situation when they had to solve a problem related to an investigation they performed by giving a real or fictitious example of a problem encountered in the laboratory and asking how he or she would handle the situation.

2.9.1 Written or oral tests

According to the CLSI guidelines (2009), assessment of an employee's cognitive skills for test procedures can be measured by written or oral tests of which the former is advantageous as it is in a documented format. There are a variety of types of questions that can assess aspects of a test procedure which include theory, technique, interpretation and problem solving questions. A theory question assesses the employee's knowledge of the background information for a given procedure. A technique question assesses the employee's knowledge of an important step in a test procedure. An interpretation question assesses the employee's ability to arrive at the correct conclusion for a given set of results or information. A problem solving question assesses the employee's critical thinking, e.g., troubleshooting when an analyzer or instrument is not performing optimally (CLSI , 2009).

2.9.2 Direct Observation Checklists

CLSI guidelines (2009), also confirm that the best assurance that employee's understand and follow documented standard operating procedures when performing their work tasks is to directly observe them while they are demonstrating these tasks. Direct observation checklists can be developed for routine work procedures and include maintenance and function checks. The direct observation checklist may be used as a training tool for an employee to conduct a self-assessment and as a tool for an observer or assessor to record the process of observation or test witnessing that cover the work tasks for test procedures by an employee. At the conclusion of the observation, the observer records whether the employee met the requirements and is competent. Direct observation checklists provide an objective means for assessing competence and this contributed to this tool was used to gather data for this study.

It has also been documented in the CLSI guidelines (2009) that with time employees discover shortcuts and workarounds that drift away from procedure specifics and may result in comprising patient safety. "An example is performing a low-power scan of Haematology slides takes time, requires additional microscope manipulation and

may yield a significant finding." Some employees skip this step to save time and therefore fail to detect any abnormalities on the edge of a blood film. The above provides an example of the importance of assessing competence through direct observation (CLSI, 2009).

2.9.3 Monitoring results, reports and records

A Laboratory Manager's or supervisor's routine review of reports and records can unveil errors that could be related to a lack of competence and should be investigated and a root cause analysis performed. Corrective action must be taken to eradicate the cause and then documented. The review should include at least some of the following items: intermediate results or worksheets; QC records; calibration records; preventative maintenance records; troubleshooting records and proficiency testing results (CLSI, 2009).

2.9.4 Problem-solving skills

Problem solving skills can be taught in case studies and assessed in simulations. The laboratory's nonconforming events are a good source of information from which to derive case study problems. Problem solving often involves rule breaking and finding another pathway. For example, an unlabeled sample is usually rejected, but an unlabeled cerebrospinal fluid might be saved by chart review, interview, and drafting an ad hoc affidavit to link the sample with the correct patient. Information contained in nonconformance reports can also be used to determine a person's problem-solving capabilities by reviewing the appropriateness of the remedial actions and the follow up investigations. Nonconformance reports should not be the only means to determine competence. Problem solving skills can also be assessed in other situations including, knowing when to escalate a problem that cannot be solved at a person's level, resolving equipment or testing procedure problems (CLSI, 2009).

2.9.5 Performing a procedure using specially provided materials

CLSI guidelines (2009), explain testing of specially provided materials (“unknowns”) as useful in determining whether personnel are competently performing their assigned work procedures. Materials include testing blind samples, previously analysed samples and known samples (CLSI, 2009).

2.9.6 Blind test samples

Material that is simulated to actual samples to assess the actual process and is introduced into the workflow where employees are unaware is called a blind sample. A blind sample is introduced similar to a patient sample where the sample container types, labeling, physician identification, hospital or laboratory are coded etc. in order for the employee not to recognize the difference. Advantages of blind samples are a more reliable assessment of routine performance and identification of problems within all phases of the path of workflow. A limitation is the feasibility for widespread use. For example, sample preparation and inadvertent reporting may cause dilemmas (CLSI, 2009).

2.9.7 Previously analyzed material

Testing of previously analysed samples allows for comparisons. This assessment of performance can be determined only for the analytic phase. Limitations of using previously analyzed samples are that the pre and post analytical phases are not assessed. However, while advantages are many and include, reduced costs, easy accessibility of samples from on-site patient’s samples that were previously analysed and already reported proficiency testing. It is possible to assess knowledge, attitude and technical skills when assessing competence using previously analysed samples, as during the testing procedure. The employee can be directly observed while testing previously analyzed samples and then asked questions to assess critical thinking skills. Upon completion, the new test results can be compared to the previously analysed test results for concordance. This multiple approach can be applied to any competence assessment activity (CLSI, 2009).

2.9.8 Theoretical testing, practical assessments or both?

Schiffgens and Bush (2001) and Epstein (2007), are in agreement that written tests assess the individuals knowledge and test taking mimics the decision making process. Direct observation includes the real time review of QC, enables assessment of technical skills, judgment and analytic decision making, but does not enable evaluation of the individuals knowledge base and advanced problem solving capabilities. Written testing and direct observations can be combined for a comprehensive evaluation, but may be considered threatening by the employee. Written tests should evaluate whether or not a staff member understands the theory and/or operating principles behind methods, instruments, policies, and procedures and reinforce knowledge learned in training (Schiffgens and Bush, 2001). Part of the approach to competency assessment, proposed by Schiffgens and Bush (2001), includes a practical examination and it is stated that the employee should be directly observed or a practical examination administered to assess mechanical techniques, judgment, decision making processes and decision making skills. The main objective is for the competency assessor to determine if the employee has followed the standard operating procedure and understands all the steps of the method or instrument.

Examples of some aspects mentioned above include: “are the tubes placed on the instrument correctly” or “is the required maintenance performed.” Schiffgens and Bush (2001), further proposes that a checklist of predetermined skills can be used to document the observation and explains further that this checklist can serve as an outline of the tasks that need to be observed by the assessor. This approach will be implemented in the study with a direct observation checklist that has been modified from the SANAS witnessing tool.

2.10 INTEGRATED ASSESSMENT USED FOR CLINICAL TECHNOLOGISTS

Personal interviews conducted on 23 March 2016 with the Chairperson of Education and training for the Professional Board of Clinical Technology, Mr. Yakeen Harilall regarding competence assessment of student clinical technologists revealed that an

integrated assessment approach is used where students are given written theory tests, proficiency assessments which are included in portfolio submissions as well as competency based testing.

2.11 GLOBAL REQUIREMENTS FOR REGISTRATION AS MEDICAL TECHNOLOGIST/BIOMEDICAL SCIENTIST

In the United Kingdom standards of proficiency are the requirement which every biomedical scientist must meet in order to become registered with the Health and Care Professions Council (HCPC, 2014). The requirement is the demonstration that the HCPC Standards of Proficiency have been met through a combination of academic qualifications and laboratory training. Once the academic requirements are met according to the HCPC's Standards of Proficiency, a period of training in an IBMS (Institute of Biomedical Science) approved training laboratory is required to complete the practical component. The practical training will involve completing an IBMS Registration Training Portfolio which enables the building up of records of evidence showing that a trainee biomedical scientist has achieved the competencies and standards outlined in the Registration Training Portfolio and therefore meet the HCPC Standards of Proficiency for a biomedical scientist (HCPC, 2014). The growing importance towards a competency based training system is not unique to the UK; in the United States of America and in other countries around the world there is a shift to increase accountability and to formalize the maintenance of standards and setting of standards for entry into practice (Carr, 2004).

In the American and Canadian context the relevant Boards offer a formal certification process that requires education, clinical training and experience, and successful completion of the certification Board Examinations for Medical Technologists. In Canada there is a competency based exam that comprises of the following: Part A which is a three hour multiple choice question (mcq) and contains mainly 80 images and part B which is two and half hours of mcq's. There is an examination blue print available that includes competency categories.

A different approach taken by the European Association for Professions in Biomedical Sciences (EPBS) involves a minimum standard of education for Biomedical Scientists which is a four year higher education bachelor level qualification including supervised clinical practice where these candidates before being licensed for independent practice should undergo a supervised and assessed clinical placement (Mendes, 2014).

2.12 THE DISCIPLINE OF CLINICAL PATHOLOGY

Society of Medical Laboratory Technology of South Africa (SMLTSA, 2012) syllabus for Intern Medical Technologists in Clinical Pathology is a combined discipline which incorporates Haematology, Microbiology and Chemical Pathology which offers guidelines to the Intern Medical Technologists.

2.13 APPROACH TO COMPETENCE ASSESSMENTS IN MEDICAL TECHNOLOGY/BIOSCIENCE LABORATORIES

There is paucity of literature regarding the technical competency in medical laboratories in a South African context. The issue of technical competence is a foundation on which the workforce of medical laboratories must be built. This study seeks to gather information from Laboratory Managers in South Africa, specifically in the KwaZulu Natal province regarding the approach and methodology employed within the pathology laboratory to assess technical competence Howanitz, Valenstein and Fine (2000) state that “the ultimate measure of employee competence assessment is that it should relate to the quality of care that patients receive”. Sharp and Elder (2004), state that competency assessment procedures is a useful tool which can help identify problems occurring in the technical aspects of laboratory practice and assess performance deficiencies before they develop into major problems.

2.13.1 Considerations for the development of a competency program

A paper published on competency assessment in the Clinical Microbiology Laboratory by Sharp and Elder (2004) reviewed the regulations related to competency and accreditation in the United States of America and provided information on the elements and development of a competency assessment program including remediation paths to follow. More work done by Stajodhar-Paden (2008) related to competence in the laboratory, also provides recommendations and solutions on how to organise and manage staff competence. Carr (2004), states that the central features of assessing clinical competence are :

- To establish the range of knowledge, skill and understanding that an individual should have achieved
- To design tasks that appropriately and accurately sample and estimate level of competence
- To establish cut of points to separate the competent from the not yet or barely competent

According to Schiffgens and Bush (2001), the competency scheme should cover the critical steps in the preanalytic, analytic and post analytic processes. They further recommend that each individual who performs a step in the process, whether technical or clerical should be assessed. When the question is raised as to who is responsible for competency? The answer should be a Laboratory Manager or a supervisor etc. (Stajodhar-Paden, 2008). Schiffgens and Bush's (2001) view is that all competency programs must assess all core competencies and address employee preparation, theoretical testing, practical examination and post evaluation follow up. The employee preparation is very pertinent to the present study as the target group is the candidates who are new in the workplace. It is important for them to have access to all relevant training material both from a theoretical and practical perspective for them to prepare adequately for the technical competence assessment. Howanitz, Valenstein and Fine (2000), provided suggestions from their study that direct observation can be used for assessing technical skills of personnel.

The rationale is that if a laboratory invests time and money in training of staff, it is critical to check whether the training was effective (Stajodhar-Paden, 2008).

2.13.2 The Laboratory as a setting of training and assessment

HPCSA requires that an approved laboratory must provide practical training and adequate instructions to students as well as every opportunity to carry out tests and procedures consistent within the category being trained. In addition, the laboratory must also be able to provide the apparatus and working environment considered necessary for good laboratory practice, to the standard determined by the Professional Board and must have in its employment a qualified Medical Technologist or pathologist who must be registered in the category in which technologists/technicians/ are to be trained (HPCSA, 2001).

The units where trainees work and learn for example intensive care units, laboratories etc. are referred to as clinical microsystems (Holmboe et al., 2010). The definition of a clinical microsystem by Nelson et al. (2007) and cited by Holmboe and his colleagues in 2010, is “a small group of people who work together on a regular basis to provide care to discrete subpopulations of patients and has clinical and business aims as well as linked processes and a shared information environment and produces performance outcomes.” Microsystems provide the platform for work-based training and assessment making it important for educators to carefully consider how the culture and functionality of these multiple microsystems affect the assessment processes and the attainment of competence for trainees (Rethans et al. 2002).

2.13.3 Adherence to competency policy and program

A study conducted by Howanitz, Valenstein and Fine (2000) regarding employee competence and performance based assessments in a College of American Pathologists Q-probes study of laboratory personnel in 522 institutions showed that 89.8% had a written competence plan, 98.1% reported reviewing employee competence at least yearly 87.5% general competence was reviewed by direct observation, 77.4% review of quality control results, 60% review of instrument preventative maintenance, 52.2% written testing and 20.8% other methods. The laboratories that had a written plan 100% used their plan for Chemistry, 94% for Haematology and 90.3% for Microbiology.

2.13.4 Documentation and communication of competency assessment including remediation

According to CLSI guidelines (2009), documentation of employment training and competence assessment is required by regulatory and accreditation programs.The laboratory must provide an effective means of documenting and tracking an employee's training, retraining, and competence assessment records across time. Competence assessment records that should be completed and retained in an employee's file following each competence assessment event include direct observation checklist completed by the observer or any other written assessment or outcome of the review of records or reports e.g., test records or results of any blind sample testing (CLSI , 2009).

Desjardins and Fleming in a competency study conducted in 2014 emphasized that the final component of a competency assessment program is communication and remedial action. They stated that without proper communication back to the individual, opportunities to correct deficiencies will be lost and the program loses its value. The above study also found that most participants verbally communicated back to the technologist but a third did so as part of the individual's performance appraisal and most laboratories indicated that remedial action would be taken in the event that an individual fails the evaluation. It is important to document the type of

remediation used and to repeat the competency assessment to determine if the employee is competent following remediation (Desjardins and Fleming, 2014). Holmboe (2010), states that we must be willing to incorporate more qualitative approaches to assessment which may include written narrative and the synthesis of conversations that occur during evaluation or assessments sessions. In some instances where the employee is still not yet competent within a prescribed period of time they are then moved to another work area in which they can perform patient testing competently. Woods et al (2000), stated that each of the competency forms should form part of the training portfolio for a staff member and additional documentation is required for each SOP. The reason for this is if there are any amendments to the SOP then appropriate training must follow and be documented to ensure that all staff members are keeping up to date in that procedure (Woods et al, 2000). Records of competence must reflect the date on which competence is confirmed to ensure traceability in the event of an investigation regarding nonconformity (Stajodhar-Paden, 2008). Assessors when reviewing compliance of competence in a laboratory against the relevant accreditation standard, look for evidence of competence defined in writing (Stajodhar-Paden, 2008). Schiffgens and Bush (2001), also concurs that retention of competency records should be based on regulatory, accrediting agency and organizational requirements.

2.13.5 Lack of standardization in competency methods

A recent study in 2014 undertaken by Desjardin's and Fleming on competency assessment of Microbiology medical laboratory technologists in Ontario showed that although some laboratories have a competency program, the methods used are not standardised nor consistently applied. Another study by Howanitz, Valenstein and Fine (2000) that surveyed employee competence assessment practices of pathology and laboratory medicine also found that there is no standardised or consistent tool being used by most laboratories and there were many opportunities for improvement with regards to employee competence assessment.

2.13.6 Remediation

The main aim of competency assessment is to identify potential gaps or problems in employee performance and to try to rectify this before it impacts on patients (Sharp and Elder, 2004). Documentation of remediation is, therefore, an essential part of a competency program as required by CAP and JACHO. Various studies have the same view that remediation should not be punitive but rather educational and focused on improving performance on patient's samples (Sharp and Elder, 2004). Various approaches can be used to remedy problems encountered during the competency assessment (Sharp and Elder, 2004). Problems must be further analyzed to determine whether it originates from the system or the employee in order to identify appropriate remediation and implement.

2.13.6.1 Remediation of system related problems

System problems will include reviewing standard operating procedures or protocols to determine if it is "clear and concise" and more importantly understandable to the employee. In proficiency testing, the unknown sample must be examined for adequacy. The tools used for competence assessment must be standardized, simple and unambiguous so that consistency can be applied to all employees being assessed (Sharp and Elder, 2004).

2.13.6.2 Remediation of employee related problems

In order to determine the cause of the employee not attaining competence it would be important to check if the employee followed the standard operating procedure correctly, step by step. It must also be established if the employee did not understand the purpose or background of the test, test components or the instrument being used as well as whether the employee was unable to resolve quality control or if the employee made an error in recording the result or the documentation (Sharp and Elder, 2004).

2.13.6.3 Types of remedial actions

A discussion with the employee takes place regarding the procedure to ascertain if further action would be necessary depending on the response of the employee. This intervention may be sometimes sufficient as it elucidates the reason for the employee not being competent (Sharp and Elder, 2004). Sharp and Elder (2004), also recommends that a discussion with all employees in a quality assurance meeting regarding the procedure can enlighten them on how the type of error can be avoided going forward.

Other types of remediation can include requesting an employee to re-read the procedure and illustrate it step by step using a flowchart as well as directly observing another competent employee or practicing another known specimen. If the above interventions fail as the employee is still not yet competent then formal training is implemented (Sharp and Elder, 2004).

In a study conducted by Desjardins and Fleming in 2014, it was recommended that the competency program should be designed to provide opportunities for non-punitive remediation and also state that re-evaluation, re-training or re-assignment can be considered when the staff member does not meet expectations.

2.13.6.4 Common tests or procedures requiring remediation

A Canadian study conducted by Desjardins and Fleming (2014), in Microbiology discipline revealed the most common competency issues requiring remediation was associated with activities listed in Table 6.

Table 6: Common competency issues requiring remedial action (Desjardins and Fleming, 2014)

Gram staining and wrong interpretations
Failure to understand or lack of familiarity with laboratory protocols
Difficulties in performing antimicrobial susceptibility testing including technical issues (eg. measurement of zone diameters)
Lack of familiarity with appropriate methods
Inconsistent interpretations of antibiograms
Laboratory information system data entry
Lack of adherence to biosafety rules

2.14 Conclusion

In this chapter an in-depth literature was presented about competency based medical education and assessment of technical competence guided by standards of training and competence within a pathology laboratory. There are currently no published studies that provide a practical sense into how to accomplish implementation of the competency-based paradigm shift within Medical Technology in a South African context. Based on the literature review, it is clear that a gap exists in assessment of technical competence within a pathology laboratory in South Africa and Africa at large. A further gap was identified in the integrated method of assessment for Medical Technologists in the conferring of a professional designation.

Similarities which were identified in the literature highlighted that most first world countries were guided by similar standards with respect to competency. The global requirements for registration with their relevant statutory bodies differed and methods of assessment of competency in some countries were different. Methods of assessment for competence also varied within health care professional groups. The approach to competency assessment in pathology laboratories was also examined and showed a lack of standardization and the need for documentation, communication, feedback and remediation if required.

The main goal was to assess technical competence of Intern Medical Technologists within a Clinical Pathology discipline. Most of the studies recommended a more

integrated and standardised approach to the method of assessment of competence in a medical laboratory. This study will seek to present another perspective of practical, technical competence and if attached to other forms of assessment may provide a more integrated assessment to display full competence for conferring a professional designation into Medical Technology and also seeks to gather information from Laboratory Managers in South Africa, specifically in the KwaZulu Natal province regarding the approach and methodology employed within the pathology laboratory to assess technical competence.

From the literature cited above one can deduce why a single method of assessment, the National Board Examination for Intern Medical Technologists is not the most appropriate system and a more integrated assessment will be more advantageous for conferring professional designation. This forms a basis for the current study where another approach of assessment will be investigated and possibly used to augment the current system. Further investigations are necessary on the most appropriate and effective assessment method for conferring a professional designation and this study aims to provide some input into this.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 INTRODUCTION

In the previous chapter a literature review of assessment of technical competence and competency in pathology laboratories was presented. The purpose of this chapter is to inform the reader about the research process which was used in this study which is the research approach, research design, research setting, sampling process, and instruments used, data collection and data analysis. Inclusion and exclusion criteria are also discussed in this chapter for the reader to understand why the researcher chose the specific participants and excluded others.

There has been a paradigm shift from structure and process based to competency – based education and measurements of outcomes (Carraccio et al, 2002). Integrated assessment involves all the different types of assessment tasks required for a professional designation such as written tests and practical demonstration of competence. Integrated assessment should assess the ability to combine key foundational, practical and reflexive competencies and apply these in a practical context for a defined purpose (DHET, 2010).

Currently the assessment being implemented to confer professional designation to Intern Medical Technologists is an external summative written Board Examination. This study will seek to present another perspective of practical, technical competence and if attached to other methods of assessment may provide a more integrated assessment to display full competence for conferring a professional designation into Medical Technology.

In this study, Intern Medical Technologists are assessed by using direct observations to determine technical competence in ten Clinical Pathology test procedures. These Intern Medical Technologists are trained in HPCSA registered laboratories. The study includes the approach of the respective laboratory to technical competency from a survey that was distributed to Laboratory Managers and training officers. This chapter concludes with a discussion on ethical considerations of the research.

3.2 RESEARCH DESIGN

According to Burns and Groove (2011), a research design is “the blue print used to conduct a study.” It serves as a guide to planning and implementing a study in a way that is most likely to achieve the intended goal.

An exploratory descriptive design with multiple methods was used in this study. According to Polit and Beck (2012), the purpose of a descriptive research design is to observe, describe and document aspects of a situation as it naturally occurs. Burns and Groove (2011) argues that descriptive designs are crafted to gain more information about characteristics within a particular field of study. A descriptive design can be used to develop theory, identify problems with current practice, justify current practice, make judgements or determine what others in similar situations are doing (Burns and Groove, 2011).

The quantitative design was chosen as it was the most appropriate method for assessing the technical competence of candidates that were eligible to write the National Board Examination within a Clinical Pathology discipline by direct observation as well as to determine how technical competence is assessed in HPCSA registered training laboratories using predetermined questions. A validated Likert type questionnaire was used to collect quantitative data from the candidates using direct observation where the questions were structured. Another questionnaire was used to collect quantitative data from Laboratory Managers and training officers where the questions were structured with one open ended question that was included at the end of the questionnaire.

3.3 STUDY SETTING

This study was conducted in two parts, at registered HPCSA laboratories in KwaZulu-Natal situated near a semi-urban area.

The first part of study was conducted with candidates who were employed at nine laboratories within KwaZulu-Natal (KZN) region who were eligible to write the forthcoming National Board Examination and the second part was with Laboratory

Managers and training officers responsible for training in the above mentioned laboratories who were requested to complete a survey to determine how technical competence is assessed in HPCSA registered training laboratories.

3.4 STUDY POPULATION

The target population in this study consisted of Intern Medical Technologists in the discipline of Clinical Pathology based at registered HPCSA medical technology public service laboratories in KwaZulu Natal who were candidates to write the forthcoming National Board Examination as well as Laboratory Managers and training officers in these laboratories.

3.5 SAMPLING PROCESS

A convenience purposive sampling was used to select the candidates who were eligible to write the National Board Examination in March 2016 as they were the current cohort. Twenty nine (29) were recruited onto the twelve month internship program for Clinical Pathology in nine (9) HPCSA registered training laboratories for Medical Technology within the KwaZulu-Natal region. Nine (9) Laboratory Managers as well as training officers of HPCSA registered training laboratories were invited to voluntarily participate in the survey.

3.5.1 Inclusion criteria:

- All candidates who are eligible to write the National Board Examination in Clinical Pathology at the above mentioned training laboratories were eligible for inclusion into this study.
- Candidates who had rotated through all three sections (viz. Haematology, Chemical Pathology and Microbiology) of a Clinical Pathology were included in the study.
- Candidates who were medical technicians with prior learning bridging to a Medical Technologist eligible to write the National Board Examination in Clinical Pathology were included.

- Laboratory Managers as well as training officers of the KZN NHLS- HPCSA registered training laboratories or acting Laboratory Managers in their absence were also eligible.

3.5.2 Exclusion Criteria:

- Candidates who had written the National Board Examination on more than one attempt.
- Those that participated in the pilot study.

3.6 SAMPLE SIZE

Twenty eight intern technologists participated in the study (n=28) in which direct observations were conducted by the principal investigator across ten Clinical Pathology procedures. The sample size is justified as it was used from a similar study conducted by Desjardins and Fleming (2014), where laboratories were requested to review their competency assessment records for randomly selected technologists, i.e., 25% and up to a maximum of twenty five (Desjardins and Fleming, 2014). The witnessing tool that was a modified validated SANAS F15 - Witnessing tool for direct observation was used to collect the data (Appendix 1). The data was collected over a period of two and a half months. The interns were directly observed on different days per Clinical Pathology discipline in their respective laboratory. There were some interns who were not available on the appointment date and the principal investigator set up alternate appointments.

Nine HPCSA registered training laboratories for Clinical Pathology participated in the study of which six (6) were Laboratory Managers and four (4) were training officers (n=10). They all filled in the questionnaires which were emailed to the Laboratory Managers and returned to the principal investigator via email in stipulated time. Most managers completed the questionnaire, however, some delegated the questionnaire to be completed by the training officer. Only one laboratory had the questionnaire completed and returned by both Laboratory Manager and training officer. Data was collected from Laboratory Managers and training officers using questionnaires (Appendix 2).

All participants gave a written informed consent. A letter of information was issued to each participant as a document used to notify the participants about the type of study they will participate in, the possible risks involved, as well as their rights.
Table 7 depicts the number of participants in this study. A statistician viewed the protocol of the study, and confirmed that the sample size is valid (Appendix 6).

Table 7: Research participants

Participants	Number
Intern Medical Technologist	28
Laboratory Managers	6
Training officers	4
TOTAL	38

3.7 DATA COLLECTION PLAN

Objective 1: To observe the most common Clinical Pathology processes used to deem Intern Medical Technologists technically competent in the National Health Laboratory Services (NHLS) laboratories using a modified validated SANAS F15 - Witnessing tool for direct observation.

- A quantitative approach was used to meet this objective. 28 intern technologists (n=28) that were candidates to write the National Board Examination participated.
- The instruments were piloted with 4 newly qualified Medical Technologists who had recently written the National Board Examination and 3 Laboratory Managers.

Objective 2: To identify possible factors that may lead to candidates not achieving technical competence levels – this was established by the questionnaire that was administered to Laboratory Managers as well as from the direct observation. It was an inferred finding.

- A quantitative approach was used to meet this objective. Question 10 of the Laboratory Managers survey requested the participant to select 2 examples of the common tests requiring remediation in a Clinical Pathology Laboratory

that they were based at. The witnessing tool where Intern Medical Technologists scored less than three was also used to gather information.

Objective 3: To compare the technical competence assessment results from the direct observation with the National Board Examination results

- A quantitative approach was used to meet this objective

Objective 4: To determine how technical competence is assessed in HPCSA registered training laboratories by using a questionnaire

- A quantitative approach was used to meet this objective by the use of a questionnaire where Laboratory Managers and training officers participated to reveal the operations of competency within their respective laboratories.

3.8 PILOT STUDY

A pilot study was conducted prior to the actual study. A pilot study is a smaller version of a proposed study, conducted to refine the study.
The following people were approached to be part of the pilot study: 4 newly qualified technologists who have completed their internship piloted the witnessing tool, 3 Laboratory Managers of a Clinical Pathology facilities registered with the HPCSA for medical technician training in the discipline of Clinical Pathology piloted the Laboratory Managers survey. Participants in the pilot study volunteered after details of the study were explained to them personally by the principal investigator or via email and all participants signed a written informed consent. Participants in the pilot study did not participate in the main study.

The findings from the pilot study suggested that no changes were required on neither the witnessing tool nor Laboratory Managers' survey.

3.9 DATA COLLECTION PROCESS

The witnessing tool was the primary instrument that was used to collect data and used to measure the competence of twenty eight Intern Medical Technologists

across ten procedures in a Clinical Pathology laboratory prior to them writing their National Board Examination. A modified Likert scale witnessing or direct observation tool adapted from the SANAS F15 Witnessing tool of activity (SANAS) was used to assess technical competencies of the candidates (Appendix 1). The witnessing tool had closed-ended statements that were directly observed by the researcher and the technical competencies were assessed using criteria that was graded on Likert scale 1-5, ranging from “Little or no competency” to “Competent to perform independently and able to assess competency of other Medical Technologists” as in Table 8.

Table 8: The rating categories of competency on the witnessing tool

1. Lacks experience - little or no competency
2. Some experience requires further practice and/or assistance
3. Competent to perform independently
4. Competent to perform independently and train junior staff/students
5. Competent to perform independently and able to assess competency of other Medical Technologists

The participants were approached directly by the researcher. A letter of information explaining the study was given to the participants (Appendix 3) and when they agreed to participate they signed the informed consent form. Direct observation of candidates was conducted by the principal investigator and the observed scores were recorded onto the witnessing tool by the principal investigator. The witnessing tool was adapted to answer the objectives of this study and it was validated by way of a pilot study. There was full participation by all intern technologists in ten procedures. The ten Clinical Pathology test procedures that interns were assessed for technical competency were within the three sections of a Clinical Pathology laboratory, i.e., Microbiology, Haematology and Chemical Pathology. These are tabulated in Table 9.

Table 9: Clinical Pathology section and test procedures

CLINICAL PATHOLOGY SECTION	TEST PROCEDURE
MICROBIOLOGY	Tuberculosis (TB) microscopy
	Stool – microscopy, culture and antimicrobial sensitivities
	Urine – microscopy, culture and antimicrobial sensitivities
	Pus swab – microscopy, culture and antimicrobial sensitivities
	Rapid plasma regain (RPR)
CHEMICAL PATHOLOGY	Chemical Pathology Analyser
HAEMATOLOGY	Full Blood count (FBC) analyser
	Erythrocyte sedimentation rate (ESR)
	Coagulation analyser
	Slide differential count (DIFF)

The rationale for selecting these ten tests are that they are the most common tests with high test request volumes within a Clinical Pathology HPCSA registered training laboratory. Samples for the interns were mainly sourced and utilized from previously analysed patient's specimens to allow for comparisons for the analytical part of the test procedure. The pre analytical component for a test procedure was any random sample received at the laboratory reception to overcome the limitation outlined in the CLSI document (2009). The same slide differential count was used for the technical competency assessment of all interns to ensure a standardised consistent methodology. It must be noted that the procedure for full blood count was unable to be directly observed for five interns due to replacement of a full blood count analyser in the Haematology section of one laboratory as the interns were not trained on the new full blood count analyser when the competency assessment was conducted.

The secondary instrument, a separate questionnaire (Appendix 2) was used to determine how technical competence is assessed in HPCSA registered training laboratories from the Laboratory Managers and training officers. Administration of the Laboratory Manager's and training officer's questionnaire was performed using electronic mail by the principal investigator after a letter of information (Appendix 4) explaining the study was distributed to participants. The questionnaires had one open-ended and eleven closed-ended questions to collect data from the Laboratory Managers and training officers. In the open ended question the laboratories were

requested to submit their competency assessment forms and asked for permission to share their forms for the benefit of all HPCSA registered training laboratories. The return rate was 100% from the nine laboratories, which included six Laboratory Managers and four training officers and this was due to one laboratory where both the Laboratory Manager and Training Officer participated.

3.9.1 The Research Instruments

The primary research instrument consisted of 38 items, with a level of measurement at an ordinal level. The questionnaire was divided into 8 sections which measured various themes as depicted in Table 10.

Table 10: Eight sections in the questionnaires used for witnessing of procedures from Intern Medical Technologists (Appendix 1)

SECTION A	Comply and adhere to Standard Operating Procedure Question 1 to 10
SECTION B	Acceptability of results, as witnessed(where applicable) Question 11 to 16
SECTION C	Internal Quality Control procedures witnessed and acceptability of the outcome Question 17 to 24
SECTION D	Proficiency testing (PT)/ External Quality Assurance (EQA) programme for this method/test and acceptability of performance(where applicable) Question 25 to 26
SECTION E	Reference standards, reference materials and/or controls used (where applicable) Question 27 to 29
SECTION F	Equipment used (where applicable) - Calibrations, Maintenance up to date etc. Question 30 to 35
SECTION G	Training and competency records of the staff member witnessed for this method Question 36 to 37
SECTION H	Accommodation and environmental conditions (where applicable) Question 38

The secondary research instrument consisted of 62 items, with a level of measurement at a nominal level. The questionnaire was divided into 12 questions which measured various themes (Appendix 2).

Permission was obtained from the National Health Laboratory Services for the study (Appendix 5).

3.9.2 Reliability Statistics of the questionnaires

Primary Instrument- Witnessing Tool

The two most important aspects of precision are reliability and validity. Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.60 or higher is considered as “acceptable”. Although the sample size was small, the respondents were a specialised grouping of individuals that should have shown a certain measure of consistency in their responses.

Table 11 reflects the Cronbach’s alpha score for some of the items that constituted the questionnaires. The reliability scores for most sections exceed the recommended Cronbach’s alpha value of 0.600 for a newly developed construct. This indicates a degree of acceptable, consistent scoring for these sections of the research.

This indicates a high (overall) degree of acceptable, consistent scoring for this research. Therefore, almost all of the individual sections also met the required reliability value.

Table 11: Items constituted in the Laboratory Managers questionnaire with Cronbach’s Alpha

Questions	Number of Items	Cronbach's Alpha
Six	6	0.731
Ten	16	0.532
Eleven	16	0.940
Overall	62	0.748

3.10 DATA ANALYSIS, DATA MANAGEMENT AND DISSEMINATION OF DATA

3.10.1 Quantitative data analysis

The results are presented as descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential

techniques include the use of correlations and chi square test values; which are interpreted using the p-values.

The data was reduced and analysed with the help of a statistician, using the statistical software SPSS version 24.0.

3.11 ETHICAL CONSIDERATIONS

Ethical clearance was obtained from the Ethics Committee of the Durban University of Technology (Appendix 7). The National Manager of Academic Affairs and Research granted permission to conduct the study on students, Laboratory Managers and training officers (Appendix 8). The researcher explained to all Intern Medical Technologists the purpose of the study and provided them with a letter of information (Appendix 3). All the participants signed informed consent forms before participating in the study (Appendix 3). Thereafter, the direct observations were conducted according to the checklist (Appendix 1).

An electronic mail was sent to Laboratory Managers and training officers of registered training laboratories with a letter of information and informed consent forms inviting them to participate in the study (Appendix 4). Surveys were also sent by electronic mail to these Laboratory Managers and training officers (Appendix 2).

Informed consent form (Appendix 3 and 4) was signed by all participants. All participants were assured of voluntary participation. Willing participants signed a written consent form after reading and understanding the information letter Participants were informed that they could withdraw from the study at any stage, if they so wished, with no questions asked and that there will be no penalty for participants. Participants were assured of total anonymity at all times since their names were not used on the direct observation checklist and survey. They were informed that the findings and recommendations would be made available to the research authorities and a copy would be kept in the University library.

Data was stored under lock and key for the duration of the study in the principal investigator's office. Hard copy of raw data etc. will be shredded after 5 years as per the University of Technology Institutional Research Ethics policy. All electronic data will be password protected for 5 years and thereafter deleted.

The following ethics principles were observed:

3.11.1 Beneficence

Beneficence in research should be ensured so that there would be no harm to the participants but maximum benefits (Polit and Beck, 2012). In this study the right to freedom from harm and discomfort was maintained as participants were not subjected to any risk of harm or injury. This was ensured by explaining to all participants about their rights to freedom from harm and discomfort and there was no harm as the participants only filled surveys or were directly observed while performing test procedures. The participants were also given a chance to verbalize their concerns and questions before signing the informed consent forms. Those who were directly observed were also assured that everything they said was confidential and that there will be no emotional harm nor compromise their future employment. All participants were informed about their right to withdraw at any time with no questions asked, also that there would be no incentive for the participants.

3.11.2 Respect for human dignity

A letter of information was given to all participants and it explained the purpose of the study, risks and discomfort. The letter also explained the importance of confidentiality where the study anonymity was ensured by not using or mentioning anybody's name. It was explained further in the letter that each participant will be allocated a number and all their details will be recorded under that number. This means that anyone who looks at the records will not be able to trace it to the participants. This was done to protect the privacy of the participants. In addition, a statement of confidentiality was signed by both the supervisors and the principal investigator. After all the explanations, participants were then asked to sign the

consent forms. Polit and Beck (2012), defines respect for human dignity as self-determination which is the right to participate or withdraw from the study at any time when they feel uncomfortable.

3.11.3 Justice

Justice is defined by Polit and Beck (2012), as treating participants fairly and ensuring privacy. In this study this was ensured by approaching Laboratory Managers and training officers who are involved and have experience with the training of Intern Medical Technologists. The right to privacy was also maintained by keeping collected data under lock and key. All participants were allowed to ask questions and to refuse to give information to ensure their self-determination.

3.12. CONCLUSION

A review of methodology of this research was discussed in this chapter. Different steps of the research process and ethical considerations were discussed Research findings are discussed in the next chapter.

CHAPTER FOUR: PRESENTATION OF RESULTS

4.1 INTRODUCTION

In the previous chapter research methodology was presented where the research process was discussed. In this chapter, data is organized systematically according to sections and the objectives. Quantitative data is analysed and results presented. The aim of this study was to assess the technical competence of candidates within Clinical Pathology laboratories that are HPCSA registered for training purposes and to determine how technical competence is assessed in these laboratories. As described in chapter 3 a total of 28 candidates, Intern Medical Technologists were recruited for assessment of technical competence by direct observation within Clinical Pathology laboratories while 6 Laboratory Managers and 4 training officers completed a survey. These quantitative data are analysed separately.

All candidates who participated were due to write the National Board Examination in March of 2016 and had completed training in all ten Clinical Pathology test procedures. Data was collected in January and February 2016, i.e., one or two months before them writing the National Board Examination. By this time students had enough exposure that enabled them to demonstrate technical competence in each of the test procedures or methods used in the assessment of technical competence.

4.2 STATEMENT OF FINDINGS, INTERPRETATION AND DISCUSSION OF THE QUANTITATIVE PRIMARY DATA

This chapter presents the results and discusses the findings obtained from the direct observation checklists and surveys in this study. The direct observation checklist was the primary tool that was used to measure the technical competence of the 28 Intern Medical Technologists. The questionnaire was the secondary research tool that was used to collect data from 6 Laboratory Managers and 4 training officers at nine Clinical Pathology laboratories that are HPCSA registered for training. The data collected from the responses was analysed with SPSS version 24.0. The results are presented as descriptive statistics in the form of graphs, cross tabulations and other

figures for the quantitative data that was collected. Inferential techniques include the use of correlations tables; which are interpreted using p-values.

The Primary Research Instrument

The research instrument consisted of 38 items, with a level of measurement at an ordinal level. The questionnaire was divided into 8 sections as described in Table 10 which measured various themes in each of the ten test procedures.

In each direct observation checklist there were 5 responses for the assessor to choose from (Likert Scale) i.e.: '1 = lacks experience – little or no competency', '2 = some experience - requires further practice and/or assistance ', '3 = competent to perform independently', '4 = competent to perform independently and train junior staff/students' and '5 = competent to perform independently and able to assess competent other Medical Technologists'. However, during data analysis levels of competence were collapsed with scores of 3, 4 and 5 while levels of non-competence were scores 1 and 2.

4.3 PRESENTATION OF QUANTITATIVE DATA

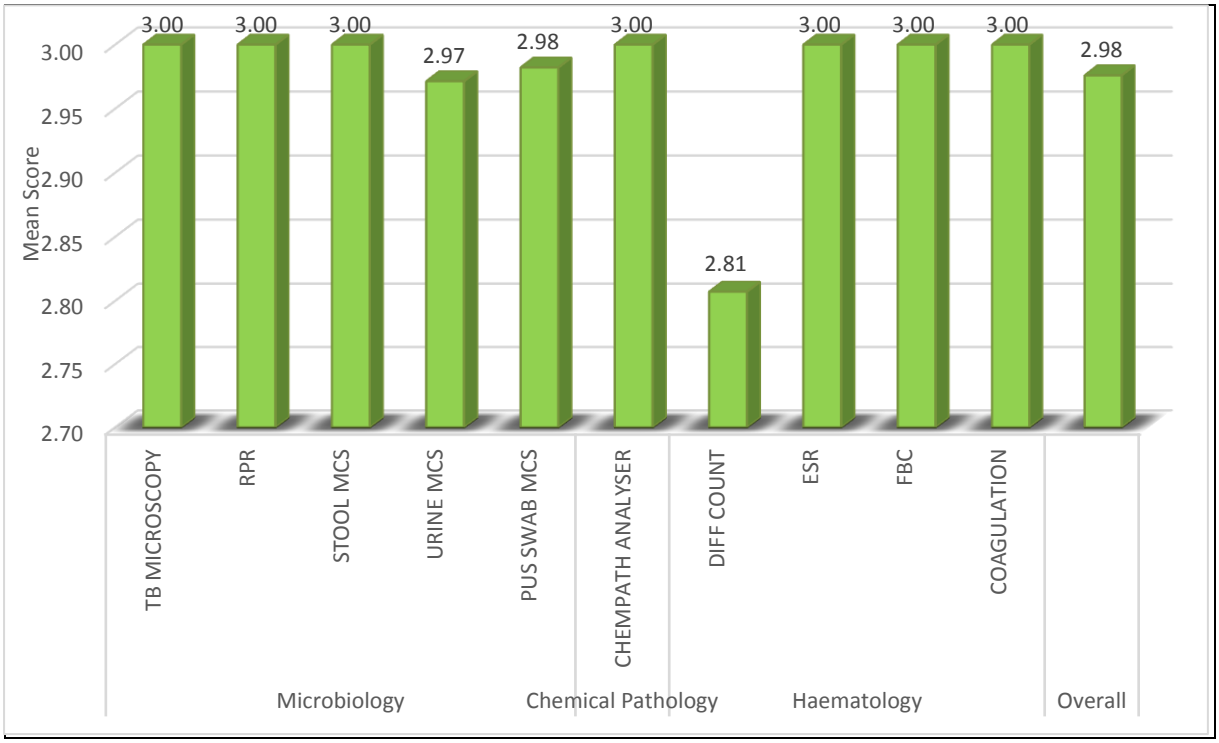
4.3.1 Direct Observation of the most common Clinical Pathology processes used to deem a Medical Technologist technically competent

4.3.1.1 Section A: Comply and adhere to Standard Operating Procedure

Table 12 and Figure 3 present the descriptive statistics of compliance and adherence to standard operating procedures for intern technologists across ten most common Clinical Pathology tests.

Table 12: Competency count summary for candidates across ten Clinical Pathology test procedures for compliance and adherence to SOP's

SECTION A	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Carefully read the information provided on the request form and verify sample numbers vs request forms	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Demonstrate knowledge of the criteria for rejecting samples	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Handle samples correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Perform the test and follow procedure correctly according to the SOP	Not yet competent	0	0	0	4	2	0	23	0	0	0
	Competent	28	28	28	24	26	28	5	28	23	28
Demonstrate knowledge of basic principle	Not yet competent	0	0	0	4	3	0	25	0	0	0
	Competent	28	28	28	24	25	28	3	28	23	28
Verbally demonstrate knowledge of the criteria for rejection of unsuitable samples	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Demonstrate knowledge of troubleshooting procedures	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Complete all the required documentation if applicable	Not yet competent	0	0	0	0	0	0	3	0	0	0
	Competent	28	28	28	28	28	28	25	28	23	28
Perform correct housekeeping and dispose of materials correctly and follow all other safety procedures	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Limitations of test procedure understood	Not yet competent	0	0	0	0	0	0	3	0	0	0
	Competent	28	28	28	28	28	28	25	28	23	28



3=competent and <3 not yet competent

Figure 3: Mean competency score of candidates for section A- compliance and adherence to SOP's across Clinical Pathology tests

The points below provide more information with regard to compliance and adherence to standard operating procedures across the ten Clinical Pathology test procedures:

- There were 10 questions or statements on section A of the direct observation checklist (Table 12).
- Most of the candidates were competent in the ten Clinical Pathology test procedures assessed except for urine MCS, pus swab MCS and differential count test procedures.
- Table 12 showed that 4 candidates for urine MCS, 2 candidates for pus swab MCS and 23 candidates for differential counts were not yet competent to perform the test and follow procedure correctly according to the SOP.
- 4 candidates for urine MCS, 3 candidates for pus swab MCS and 25 candidates for differential counts were not yet competent to demonstrate knowledge of basic principles of tests.
- 25 candidates were not yet competent to complete all the required documentation for differential counts.

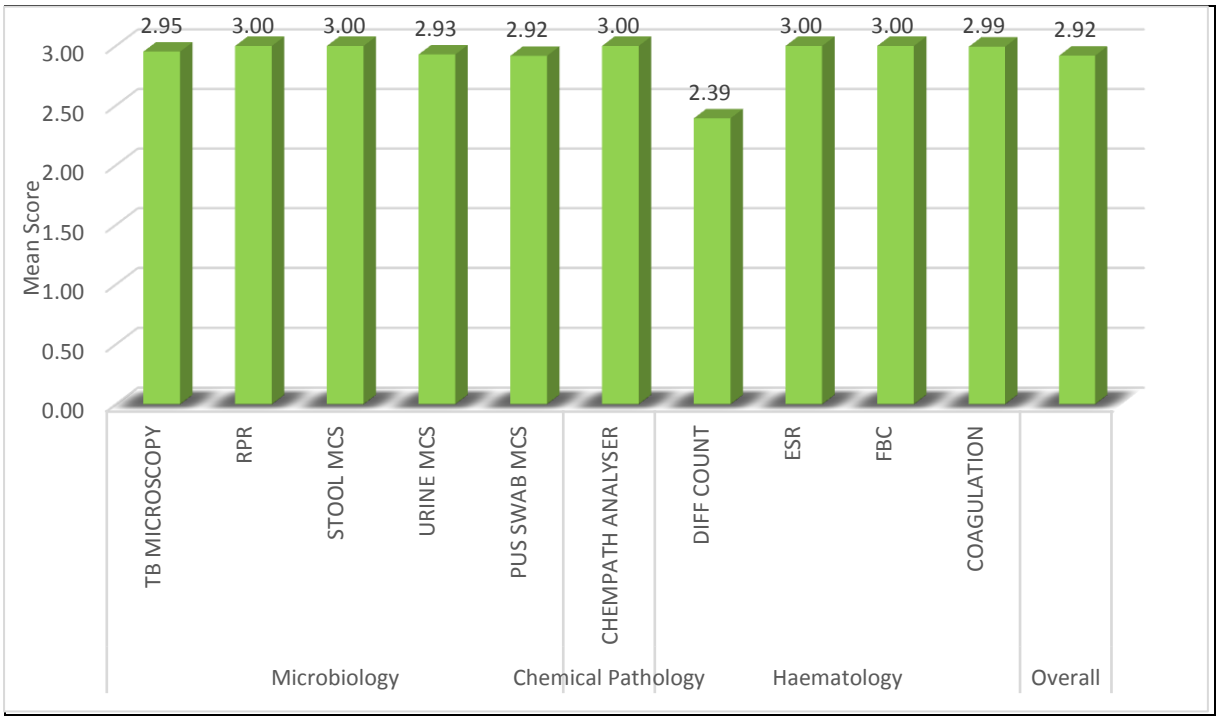
- In Figure 3, a mean score of 3 indicated that the candidates were competent to perform independently with respect to compliance and adherence to the standard operating procedures as observed by the assessor of the candidates for some of test procedures or methods
- In Figure 3, a mean score of less than 3 indicated that some candidates were not yet competent in the urine MCS, pus swab MCS and differential count as they had some experience, however, required further practice and assistance.

4.3.1.2 Section B: Acceptability of results, as witnessed

Table 13 and Figure 4 present the descriptive statistics of acceptability of results, as witnessed for intern technologists across ten Clinical Pathology tests.

Table 13: Competency count summary for candidates across ten Clinical Pathology test procedures for acceptability of results as witnessed

SECTION B	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Correctly and accurately record all findings	Not yet competent	4	0	0	3	4	0	25	0	0	0
	Competent	24	28	28	25	24	28	3	28	23	28
Follow established procedure for results reporting and enter correctly on LIS	Not yet competent	4	0	0	1	2	0	24	0	0	0
	Competent	24	28	28	27	26	28	4	28	23	28
Demonstrate knowledge of interpreting results and understanding of the clinical significance abnormal results	Not yet competent	0	0	0	4	4	0	24	0	0	1
	Competent	28	28	28	24	24	28	4	28	23	27
Follow the laboratory procedure for critical findings	Not yet competent	0	0	0	0	0	0	4	0	0	0
	Competent	28	28	28	28	28	28	24	28	23	28
Follow the correct procedure when providing telephonic results	Not yet competent	0	0	0	0	2	0	0	0	0	0
	Competent	28	28	28	28	26	28	28	28	23	28
Demonstrate knowledge of interpreting results	Not yet competent	0	0	0	4	2	0	25	0	0	0
	Competent	28	28	28	24	26	28	3	28	23	28



3=competent and <3 not yet competent

FIGURE 4: Mean competency score of candidates for section B – Acceptability of results as witnessed across Clinical Pathology tests

The points below provide more information with regard to acceptability of results as witnessed across the ten Clinical Pathology test procedures:

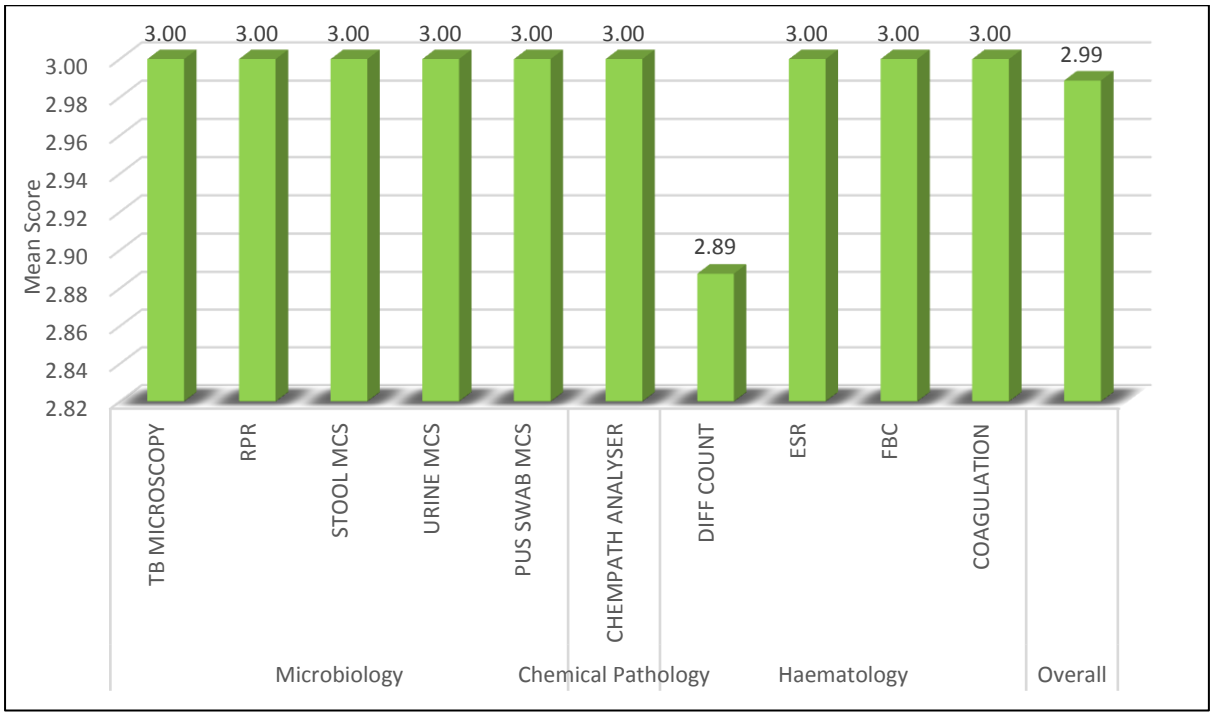
- There were six questions or statements on section B of the direct observation checklist (Table 13)
- Most of the candidates were competent in Clinical Pathology test procedures assessed except for TB microscopy, urine MCS, pus swab MCS, differential count and coagulation test procedures.
- Table 13 showed that 4 candidates for TB microscopy, 4 candidates for urine MCS, 4 candidates for pus swab MCS and 2 candidates for differential counts were not yet competent to correctly and accurately record all findings.
- 4 candidates for TB microscopy,1 candidate for urine MCS, 2 candidates for pus swab MCS and 24 candidates for differential counts were not yet competent to follow established procedures for results reporting and entering correctly on laboratory information system (LIS).

4.3.1.3 Section C: Internal Quality Control procedures witnessed and acceptability of the outcome

Table 14 and Figure 5 present the descriptive statistics of internal quality control procedures and acceptability of the outcome witnessed for intern technologists across ten Clinical Pathology tests.

Table 14: Competency count summary for candidates across ten Clinical Pathology test procedures for internal quality control procedures witnessed and acceptability of the outcome

SECTION C	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Handle controls correctly	Not yet competent	0	0	0	0	0	0	4	0	0	0
	Competent	28	28	28	28	28	28	24	28	23	28
Use appropriate quality control procedure	Not yet competent	0	0	0	0	0	0	3	0	0	0
	Competent	28	28	28	28	28	28	25	28	23	28
Demonstrate knowledge of frequency of running controls during a 24 hour period or per batch	Not yet competent	0	0	0	0	0	0	25	0	0	0
	Competent	28	28	28	28	28	28	3	28	23	28
Interpret QC results correctly, verify and sign off QC results	Not yet competent	0	0	0	0	0	0	25	0	0	0
	Competent	28	28	28	28	28	28	3	28	23	28
Take corrective action if required or describe corrective action for out of range control results	Not yet competent	0	0	0	0	0	0	25	0	0	0
	Competent	28	28	28	28	28	28	3	28	23	28
Take or verbally describe the appropriate corrective action in the event of failed control values	Not yet competent	0	0	0	0	0	0	25	0	0	0
	Competent	28	28	28	28	28	28	3	28	23	28
Take corrective action or describe corrective action for inaccurate control results and how to troubleshoot	Not yet competent	0	0	0	0	0	0	25	0	0	0
	Competent	28	28	28	28	28	28	3	28	23	28
Interpret L.J. charts correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	0	0	0	0	0	28	0	0	23	28



3=competent and <3 not yet competent

FIGURE 5: Mean competency score of candidates for section C –Internal quality control procedures witnessed and acceptability of outcome

The points below provide more information with regard to internal quality control procedures witnessed and acceptability of the outcomes witnessed across the ten Clinical Pathology test procedures:

- There were 8 questions or statements on section C of the direct observation checklist (Table 14).
- Most of the candidates were competent in most of the Clinical Pathology test procedures assessed except for differential count.
- Table 14 showed that 24 candidates for differential counts were not yet competent to handle controls correctly.
- 25 candidates for differential counts were not yet competent to perform the following activities : use appropriate quality control procedure, demonstrate knowledge of frequency of running controls during a 24 hour period or per batch and interpret QC results correctly, verify and sign off QC results, take corrective action if required or describe corrective action for out of range control results, take or verbally describe the appropriate corrective action in

the event of failed control values and take corrective action or describe corrective action for inaccurate control results and how to troubleshoot.

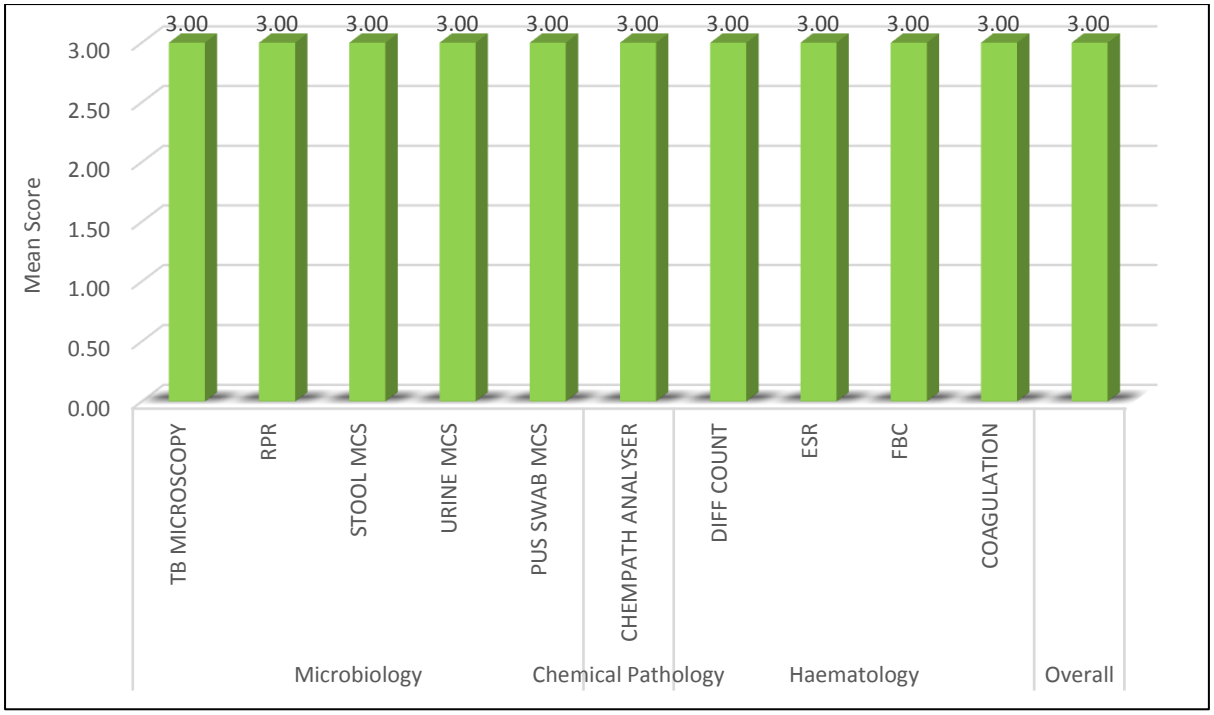
- A mean score of 3 indicated that the candidates were competent to perform independently with respect to acceptability of results as witnessed by the assessor for some of the test procedures or methods.
- A mean score of less than 3 indicated that some candidates were not yet competent in differential count as they had some experience, however, require further practice.

4.3.1.4 Section D: Proficiency testing (PT)/ EQA programme for this method/test and acceptability of performance

Table 15 and Figure 6 present the descriptive statistics of proficiency testing (PT)/ EQA programme for test procedures and acceptability of performance witnessed for Intern Technologists across ten Clinical Pathology tests.

TABLE 15: Competency count summary for candidates across ten Clinical Pathology test procedures for proficiency testing (PT)/ EQA programme for this method/test and acceptability of performance

SECTION D	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Show EQA results for method/test	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Verbally demonstrate an understanding in corrective action processes in the event of failed EQC	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28



3=competent and <3 not yet competent

Figure 6: Mean competency score of laboratories for section D –Proficiency testing (PT)/EQA programme and acceptability of performance

The points below provide more information with regard to proficiency testing (PT)/EQA programme and acceptability of performance across the ten Clinical Pathology test procedures in the laboratories:

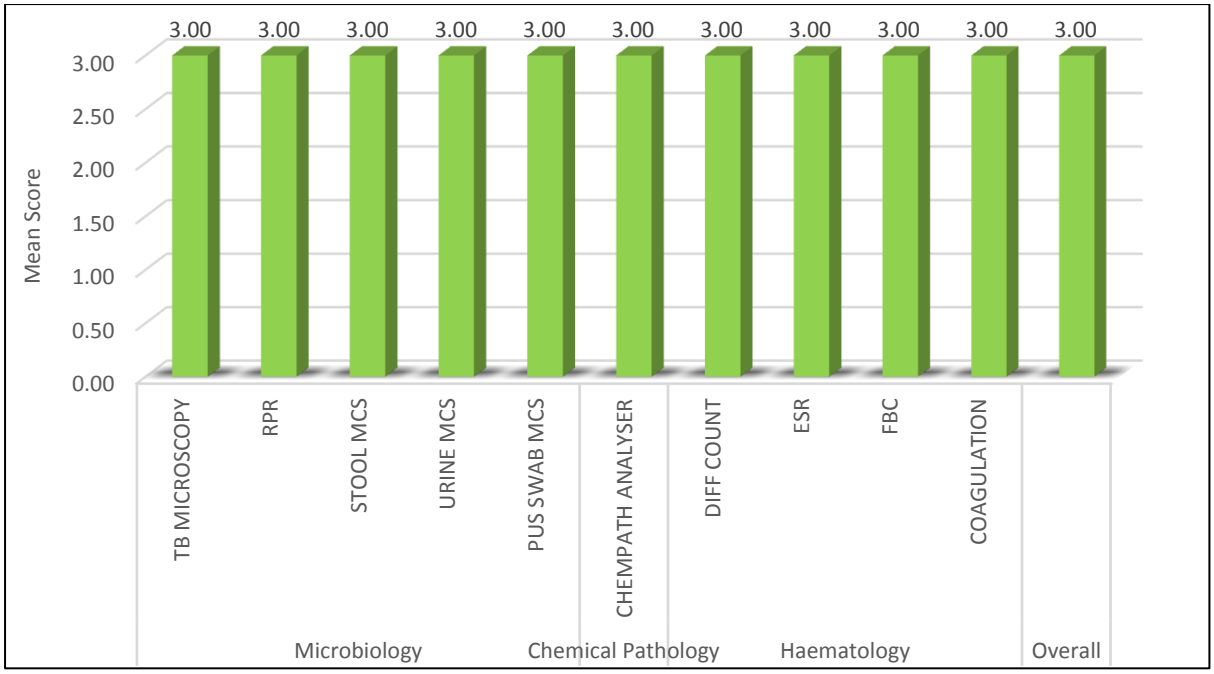
- There were 2 questions or statements on section D of the direct observation checklist (Table 15).
- The laboratories were competent in the entire Clinical Pathology test procedures assessed.
- A mean score of 3 indicated that the candidates were able to demonstrate that the laboratory was competent by providing the proficiency results for the entire range of Clinical Pathology test procedures.

4.3.1.5 Section E: Reference standards, reference materials and/or controls used

Table 16 and Figure 7 present the descriptive statistics of reference standards, reference materials and/or controls used for intern technologists across ten Clinical Pathology tests.

TABLE 16: Competency count summary for candidates across ten Clinical Pathology test procedures for reference standards, reference materials and/or controls used.

SECTION E	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Check lot numbers of controls and calibrators	Not yet competent	**0**	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Give correct details regarding control stability	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Make up and label reagents and controls correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28



3=competent and <3 not yet competent

Figure 7: Mean competency score of laboratories for section E –Reference standards, reference materials and/or controls used

The points below provide more information with regard to reference standards, reference materials and/or controls used across the ten Clinical Pathology test procedures in the laboratories:

- There were 3 questions or statements on section D of the direct observation checklist (Table 16).
- All of the candidates were able to demonstrate that they were competent in the entire range of Clinical Pathology test procedures assessed.
- A mean score of 3 indicated that all the candidates were competent to perform independently with respect to reference standards and reference materials and/or controls used.

4.3.1.6 Section F: Equipment used (where applicable) - Calibrations, Maintenance

Table 17 and Figure 8 present the descriptive statistics of equipment used (where applicable) – with respect to calibrations and maintenance used by intern technologists across ten Clinical Pathology tests.

TABLE 17: Competency count summary for candidates across ten Clinical Pathology test procedures for calibration and maintenance of equipment used

SECTION F	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Able to demonstrate or describe start up procedures correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Perform all checks as instructed	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Demonstrate knowledge of other required maintenance and service requirements	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Take corrective action or verbally describe corrective action procedures in the event of instrument malfunction	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Give the correct details with regard to frequency of calibration (if applicable)	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Perform scheduled maintenance correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28

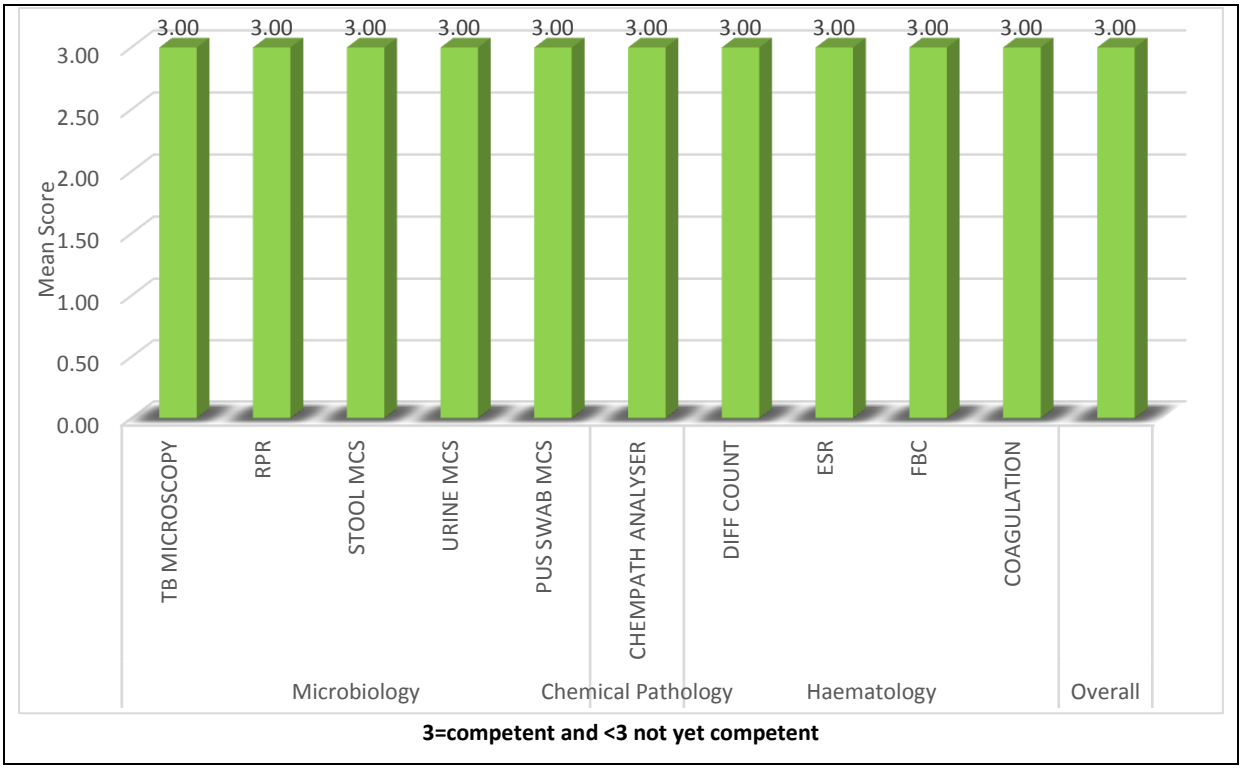


Figure 8: Mean competency score of laboratories for section F – Calibration and maintenance of all equipment used

The points below provide more information with regard to calibration and maintenance of all equipment used across the ten Clinical Pathology test procedures in the laboratories:

- There were 6 questions or statements on section F of the direct observation checklist (Table 17).
- All the candidates were competent in the entire range of Clinical Pathology test procedures assessed.
- A mean score of 3 indicated that all the candidates were competent to perform independently with respect to calibrations and maintenance of equipment.

4.3.1.7 Section G - Training and competency records of the staff member witnessed

Table 18 and Figure 9 present the descriptive statistics of training and competency records witnessed as provided by intern technologists across ten Clinical Pathology tests.

Table 18: Competency count summary for candidates across ten Clinical Pathology test procedures for training and competency records

SECTION G	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Provide training records for this test /method	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	0	0	0	0	0	0	0	8	8	8
Provide competency records for this test / method	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	0	0	0	0	0	0	0	8	8	8

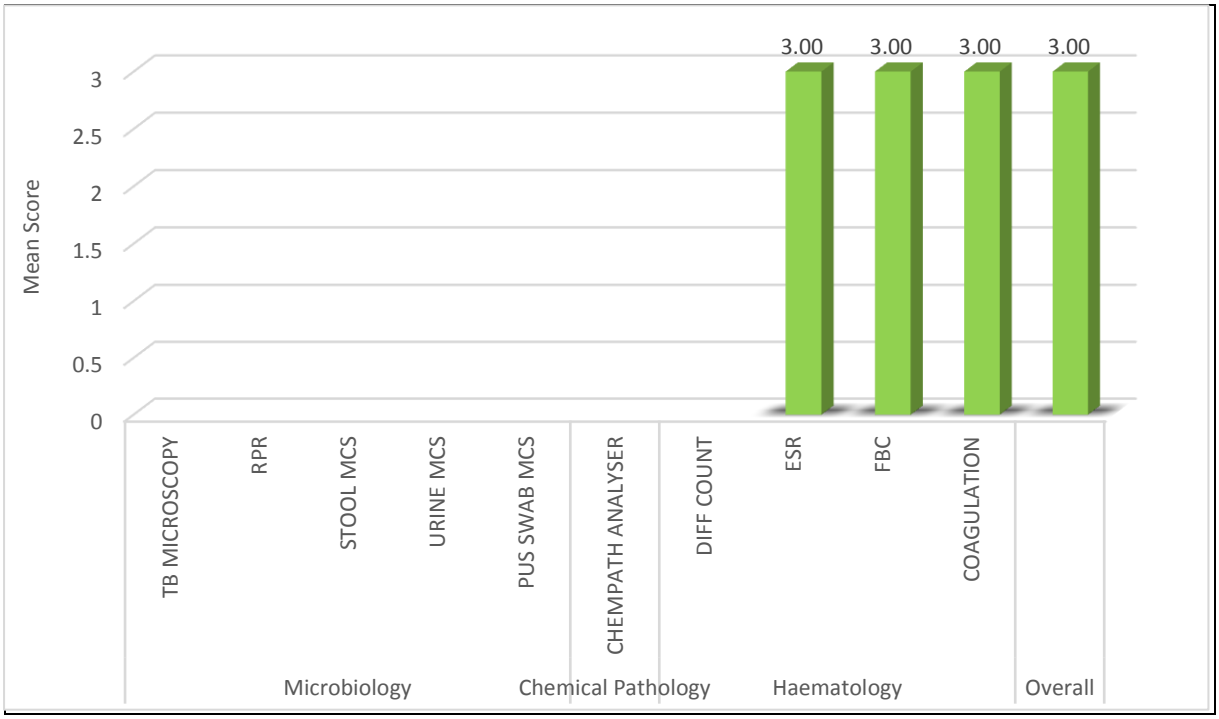


Figure 9: Mean competency score of laboratories for section G – Training and competency records as witnessed

The points below provide more information with regard to training and competency records witnessed as provided by intern technologists across the ten Clinical Pathology test procedures in the laboratories:

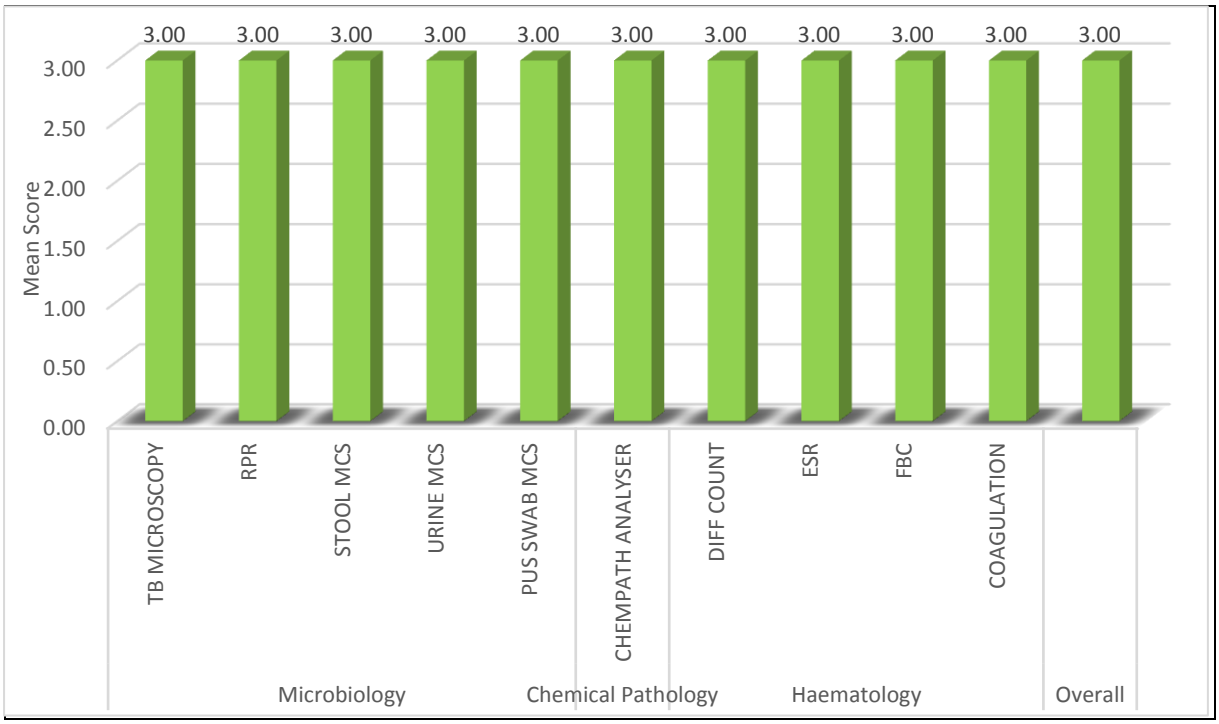
- There were 2 questions or statements on section G of the direct observation checklist (Table 18).
- Most of the candidates were unable to provide the neither training nor competency records except for eight candidates that were able to provide both training and competency records signed by both the candidate and trainer or assessor in FBC, coagulation and ESR methods.
- A mean score of 3 indicated that all eight of the candidates were competent to perform independently in the following clinical test procedures: ESR, FBC and coagulation as witnessed from the signed training and competency records provided.

4.3.1.8 Section H - Accommodation and environmental conditions

Table 19 and Figure 10 present the descriptive statistics of accommodation and environmental conditions in the laboratory as witnessed by intern technologists across ten Clinical Pathology tests.

Table 19: Competency count summary for candidates across ten Clinical Pathology test procedures for accommodation and environmental conditions of the laboratory

SECTION H	COMPETENCY	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Verbally demonstrate knowledge of laboratory factors affecting the test	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28



3=competent and <3 not yet competent

Figure 10: Mean competency score of laboratories for section H – Accommodation and environmental conditions

The points below provide more information with regard to accommodation and environmental conditions in the laboratory as witnessed by intern technologists across ten Clinical Pathology tests:

- There was 1 question or statement on section H of the direct observation checklist (Table 19).
- All of the candidates were able to demonstrate that they were competent in the entire Clinical Pathology test procedures assessed as they were able to verbally demonstrate knowledge of laboratory factors affecting the various Clinical Pathology test procedures.
- A mean score of 3 indicated that all the candidates were competent to verbally demonstrate knowledge of laboratory factors affecting the tests.

4.3 CLINICAL PATHOLOGY DISCIPLINE ANALYSIS

In total, 28 candidates eligible to write the next National Board Examination were directly observed in their respective registered HPCSA Clinical Pathology laboratory and assessed for technical competence in ten test procedures. The Clinical Pathology laboratory has three main sections or sub-disciplines: Microbiology, Chemical Pathology and Haematology.

The Table 20 below indicates the overall mean scores of competency level by test method and sub-discipline directly observed within Clinical Pathology.

Table 20: Competency score per method broken down per section directly observed

Discipline	Test/Method	A	B	C	D	E	F	G	H	Over all
Microbiology	TB MICROSCOPY	3.00	2.95	3.00	3.00	3.00	3.00	0.00	3.00	2.99
	RPR	3.00	3.00	3.00	3.00	3.00	3.00	0.00	3.00	3.00
	STOOL MCS	3.00	3.00	3.00	3.00	3.00	3.00	0.00	3.00	3.00
	URINE MCS	2.97	2.93	3.00	3.00	3.00	3.00	0.00	3.00	2.98
	PUS SWAB MCS	2.98	2.92	3.00	3.00	3.00	3.00	0.00	3.00	2.98
Chemical Pathology	CHEMPATH ANALYSER	3.00	3.00	3.00	3.00	3.00	3.00	0.00	3.00	3.00
Haematology	DIFF COUNT	2.81	2.39	2.89	3.00	3.00	3.00	0.00	3.00	2.87
	ESR	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
	FBC	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
	COAGULATION	3.00	2.99	3.00	3.00	3.00	3.00	3.00	3.00	3.00

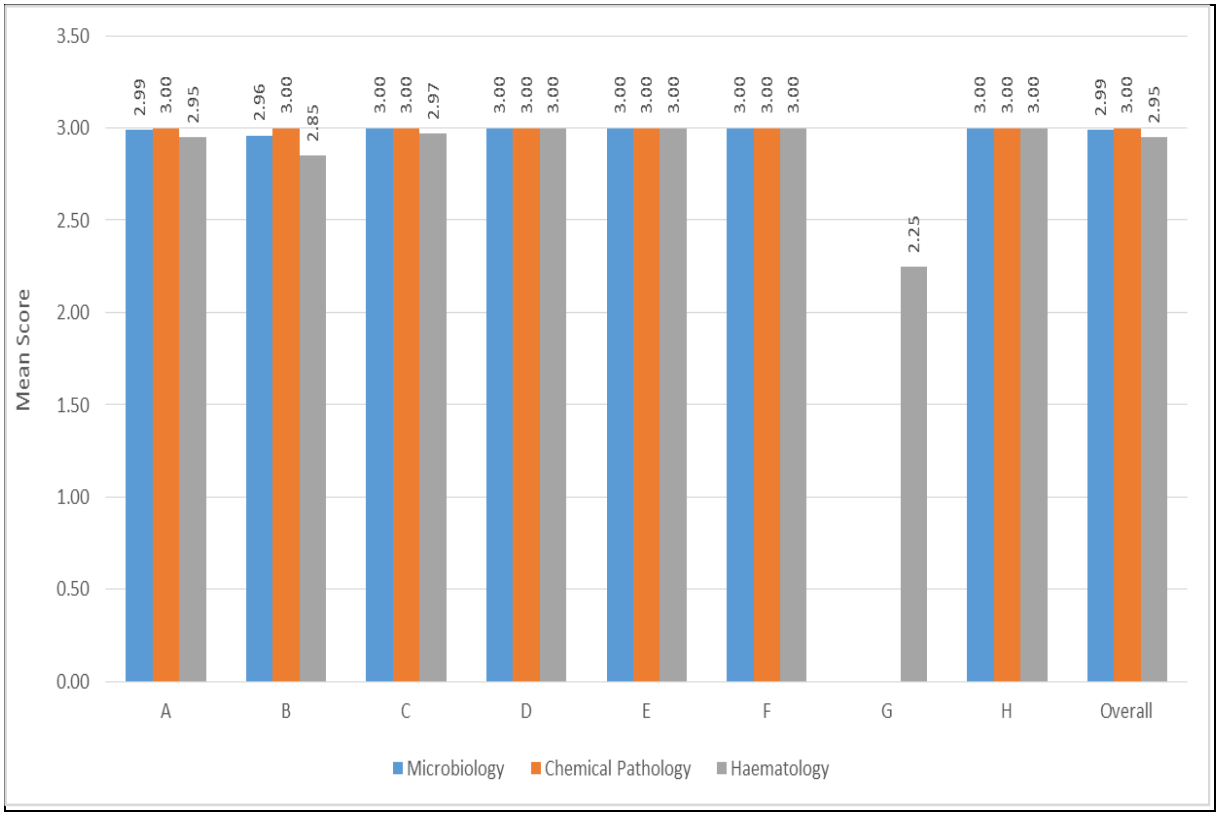


Figure 11: Graphical output of the competency mean values per section and sub-discipline

From Table 20 and Figure 11 it is noted that sections D, E, F and H have identical mean scores (mean = 3.0).

- The ratings of 3 imply that the candidates are competent to perform independently.
- All candidates should be competent to perform independently prior to writing the National Board Examination in order for professional designation to be conferred for independent practice.
- The patterns are similar across sub disciplines but it is observed that the Haematology scores are lower than the other two sub disciplines.

To determine whether this difference is significant, a one way ANOVA was performed. The results are shown in Table 21.

Table 21: Analysis of sub-disciplines

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.048	2	.024	22.507	.000
Within Groups	.086	81	.001		
Total	.134	83			

The result indicates that the mean values amongst the sub disciplines are significantly different ($p < 0.05$). This is important as each sub-discipline has test procedures that are specific to the standard operating procedure so it is to be expected that the mean values amongst sub-disciplines are significantly different. An inspection of the mean values indicates that Haematology has a lower mean than the other two.

4.4.1 Graphical output of the results is shown below per sub-disciplines of Clinical Pathology

4.4.1.1 Microbiology

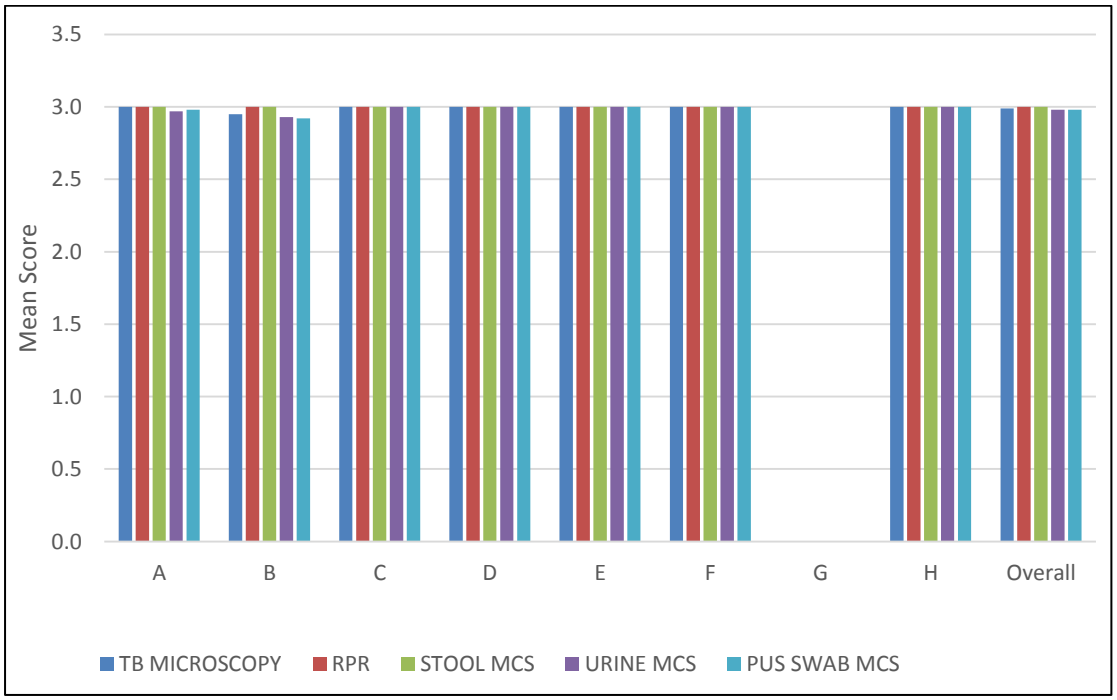


Figure 12: graphical output of the competency mean values for test procedures in Microbiology

In the Microbiology section A, B, G are below 3. Section A is compliance and adherence to the standard operating procedure while section B is acceptability of results, and section G is training and competency records of the staff member witnessed for this method.

In all Microbiology methods, section G was zero as all training and competency records were not provided to the assessor.

The methods where candidates had a mean score of below 3 was TB microscopy, urine MCS and pus swab MCS. A score of less than 3 implies that some of these candidates are not yet competent and have some experience but still need more practice and assistance. Section C, the acceptability of results as witnessed was below 3 for the above mention three methods. For urine and pus swab MCS the adherence and compliance to the standard operating procedure was below 3.

Candidates were competent to perform independently on the methods of stool MCS and RPR, however, lacked the training and competency records or documents that confirm their competence level.

4.4.1.2 Chemical Pathology

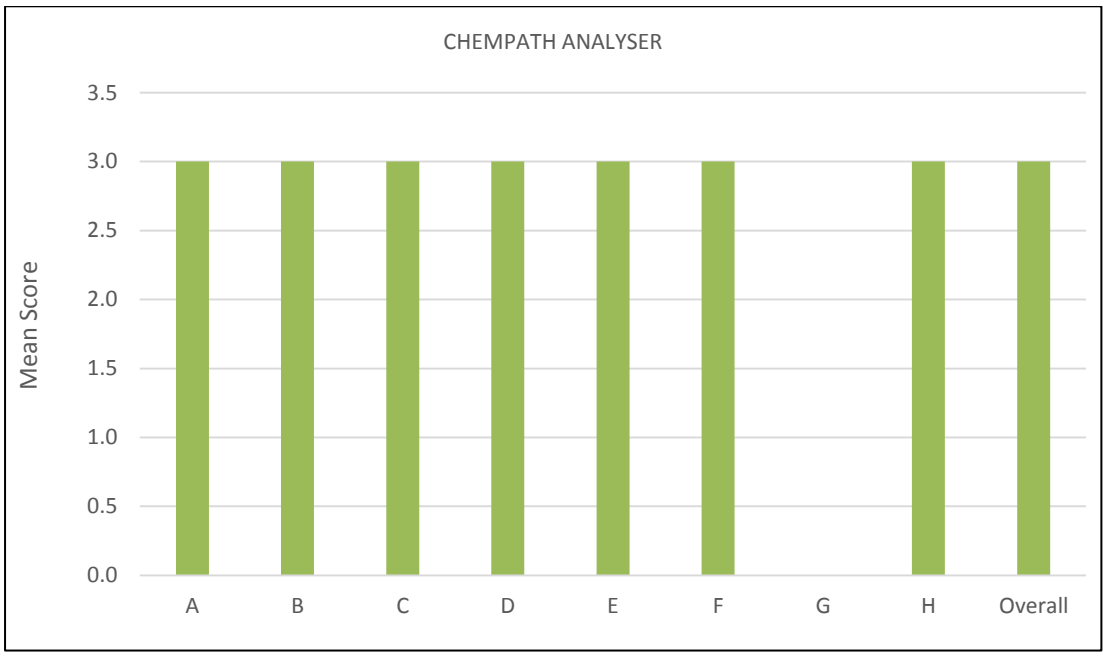


Figure 13: Graphical output of the competency mean values for test procedures in Chemical Pathology

In Chemical Pathology all candidates performed at a mean score of 3 in all sections of the operation of the Chemical Pathology analyser which means that they are competent except that section G was zero. This is concerning as there were no training and competency records provided by the candidates to the assessor.

4.4.1.3 Haematology

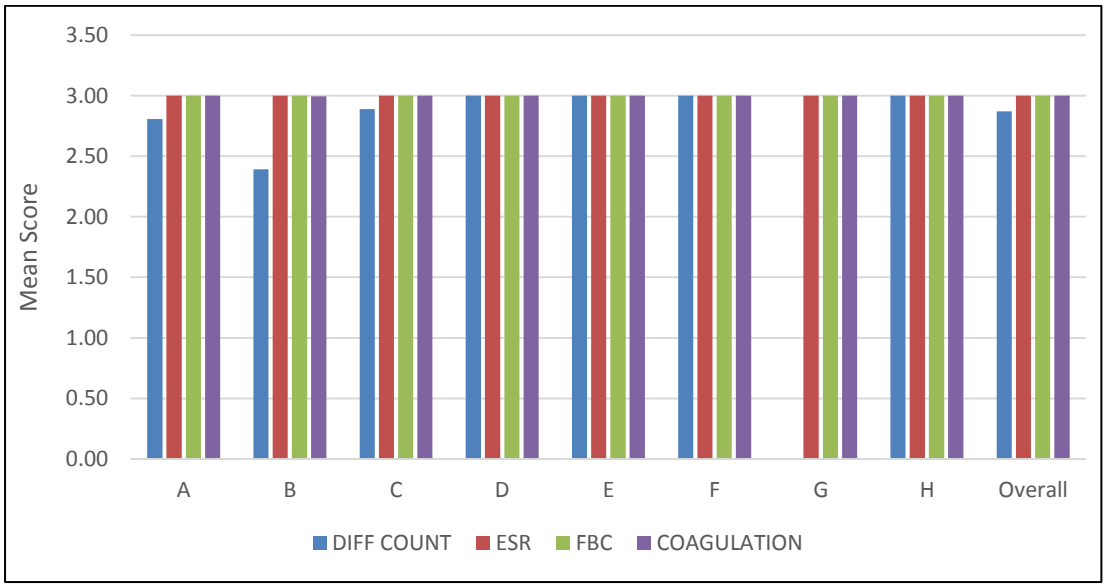


Figure 14: Graphical output of the competency mean values for test procedures in Haematology

In the Haematology section, A, B, C, and G are below 3. Section A is compliance and adherence to the standard operating procedure while section B is acceptability of results, as witnessed, section C is internal quality control procedures witnessed and acceptability of the outcome and section G is training and competency records of the candidates provided for these methods.

In three Haematology methods, section G was 3 as training and competency records were provided for some candidates for ESR, FBC and coagulation and these candidates were competent to perform independently and therefore had a score of 3. In the differential count method, section G was zero as all training and competency records were not provided by the candidates.

To determine whether the scores differed significantly from the required value of 3, a median test was performed. A comparison between a competency score of 3 which is considered as the standard of competence for independent practice was performed using the one- sample Wilcoxon signed rank test. The results are shown in Table 22.

Most of the distributions had a median that is not significantly different from the required standard score of 3 except for section A and B for Microbiology.

For both Microbiology and Chemical Pathology, in all but one instance in section G there was no difference between 3 and the experimental value ($p > 0,05$). For section G the p value = 0 implying a significant difference, this was as a result of neither training nor competency records provided by the candidates in Microbiology and Chemical Pathology sub disciplines.

Table 22: Medians test using the one sample Wilcoxon signed rank test for Clinical Pathology sub-disciplines

MICROBIOLOGY HYPOTHESIS TEST SUMMARY		
Null hypothesis	**Significance**	**Decision**
The median of A equals 3.00	0,026	Reject the null hypothesis
The median of B equals 3.00	0.004	Reject the null hypothesis
The median of C equals 3.00	1.000	Retain the null hypothesis
The median of D equals 3.00	1.000	Retain the null hypothesis
The median of E equals 3.00	1.000	Retain the null hypothesis
The median of F equals 3.00	1.000	Retain the null hypothesis
The median of G equals 3.00	.	Unable to compute
The median of H equals 3.00	1.000	Retain the null hypothesis
CHEMICAL PATHOLOGY HYPOTHESIS TEST SUMMARY		
Null hypothesis	**Significance**	**Decision**
The median of A equals 3.00	1.000	Retain the null hypothesis
The median of B equals 3.00	1.000	Retain the null hypothesis
The median of C equals 3.00	1.000	Retain the null hypothesis
The median of D equals 3.00	1.000	Retain the null hypothesis
The median of E equals 3.00	1.000	Retain the null hypothesis
The median of F equals 3.00	1.000	Retain the null hypothesis
The median of G equals 3.00	.	Unable to compute
The median of H equals 3.00	1.000	Retain the null hypothesis
HAEMATOLOGY HYPOTHESIS TEST SUMMARY		
Null hypothesis	**Significance**	**Decision**
The median of A equals 3.00	0,000	Reject the null hypothesis
The median of B equals 3.00	0.000	Reject the null hypothesis
The median of C equals 3.00	0.000	Reject the null hypothesis
The median of D equals 3.00	1.000	Retain the null hypothesis
The median of E equals 3.00	1.000	Retain the null hypothesis
The median of F equals 3.00	1.000	Retain the null hypothesis
The median of G equals 3.00	.	Unable to compute
The median of H equals 3.00	1.000	Retain the null hypothesis

Asymptomatic significances are displayed. The significance level is 0.05

4.5 IDENTIFICATION OF POSSIBLE FACTORS THAT MAY LEAD TO CANDIDATES NOT ACHIEVING TECHNICAL COMPETENCE LEVELS

4.5.1 Examples of the most common issues requiring remediation in the Clinical Pathology laboratory identified from the Laboratory Manager's and training officers survey

Question ten of the survey sent to Laboratory Managers and training officers requested them to select two examples of the most common issues requiring remediation in the Clinical Pathology laboratory. Multiple responses were allowed from a list of fifteen methods. Figure 15 shows that there were no issues requiring remediation for RPR, reticulocyte count and ESR methods. This is consistent with the finding of direct observation of candidates for technical competence of the RPR and ESR method. 10% of respondents identified that sputum MCS, blood culture MCS, urine MCS, blood gas analyser and preparation and examination of peripheral blood smears (differential counts) required remediation while 20% identified that pus swab MCS, stool MCS and TB microscopy and culture required remediation, thirty per cent identified FBC, coagulation, Chemical Pathology analyser and CSF MCS required remediation and 40% selected the identification of malarial parasites as issues requiring remediation in a Clinical Pathology laboratory.

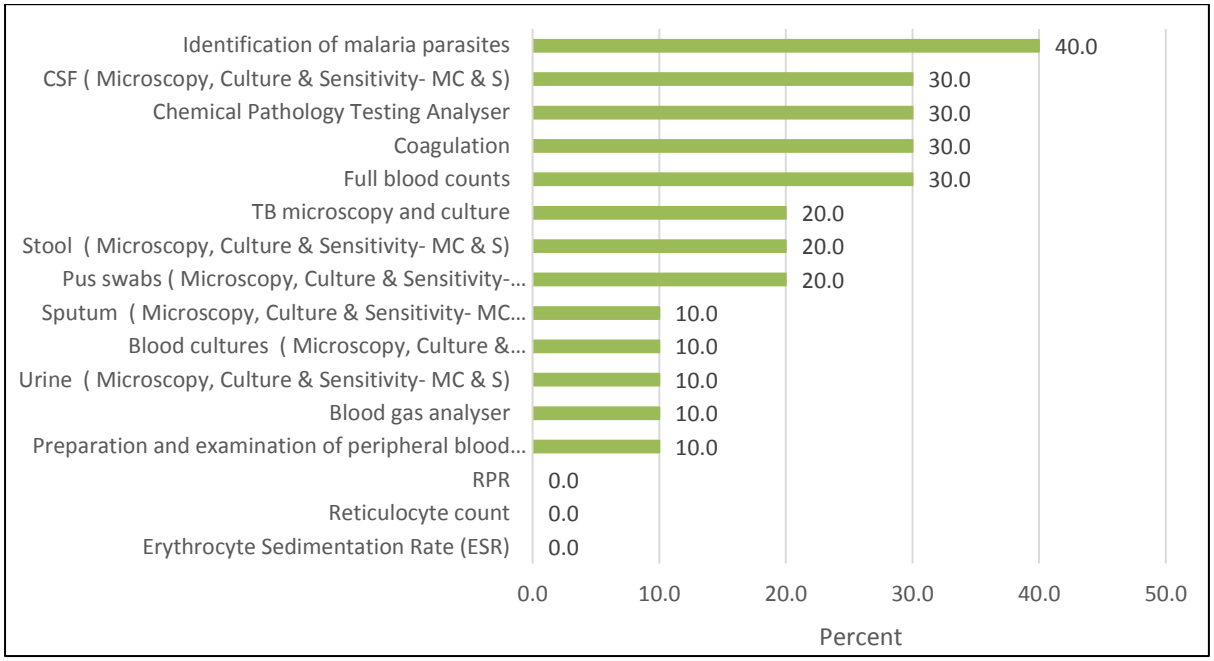


Figure 15: Examples of the most common issues requiring remediation in the Clinical Pathology laboratory identified from Question 10 of the Laboratory Manager's and training officers survey

4.6 COMPARISON OF THE TECHNICAL COMPETENCE ASSESSMENT RESULTS FROM THE DIRECT OBSERVATION WITH THE NATIONAL BOARD EXAMINATION RESULTS

Twenty nine intern technologists were appointed onto the program and one resigned, therefore, twenty eight were assessed for technical competence in each of the sub disciplines, i.e., Microbiology, Chemical Pathology and Haematology. Twenty seven (n=27) candidates wrote the National Board Examination as one candidate from the twenty eight assessed for technical competency deferred due to severe illness.

Table 23: Means and standard deviations of technical competence and National Board Examination per sub-disciplines

	DIRECT OBSERVATION			NATIONAL BOARD EXAMINATION RESULTS				
	Microbiology	Chemical Pathology	Haematology	Micro Exam	Chem Exam	Haem Exam	Gen Exam	Average Exam
N	28	28	28	27	27	27	27	27
Mean	3.2807	3.2100	3.2948	54.2593	65.1481	57.4074	33.2593	56.3704
Std. Deviation	.01542	.00000	.29943	7.99323	9.57442	10.26293	13.06373	8.12474

Bivariate correlation was performed on the data. The results are shown in Table 24.

The results indicate the following patterns. Positive values indicate a directly proportional relationship between the variables and a negative value indicates an inverse relationship. All significant relationships are indicated by a * or **.

The correlation value between “Microbiology direct observation” and “Microbiology National Examination” is 0.488 which is a directly related proportionality. This implies that an increase in the Microbiology technical competency assessment score results in a higher Microbiology examination mark, and *vice versa*.

From Table 24 it is evident that there are no significant correlation values between Haematology and Chemical Pathology technical competency assessments and professional Board Examination results in that sub-discipline. This finding could mean that a candidate may be technically competent and fail the Board Examination or the opposite may be the case.

The general section of the Board Examination has significant correlations with Microbiology and Chemical Pathology technical competency assessment results with values of 0,398 and 0,405, respectively. The general section includes general laboratory practice and quality management systems that are embedded in each sub-discipline.

Table 24: Correlation between Technical competence per sub discipline and National Board Examination results per sub discipline

Correlations									
		Microbiology	Chemical Pathology	Haematology	Micro_ Exam	Chem_ Exam	Haem_ Exam	Gen_ Exam	Average_ Exam
Microbiology	Pearson Correlation	1	.[a]	.069	.488**	.275	.387*	.398*	.455*
	Sig. (2-tailed)		.	.732	.010	.165	.046	.040	.017
	N	27	27	27	27	27	27	27	27
Chemical	Pearson Correlation	.[a]	.[a]	.[a]	.[a]	.[a]	.[a]	.[a]	.[a]
	Sig. (2-tailed)	.		.	.	.	.	.	.
	N	27	27	27	27	27	27	27	27
Haematolog	Pearson Correlation	.069	.[a]	1	.361	.295	-.048	.405*	.235
	Sig. (2-tailed)	.732	.		.064	.135	.811	.036	.237
	N	27	27	27	27	27	27	27	27
Micro_Exam	Pearson Correlation	.488**	.[a]	.361	1	.714**	.663**	.573**	.892**
	Sig. (2-tailed)	.010	.	.064		.000	.000	.002	.000
	N	27	27	27	27	27	27	27	27
Chem_Exam	Pearson Correlation	.275	.[a]	.295	.714**	1	.646**	.410*	.871**
	Sig. (2-tailed)	.165	.	.135	.000		.000	.034	.000
	N	27	27	27	27	27	27	27	27
Haem_Exam	Pearson Correlation	.387*	.[a]	-.048	.663**	.646**	1	.375	.869**
	Sig. (2-tailed)	.046	.	.811	.000	.000		.054	.000
	N	27	27	27	27	27	27	27	27
Gen_Exam	Pearson Correlation	.398*	.[a]	.405*	.573**	.410*	.375	1	.606**
	Sig. (2-tailed)	.040	.	.036	.002	.034	.054		.001
	N	27	27	27	27	27	27	27	27
Average_Ex	Pearson Correlation	.455*	.[a]	.235	.892**	.871**	.869**	.606**	1
	Sig. (2-tailed)	.017	.	.237	.000	.000	.000	.001	
	N	27	27	27	27	27	27	27	27

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

a. Cannot be computed because at least one of the variables is constant.

4.7 STATEMENT OF FINDINGS, INTERPRETATION AND DISCUSSION OF THE QUANTITATIVE SECONDARY DATA

The questionnaire was the secondary research tool that was used to collect data and was distributed to Laboratory Managers and training officers at nine Clinical Pathology laboratories that are HPCSA registered for training. The data collected from the responses was analysed with SPSS version 24.0. The results are presented as descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential techniques include the use of correlations and chi square test values; which are interpreted using the p-values.

4.7.1 The Sample

Questionnaires were despatched to nine laboratories and 10 questionnaires were returned at least one from each laboratory which gave a 100% response rate.

4.7.2 The Research Instrument

The secondary research instrument consisted of 62 items, with a level of measurement at a nominal level. The questionnaire was divided into 12 questions which measured various themes.

4.7.3 Reliability Statistics

The two most important aspects of precision are **reliability** and **validity**. Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.60 or higher is considered as “acceptable”. Table 25 reflects the Cronbach’s alpha score for all the items that constituted the questionnaire. Although the sample size was small, the respondents were a specialised grouping of individuals that should have shown a certain measure of consistency in their responses.

Table 25: Cronbach's alpha score for all the items that constituted the questionnaire.

Questions	Number of Items	Cronbach's Alpha
Six	6	0.731
Ten	16	0.532
Eleven	16	0.940
Overall	62	0.748

The reliability scores for most sections exceed the recommended Cronbach's alpha value of 0.600 for a newly developed construct. This indicates a degree of acceptable, consistent scoring for these sections of the research.

4.7.4 Section Analysis

The section that follows analyses the scoring patterns of the respondents per variable per section. The results are first presented using summarised percentages for the variables that constitute each section. Results are then further analysed according to the importance of the statements.

4.7.5 DETERMINATION OF COMPETENCY WITHIN A REGISTERED TRAINING LABORATORY

4.7.5.1 Technical competence laboratory policy

The question posed in the survey was, "does the laboratory have a policy that guides technical competency?" and 100% of the respondents indicated that these were in existence.

4.7.5.2 Responsibility for ensuring competency levels of staff are assessed

This section of the survey allowed for multiple responses and nearly all of the respondents (90%) identified the Laboratory Manager as having the mandate of ensuring that competency levels of staff are assessed while 50% identified the quality supervisor, 30% as other, 10% delegated department supervisors and 10% as qualified Medical Technologists and technicians as the responsible officers for ensuring competency levels of staff are assessed Figure 16.

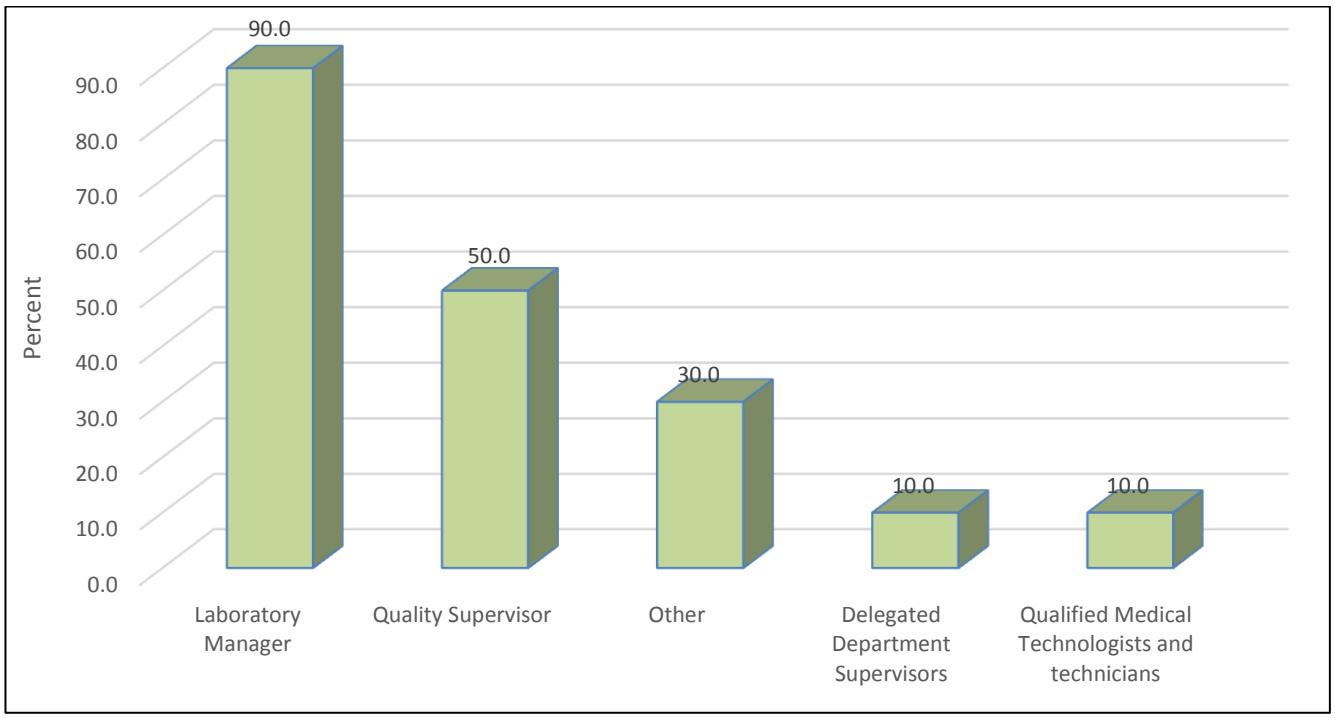


Figure 16: Responsible officer for ensuring competency levels of staff are assessed

4.7.5.3 Frequency of competency testing in the laboratory

All of the respondents, 100% selected that the frequency of competency testing in the laboratory was upon initial employment and once in two years thereafter.

4.7.5.4 Laboratory Accreditation

Respondents were requested to select the accreditation that the laboratory had and the options available was ISO15189, SLMTA, SLIPTA and if there was no response it was assumed that the laboratory was not accredited or working towards any accreditation. Figure 17 shows that five different respondents each had ISO 15189 or SLIPTA accreditation. One additional respondent had both (giving a total of 9). It must be noted that multiple responses were allowed on the survey questionnaire.

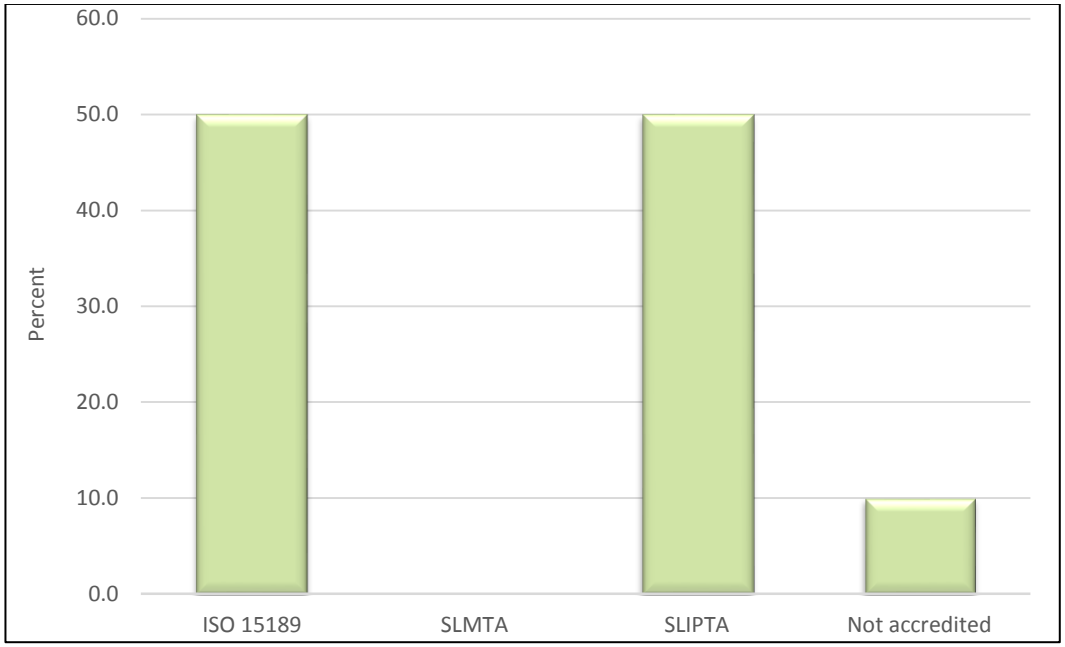


Figure 17: Laboratory accreditation

4.7.5.5 Laboratory personnel assessors of competency

The survey questioned, “who in your laboratory assesses competency?” and three options were given which included trainer, laboratory supervisor and Medical Technologists. Multiple responses were allowed as the Laboratory Manager who is generally the responsible officer for competency in the laboratory may delegate the assessment of competency to more than just a laboratory supervisor especially in laboratories with large staff complements. The results are tabulated in Table 26 according to the respondents. Three respondents selected all three categories of personnel as competency assessors while two respondents selected two categories of competency assessors and five respondents had just a single choice of category

of competency assessor. The frequency and percent of categories of laboratory personnel as assessors of competency is represented in Table 26:

Table 26: Frequency and percent of categories of laboratory personnel as assessors of competency

	Frequency	Percent
Trainer	**6**	**60.0**
Laboratory Supervisors	**6**	**60.0**
Medical Technologists	**6**	**60.0**

4.7.5.6 Methods of competency assessment used in the laboratory

This section of the survey requested that the respondents select the methods of competency that were used in their respective laboratories. Multiple responses were allowed amongst the six options (Figure 18). 100% of the respondents selected witnessing, direct observation of routine work processes and procedure including instrument maintenance. 90% responded that they use monitoring of quality control performance. 70% responded testing of unknown samples and another 70% of respondents use monitoring, recording and reporting of results. 50% of respondents use reviewing of worksheets or work records and 40% of respondents use assessment of problem solving skills.

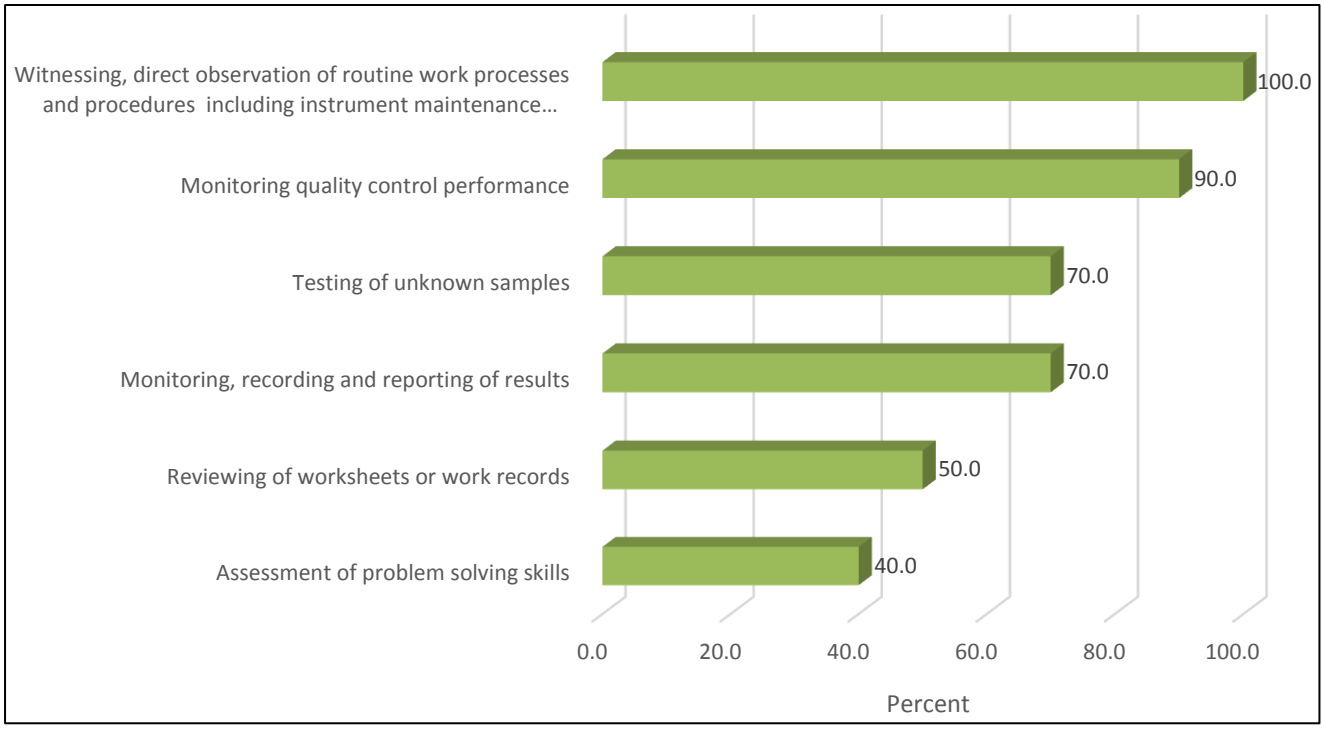


Figure 18: Methods of competency assessment used in the laboratory

4.7.5.7 Laboratory criteria to define successful completion of competency assessment

The survey posed the question "does the laboratory have clear criteria to define successful completion of competency assessment?" Nine of the ten (90%) respondents agreed that they had clear criteria to define competency assessment while one respondent indicated that defining criteria for competency assessments was still work in progress (Table 27).

Table 27: Frequency and percent of categories of laboratory personnel as assessors of competency

	Frequency	Percent
Yes	**9**	**90.0**
In progress	**1**	**10.0**
Total	**10**	**100.0**

4.7.5.8 Feedback given to staff members and remedial action handled in the laboratory

The survey questioned “how feedback was given to staff members and remedial action handled in the laboratory?” Multiple responses were allowed. A total of 12 responses were received. 100% of the respondents selected the option that documented corrective action which included re-training and re-assessment was used in their laboratories and 20% responded that verbal feedback is given following competency assessment (Table 28).

Table 28: Remedial action and feedback mechanisms following competency assessment

	Frequency	Percent
Verbal feedback	**2**	**20.0**
Documented during performance appraisal	**0**	**0.0**
Documented corrective action which includes re-training & re-assessment	**10**	**100.0**

4.7.5.9 Self-assessment on the quality of competency assessment in your laboratory

Respondents were also requested from the survey to perform a self-assessment on the quality of competency assessment in the laboratory and multiple responses were allowed. 40% responded that the competency assessment was moderately developed with room for improvement, 50% responded that the competency assessments were well developed and 30% responded that that it was extremely well developed (Figure 19).

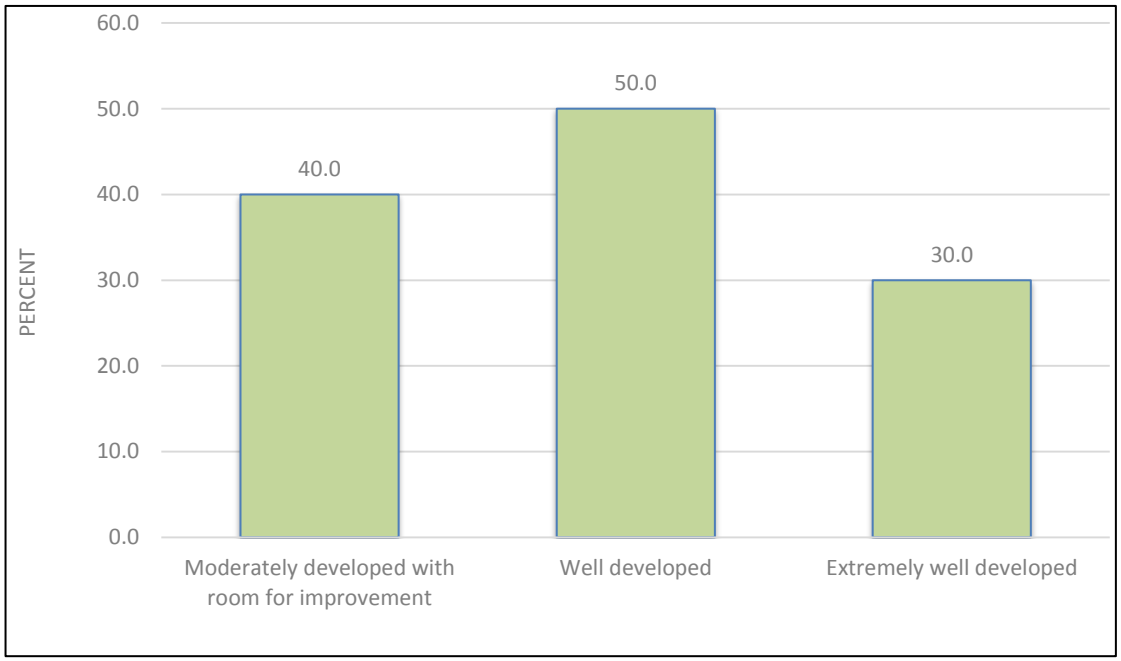


Figure 19: Self- assessment on quality of competency assessment in the laboratory

4.7.5.10 Competency assessment documents or forms

The survey requested the respondents to submit and attach competency assessment forms for fifteen Clinical Pathology laboratory tests or procedures (Figure 20), 50% of the respondents submitted competency assessment documents for ESR, coagulation and full blood counts, 40% submitted documents for CSF (MC & S) and Chemical Pathology analyser; 30% submitted documents for TB, sputum, blood cultures, stool, urine and pus swabs microscopy, culture and sensitivity competency documents; and 20% of the respondents submitted documents for blood gas analyser, preparation and examination of peripheral blood smears, identification of malaria parasites and reticulocyte counts. Only 10% submitted competency documents for RPR. It must be noted that some respondents only submitted one competency document whilst others submitted up to five competency documents.

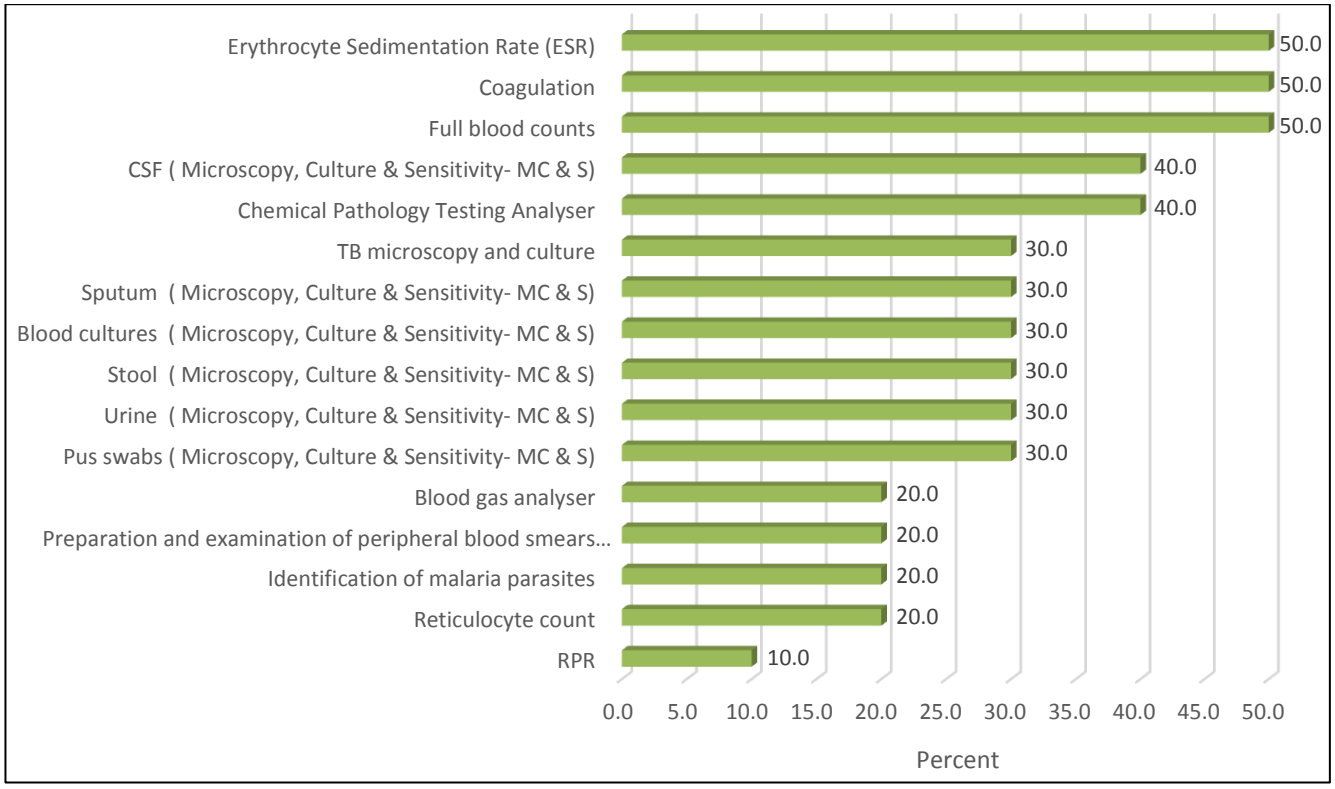


Figure 20: Competency assessment documents submitted per Clinical Pathology test or procedure in the laboratory

4.7.5.11 Permission to share competency forms

The survey also requested following the submission of the competency documents if permission be granted to share competency documents in order to benefit all training laboratories. 88,9 % of the respondents agreed that the competency documents be shared by all the training Laboratories while 11.1 % stated that they would not like to share their competency documents.

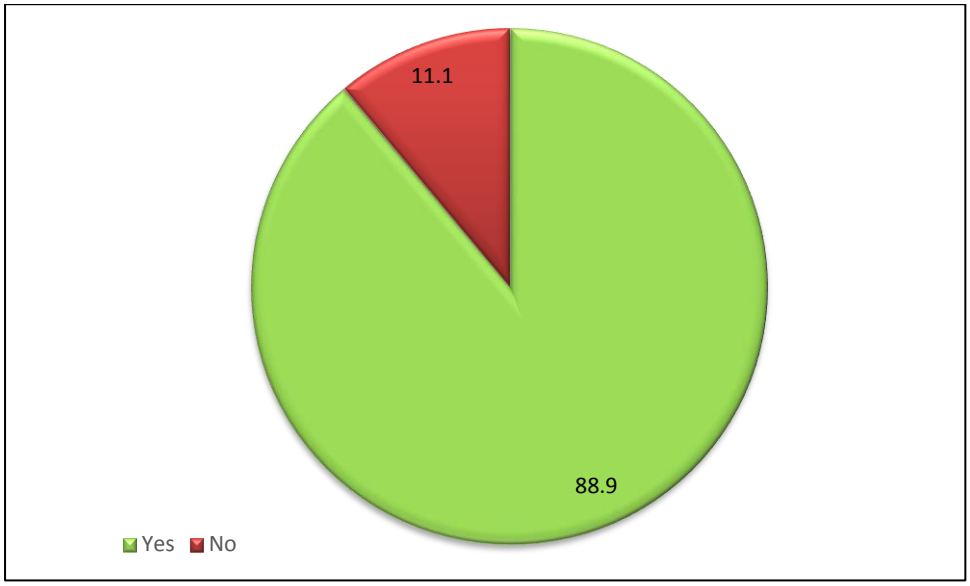


Figure 21: Respondents permission to share competency forms

CHAPTER FIVE: DISCUSSION AND CONCLUSION

5.1 INTRODUCTION

"Assessment drives learning and is the most appropriate engine on which to harness the curriculum," (Val Wass et al, 2001). There must be a synergy between the assessment programmes and the teaching and learning formats to achieve competence and this cannot be properly assessed in a single test format. (Val Wass et al, 2001). A distinction should be made between the use of formative versus summative assessments and it is vital when selecting a method for evaluating competence of high stake assessments such as licensing and certification exams (Epstein, 2007).

In the previous chapter, the research results were presented and this chapter focuses on the discussion of the results. The discussion of the results is guided by the study objectives, findings from the direct observation of the candidates on the technical competence of ten Clinical Pathology procedures and Laboratory Managers and trainers questionnaires as well as by the themes that emerged from the analysis of direct observation checklists and Laboratory Managers and trainers questionnaires. Recommendations are suggested based on the results of the research investigation.

5.2 OVERVIEW OF RESEARCH DISCUSSION

This study aimed at assessing technical competence of candidates with the goal of augmenting the single written Board Examination into an integrated assessment system for conferment of professional designation. A quantitative direct observation instrument was used with candidates to assess technical competence and determine how competence was assessed in laboratories. Some findings from the quantitative survey included direct observation of technical competence compared to that of the National Board Examination results and also the findings received from the Laboratory Managers and trainers' survey used.

5.3 DISCUSSION

5.3.1 Non-compliance and non-adherence to Standard Operating Procedure

A common element observed for the three test procedures that the candidates were not yet competent in all three were manual test procedures. A manager or trainer should ask the following questions before using the retraining route for an employee:

- Have all work processes been clearly documented?
- Are there documented procedures for all activities in the work process?
- Are the documented procedures clear and easy to understand?
- Does the service have a documented training program for all work processes and procedures?
- Has the employee been trained in the process or procedure in question and was the training documented?
- How was the effectiveness of the employees training determined?
- Is the employee the only person with this performance problem?
  (CLSI, 2009)

When there is non-compliance with the SOP it must be established whether the SOP is clear, or is there a lack of understanding or an oversight from the candidate in some steps, or were they trained by more experienced staff incorrectly. Missing steps on the SOP could also have a negative impact on the patient's result. The main source of laboratory errors prior to automation was performance of methods, methods and reagents (Howanitz, Valenstein and Jones 2000).

Notably every laboratory has a different SOP and this could be possibly due to different instruments or methods used in that laboratory.

In a study performed by Woods et al (2000), he stated that if a standard operating procedure is altered then appropriate training must be documented to ensure that all members of staff are kept up to date in that procedure. The reason for this is that if there are any amendments to the SOP then appropriate training must follow and be documented to ensure that all staff members are keeping up to date in that procedure (Woods et al.,2000).

The process of the direct observation of employee aids in identifying any deviation from the SOP. Employees discover shortcuts and workarounds that drift away from procedure specifics and may result in comprising patient safety (CLSI, 2009).

5.3.2 Non-acceptability of patients results, as witnessed

When SOP's are not been adhered to, the results will not be accurate, acceptable or correct. Also procedure for results reporting will not be able to be followed. Candidates were unable to demonstrate knowledge of interpreting results and understanding of the clinical significance of abnormal results.

5.3.3 Internal Quality Control procedures witnessed and acceptability of the outcome

Differential count was the only test procedure that the candidates could not demonstrate internal quality control procedures in. This could be as a result of no training in that test procedure or that the students did not grasp the training provided.

5.3.4 Proficiency testing (PT)/ External Quality Assurance (EQA) programme for this method/test and acceptability of performance

All laboratories are expected as part of the accreditation requirements to participate in PT programs for all tests performed (ISO, 2012). The laboratory proficiency testing or external quality control (EQC) is performed by qualified staff registered with the HPCSA independent practice and the records are filed within the laboratory. The candidates were able to provide these proficiency testing records for the relevant tests and explain the corrective action processes that would be followed in the event of a failed EQC.

5.3.5 Reference standards, reference materials and/or controls used

As part of the accreditation requirements, all laboratories have checklists and mechanisms to ensure that the lot numbers of reagents and quality control measures are checked and that stability is maintained correctly (ISO, 2012). Candidates were

able to produce these checklists with the relevant lot numbers and the reagents were appropriately stored at the correct temperatures. Some candidates produced checklists with their signatures on them as they performed certain checks.

5.3.6 Equipment used (where applicable) - Calibrations, Maintenance

Candidates were competent in start-up procedures of equipment and provided signed checklists as evidence that they performed all relevant checks, maintenance and calibrations, where applicable.

5.3.7 Training and competency records of the staff member witnessed

In professional training the student is allowed to develop and practice skills in a setting similar to the work environment, and this must be documented.

The candidates were unable to provide training and competency documents, except for 8 candidates who were able to provide training and competency records for three test procedures. This is very concerning as it is considered that if an action is not documented then it is not performed. Furthermore, there was no documented record of the objectives and activities that the training was conducted against, which leaves room for much debate on whether the candidate was trained or not. Formalised training coupled with competency assessment with documented records is an accreditation requirement which all laboratories must comply with.

In a study done by Woods et al (2000), the suggestion was that each of the competency form should form part of the training portfolio for that member of staff. Schiffigens and Bush's (2001) view is that retention of competency records should be based on regulatory, accrediting agency and organisational requirements. Achieving and maintaining staff competence require constant care and this requires both time and money (Stajdohar-Paden, 2008). Despite the utilisation of both financial and human resources when used optimally, it should not be regarded as an expense but an investment (Stajdohar-Paden, 2008).The rationale is that if a laboratory invests time and money in training of staff, it is critical that it has systems in place to check whether the training was effective (Stajodhar-Paden, 2008).

Records of competence must reflect the date on which competence was confirmed to ensure traceability in the event of an investigation regarding nonconformity (Stajodhar-Paden, 2008). Assessors when reviewing compliance of competence in a laboratory against the relevant accreditation standard, look for evidence of competence defined in writing (Stajodhar-Paden, 2008). Schiffgens and Bush (2001) also concurs that retention of competency records should be based on regulatory, accrediting agency and organizational requirements.

Some medical errors can be due to either training not being provided or provided training not being effective and when documents are not available the problem enlarges as training that is not documented is considered as not done. Planned and organized training and competence assessment processes are vital to verify and document that employees have and can demonstrate the requisite knowledge, skills and attitudes to perform their duties (CLSI, 2009).

5.3.8 Accommodation and environmental conditions

There was no statistically significant association in accommodation and environmental conditions when assessing technical competence of candidates as the laboratory temperatures and environment was acceptable.

5.4 IDENTIFICATION OF POSSIBLE FACTORS THAT MAY LEAD TO CANDIDATES NOT ACHIEVING TECHNICAL COMPETENCE LEVELS

According to the study by Desjardin and Fleming (2014) in Medical Microbiology laboratories in Ontario, Canada, the most common competency issue requiring remediation was associated with Gram staining and interpretation. Additional common areas of concern included failure to understand or lack of familiarity with laboratory protocols, difficulties in performing antimicrobial susceptibility testing, including technical issues, lack of familiarity with appropriate methods, inconsistent interpretations of antibiograms, failure to recognize unusual phenotypes and reporting inconsistencies. Other areas which often required remedial action included laboratory information systems data entry and biosafety. These common competency issues are mostly associated with manual testing procedures.

Differential counts of peripheral blood smears are also another test procedure that requires remediation. The possible factors that lead to this are that students are learning this theoretically and not trained in practice on how to perform this testing. Performing this test with competence requires a high level of skill in identifying cells correctly and may be very time consuming on both the learner and trainer during the training process.

The results from the survey completed by Laboratory Managers and Trainers regarding the examples of the most common issues requiring remediation in a Clinical Pathology Laboratory were based on qualified Medical Technologists and medical technicians in the laboratory. It must be noted that the results of the Intern Medical Technologists assessed for technical competency against the ten test procedures showed a different pattern for the test procedures. The manual test methods proved to be most challenging and those test procedures required remediation for intern technologists.

5.5 COMPARISON OF THE TECHNICAL COMPETENCE ASSESSMENT RESULTS FROM THE DIRECT OBSERVATION WITH THE NATIONAL BOARD EXAMINATION RESULTS

There was no correlation between the Haematology and Chemical Pathology sections of the National Board Examination and the assessment of technical competence using direct observation. This may be due to the high level of automation for Chemical Pathology and most of the test procedures in Haematology being automated as well.

This finding supports the Laboratory Manager's view that a candidate can fail the written National Board Examination and be technically competent in the laboratory. The opposite is also true, i.e., a candidate can pass the National Board Examination but not be technically competent in all the test procedures.

Epstein (2007), confirms that, "assessment drives learning and may have both intended and unintended consequences. Students study more thoughtfully when they anticipate certain examination formats, and changes in the format can shift their focus to clinical rather than theoretical issues. The unintended effects of assessment

include the tendency for students to cram for examinations and to substitute superficial knowledge for reflective learning."

Schiffgens and Bush (2001), states that competency programs must address all core competencies and address employee preparation, i.e., training, theoretical testing, practical examination and post evaluation follow-up. A disadvantage of the National Board Examination is that it does not provide sufficient feedback to drive learning (Epstein, 2007). An integrated assessment or multiple assessment methods over time can partially compensate for the flaws in any single method (Epstein, 2007).

Epstein (2007), acknowledges that the content, format and frequency of assessment as well as the timing and format of feedback should follow from the goals of the medical education program. Educators should be mindful of the impact of assessment on learning, the potential unintended effects of assessment, the limitations of each method (including cost), and the prevailing culture of the program or institution in which assessment is occurring.

Carr (2004), believes that it is important to directly observe trainees to ensure effective assessment of clinical or technical skills. This type of assessment can be costly and time consuming.

5.6. DETERMINATION OF COMPETENCY WITHIN A REGISTERED TRAINING LABORATORY

5.6.1 Technical competence laboratory policy

One hundred per cent of respondents in this study indicated that the laboratories do have a policy that guides technical competency and a similar high percentage of 89, 2% of 522 institutions had a written competency plan in a study by Sharp and Elder, (2004).

5.6.2 Responsibility for ensuring competency levels of staff are assessed

In the present study, the majority of the participants, (i.e.,90%) stated that Laboratory Managers are responsible for ensuring that competency levels of staff are assessed while other responses were 50% identified the quality supervisor, 30% as other, 10% delegated department supervisors and 10% as qualified Medical Technologists and

technicians as the responsible officers for ensuring competency levels of staff are assessed. It is the Laboratory director's responsibility to assure that all staff are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently whenever necessary (Sharp and Elder, 2004).

5.6.3 Frequency of competency testing in the laboratory

All of the respondents 100%, selected the option that the frequency of competency testing in the laboratory was upon initial employment and once in two years thereafter. In studies by Sharp and Eder (2004) as well as Desjardins and Fleming (2014), the frequency of competency testing was reported as initially within six months and annually thereafter for laboratories in the United States which are guided by different accreditation systems to our South African laboratories.

5.6.4 Laboratory Accreditation

The findings in this study show that most laboratories had ISO 15189 accreditation or were on the SLIPTA program whereas one laboratory was not on any formal programme to attain laboratory accreditation at the time of the survey. It is to be expected that some laboratories responded with both SLIPTA and IS0 15189, as Yao (2014) agrees that SLIPTA is that pathway to achieving ISO 15189 accreditation. ISO 15189 standard requires that the laboratory shall assess the competence of each person to perform technical tasks according to established criteria (ISO, 2012). Sharp and Elder (2004) has indicated that " care must be taken to assure staff that the purpose of these programs although a accreditation requirement, is to identify areas where improvements can be made to ensure quality patient care." None of the Laboratory Managers attended the SLMTA programme and are using this system in the laboratories.

5.6.5 Laboratory personnel assessors of competency

Laboratory supervisors, trainers and Medical Technologists were the personnel identified to assess or evaluate competency in the present study. It must be noted that some laboratories gave multiple responses. In the study by Sharp and Elder (2004) it is stated that, “the technical supervisor is responsible for evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report results promptly, accurately and proficiently and supervisor’s may designate certain employees to assist with assessments.”

5.6.6. Methods of competency assessment used in the laboratory

The findings in the present study are similar to the study by Sharp and Elder, (2004) where a survey was conducted across 522 institutions that participated in the CAP 1996 Q-probes program. The results of the methods of competency were 87.5% of laboratories surveyed used direct observation, 77.4% used review of test or QC results, 60% review of instrument preventative maintenance, written testing in 52.2% and other methods of assessment in 20.8% (Sharp and Elder, 2004). It must be noted that some laboratories in the present study indicated that they use multiple methods for competency assessment. Desjardins and Fleming (2014), maintains that “although most accredited laboratories have a program to assess on-going competency of their staff, the methods used are not standardised or consistently applied, indicating there is room for improvement.”

5.6.7 Laboratory criteria to define successful completion of competency assessment

In the present study 90% respondents agreed and selected that they had clear criteria to define competency assessment while one respondent indicated that defining criteria for competency assessments was still work in progress. The study conducted by Desjardins and Fleming in 2014 revealed that 75% of the laboratories evaluated also have established criteria for passing or failing an assessment.

5.6.8 Feedback given to staff members and remedial action handled in the laboratory

100% of the respondents in the present study selected the option that documented corrective action which included corrective action was used in their laboratories and 20% responded that verbal feedback is given following competency assessment. In a similar study by Desjardins and Fleming (2014), 93% of the respondents indicated that remedial action was taken if the individual failed the evaluation and used retraining, reviews, programs for continuing education for staff members that did not perform well on the competency assessments as part of the remediation. Sharp and Elder (2004) states that, “regardless of the method selected for remediation, it is necessary to repeat the competency assessment once remediation has been completed in order to document successful attainment of competency.” In the case of the corrective action not being successful, the individual cannot perform testing in that area until deemed competent (Sharp and Elder, 2004). Communication and feedback to individuals which can be considered non punitive remediation are very important as it results in quality improvement (Desjardins and Fleming, 2014).

5.6.9 Self-assessment on the quality of competency assessment in your laboratory

In this study, 40% responded that the competency assessment was moderately developed with room for improvement, 50% responded that the competency assessments were well developed and 30% responded that that it was extremely well developed in this study. A similar pattern was observed by Desjardins and Flemings (2014) study, where 47% of respondents indicated that they would rate their laboratory’s competency assessment program as moderately well developed and 30% as less than moderately well developed and 23 % as better than moderately well developed.

5.6.10 Competency assessment documents or forms

It was noted from the competency documents and forms submitted from laboratories that each one was different. There was a lack of standardisation and inconsistent application and the need for improvement was also acknowledged by Desjardins and Flemings (2014).

5.6.11 Permission to share competency forms

88,9 % of the respondents agreed to share competency forms. The rationale for this was to benchmark and compare best practice with a view to standardise competency forms.

5.7 CONCLUSION

A formal defined competency program provides the laboratory with a valuable tool for identifying and correcting issues of employee competency (Sharp and Elder, 2004). Schiffgens and Bush (2001), concurs that written testing and direct observations can be combined for a comprehensive evaluation. Assessment programmes must also match the competencies being learnt and the teaching formats used and these cannot properly be assessed by a single test format (Val Wass et al, 2001). Epstein and Hunder (2002) agree that, medical educators, professional societies and licensing boards should view professional competence more comprehensively to improve the process of assessment.

From this study it can be concluded that assessment of technical competency for Intern Medical Technologists in the Clinical Pathology discipline does add value as it provides a mechanism for feedback and remediation for those not yet competent as well as provides a system to monitor compliance of training and competency records. This could augment current assessment systems of Intern Medical Technologists for conferment of professional designation and a policy review is recommended.

5.8 LIMITATIONS

Limitations in this study are that was very time consuming for the researcher to perform technical competence assessments.

5.9 RECOMMENDATIONS

Based on the findings of the study, the following recommendations are made with special reference to assessment of technical competence and licensure exams for professional designation as well as determination of competence in laboratories:

- Regulation of training and competency records for Intern Medical Technologists combined with the National Board Examination as an integrated assessment for the conferment of professional designation for independent practice by the HPCSA.
- HPCSA registered training laboratories should include the adherence of signed training and competency records of all interns as part of their training policies and have stricter monitoring and evaluation of the implementation of this.
- There needs to be more focus and commitment in the training and competency assessment of Intern Medical Technologists in the manual test procedures especially for differential counts of peripheral blood smears.

5.10 FURTHER RESEARCH

IA similar study such as this should be conducted in other Medical Technology disciplines, e.g.Virology. Further research on standardised development and implementation of Portfolio of Evidence (PoE) for workplace based learning in Biomedical Science that includes all training and competency records is warranted and the implementation thereof. Further research will be required to create a model of integrated assessment for evaluating competence of practitioners who require professional designation in Medical Technology. Competency based education has a

learner centred approach and research into learner preferences of assessment methods for conferment of professional designation is required.

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Direct Observation Checklist

Discipline:

Date

Brief Description of method/operation evaluated:

		1. Lacks experience - little or no competency	2. Some experience requires further practice and/or assistance	3. Competent to perform independently	4.Competent to perform independently and train junior staff/students	5. Competent to perform independently and able to assess competency of other medical technologists
Section A: Comply and adhere to Standard Operating Procedure						
1	Carefully read the information provided on the request form and verify sample numbers vs request forms					
2	Demonstrate knowledge of the criteria for rejecting samples					
3	Handle samples correctly					
4	Perform the test and follow procedure correctly according to the SOP					
5	Demonstrate knowledge of basic principle					
6	Verbally demonstrate knowledge of the criteria for rejection of unsuitable samples					
7	Demonstrate knowledge of troubleshooting procedures					
8	Complete all the required documentation if applicable					
9	Perform correct housekeeping and dispose of materials correctly and follow all other safety procedures					
10	Limitations of test procedure understood					
Additional Comments						
Section B: Acceptability of results, as witnessed(where applicable)						
11	Correctly and accurately record all findings					
12	Follow established procedure for results reporting and enter correctly on LIS					
13	Demonstrate knowledge of interpreting results adn understanding of the clinical significance abnormal results					
14	Follow the laboratory procedure for critical findings					
15	Follow the correct procedure when providing telephonic results					
16	Demonstrate knowledge of interpreting results					
Section C: Internal Quality Control procedures witnessed and acceptability of the outcome						
17	Handle controls correctly					
18	Use appropriate quality control procedure					
19	Demonstrate knowledge of frequency of running controls during a 24 hour period or per batch					
20	Interpret QC results correctly,verify and sign off QC results					

		1. Lacks experience - little or no competency	2. Some experience requires further practice and/or assistance	3. Competent to perform independently	4.Competent to perform independently and train junior staff/students	5. Competent to perform independently and able to assess competency of other medical technologists
21	Take corrective action if required or describe corrective action for out of range control results					
22	Take or verbally describe the appropriate corrective action in the event of failed control values					
23	Take corrective action or describe corrective action for inaccurate control results and how to troubleshoot					
24	Interpret L.J. charts correctly					
Section D: Proficiency testing (PT)/ EQA programme fot this method/test and acceptability of performance(where applicable)						
25	Show EQA results for method/test					
26	Verbally demonstrate an understanding in corrective action processes in the event of failed EQC					
Section E: Reference standards, reference materials and/or controls used (where applicable)						
27	Check lot numbers of controls and calibrators					
28	Give correct details regarding control stability					
29	Make up and label reagents and controls correctly					
Section F: Equipment used (where applicable) - Calibrations, Maintenance up to date etc.						
30	Able to demonstrate or describe start up procedures correctly					
31	Perform all checks as instructed					
32	Demonstrate knowledge of other required maintenance and service requirements					
33	Take corrective action or verbally describe corrective action procedures in the event of instrument malfunction					
34	Give the correct details with regard to frequency of calibration (if applicable)					
35	Perform scheduled maintenance correctly					
Section G: Training and competency records of the staff member witnessed for this method						
36	Provide training records for this test /method					
37	Provide competency records for this test / method					
Section H: Accomodation and enviromental conditions (where applicable)						
38	Verbally demonstrate knowledge of laboratory factors affecting the test					

Appendix 2: LABORATORY MANAGER & TRAINING OFFICERS SURVEY COMPETENCY IN NHLS TRAINING LABORATORIES

1. Does the laboratory have a policy that guides technical competency?

Yes ❑

No ❑

In progress ❑

2. Who is responsible for ensuring competency levels of staff are assessed?

Laboratory Manager ❑

Quality Supervisor ❑

Other ❑

3. What is the frequency of competency testing in your laboratory?

Upon initial employment ❑

Annually ❑

Upon initial employment and once in two years thereafter ❑

4. Select the accreditation the laboratory has?

ISO 15189 ❑

SLMTA ❑

SLIPTA ❑

5. **Who in your laboratory assesses competency?**

Trainer ❑

Laboratory Supervisors ❑

Medical Technologists ❑

6. **Select the methods of competency assessment that are used in your laboratory?**

Witnessing, direct observation of routine work processes and procedures

including instrument maintenance and functional checks ❑

Monitoring quality control performance ❑

Reviewing of worksheets or work records ❑

Monitoring, recording and reporting of results ❑

Assessment of problem solving skills ❑

Testing of unknown samples ❑

7. **Does the laboratory have clear criteria to define successful completion of competency assessment?**

Yes ❑

No ❑

In progress ❑

8. **How is feedback given to staff members and remedial action handled in the laboratory?**

Verbal feedback ❑

Documented during performance appraisal ❑

Documented corrective action which includes re-training & re-assessment ❑

9. **Perform a self - assessment on the quality of competency assessment in your laboratory?**

Moderately developed with room for improvement ❑

Well developed ❑

Extremely well developed ❑

10. **Select two examples of the most common issues requiring remediation in the Clinical Pathology laboratory?**

Full blood counts ❑

Coagulation ❑

Erythrocyte Sedimentation Rate (ESR) ❑

Reticulocyte count ❑

Identification of malaria parasites ❑

Preparation and examination of peripheral blood smears (Differential count) ❑

Chemical Pathology Testing Analyser ❑

Blood gas analyser ❑

CSF (Microscopy, Culture & Sensitivity- MC & S) ❑

Pus swabs (Microscopy, Culture & Sensitivity- MC & S) ❑

Urine (Microscopy, Culture & Sensitivity- MC & S) ❑

Stool (Microscopy, Culture & Sensitivity- MC & S) ❑

Blood cultures (Microscopy, Culture & Sensitivity- MC & S) ❑

Sputum (Microscopy, Culture & Sensitivity- MC & S) ❑

TB microscopy and culture ❑

RPR ❑

11. **Select the sections of Clinical Pathology that you have submitted and attached blank forms of competency assessment?**

Full blood counts ❑

Coagulation ❑

Erythrocyte Sedimentation Rate (ESR) ❑

Reticulocyte count ❑

Identification of malaria parasites ❑

Preparation and examination of peripheral blood smears (Differential count) ❑

Chemical Pathology Testing Analyser ❑

Blood gas analyser ❑

CSF (Microscopy, Culture & Sensitivity- MC & S) ❑

Pus swabs (Microscopy, Culture & Sensitivity- MC & S) ❑

Urine (Microscopy, Culture & Sensitivity- MC & S) ❑

Stool (Microscopy, Culture & Sensitivity- MC & S) ❑

Blood cultures (Microscopy, Culture & Sensitivity- MC & S) ❑

Sputum (Microscopy, Culture & Sensitivity- MC & S) ❑

TB microscopy and culture ❑

RPR ❑

12. **Do you grant permission to share competency forms for comment to benefit all training laboratories?**

Yes ❑

No

Appendix 3:

LETTER OF INFORMATION

Title of the Research Study: Assessment of technical competence of candidates within a Clinical Pathology discipline.

Principal Investigator/s/researcher: Melini Baruth

Co-Investigator/s/supervisor/s: Supervisor: Prof J.K Adam(D. Tech)

Co-Supervisor: Mr R Phili (M.A) & Mr Mohapi (M.Ed)

Brief Introduction and Purpose of the Study: Hi my name is Melini Baruth and I am studying for a Masters degree at the Durban University of Technology. I would greatly appreciate it if you could take part in my research. I will be directly observing technical competence of candidates in the Clinical Pathology discipline and recording the results. I am assessing technical competence to provide recommendations which may potentially result in changes to the current practice of writing a board exam as the only assessment in order to practice as a Medical Technologist.

Outline of the Procedures: The study approach will be to determine the technical competence of a total of 25 participants who are eligible to write the next National Board Examination in Clinical Pathology will be recruited for the study. A direct observation tool will be used to assess technical competence of the candidates in the Clinical Pathology discipline. Data analysis will be performed on the information collected.

Risks or Discomforts to the Participant: There will be no risks or discomfort to you.

Benefits: The results of this study are expected to benefit the interns indirectly, as it may result in changes to the current practice of summative assessments.

Reason/s why the Participant May Be Withdrawn from the Study: Your participation in this research is completely voluntary. You may withdraw at any time and this will not affect your current duties and/or learning.

Remuneration: There will be no form of remuneration. Participation is voluntary.

Costs of the Study: You will not be asked to cover any cost relating to the study.

Confidentiality: All the information collected will be kept confidential. You will be allocated a number and all your details will be recorded under that number. This means that anyone who looks at my records will not be able to trace it to you. This is done to protect your privacy. In addition, a statement of confidentiality will be signed by both my supervisors and me.

Research-related Injury: There will be no research-related injury.

Persons to Contact in the Event of Any Problems or Queries:
Please contact the researcher (031 327 6705), my supervisor (031 373 5291) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,

- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.

- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.

- I may, at any stage, without prejudice, withdraw my consent and participation in the study.

- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

_____ _____ _____ _____

Full Name of Participant **Date** **Time** **Signature / Right Thumbprint**

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher	**Date**	**Signature**
Full Name of Witness (If applicable)	**Date**	**Signature**
Full Name of Legal Guardian (If applicable)	**Date**	**Signature**

Appendix 4

LETTER OF INFORMATION

Title of the Research Study: Assessment of technical competence of candidates within a Clinical Pathology discipline

Principal Investigator/s/researcher: Melini Baruth

Co-Investigator/s/supervisor/s: Supervisor: Prof J.K Adam(D. Tech)

Co-Supervisor: Mr R Phili (M.A) & Mr Mohapi (M.Ed)

Brief Introduction and Purpose of the Study: Hi my name is Melini Baruth and I am studying for a Masters degree at the Durban University of Technology. I would greatly appreciate it if you to take part in my research by completing a questionnaire for my study for Laboratory Managers and training officers. I am keen to determine how technical competence is assessed in your laboratory and to provide recommendations which may potentially result in changes to the current practice of writing a board exam as the only assessment in order to practice as a Medical Technologist.

Outline of the Procedures: A survey will also be compiled and sent to all Laboratory Managers and training officers of HPCSA accredited laboratories regarding technical competency assessment. Data analysis will be performed on the information collected.

Risks or Discomforts to the Participant: There will be no risks or discomfort to you.

Benefits: The results of this study are expected to benefit the interns directly, as it may result in changes to the current practice of summative assessments.

Reason/s why the Participant May Be Withdrawn from the Study: Your participation in this research is completely voluntary. You may withdraw at any time and this will not affect your current duties and/or learning.

Remuneration: There will be no form of remuneration. Participation is voluntary.

Costs of the Study: You will not be asked to cover any cost relating to the study.

Confidentiality: All the information collected will be kept confidential. You will be allocated a number and all your details will be recorded under that number. This means that anyone who looks at my records will not be able to trace it to you. This is done to protect your privacy. In addition, a statement of confidentiality will be signed by both my supervisors and me.

Research-related Injury: There will be no research-related injury.

Persons to Contact in the Event of Any Problems or Queries:
Please contact the researcher (031 327 6705), my supervisor (031 373 5291) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, Melini Baruth about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,

- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.

- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.

- I may, at any stage, without prejudice, withdraw my consent and participation in the study.

- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

_____ _____ _____ _____

Full Name of Participant **Date** **Time** **Signature / Right Thumbprint**

I, Melini Baruth herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher	**Date**	**Signature**
Full Name of Witness (If applicable)	**Date**	**Signature**
Full Name of Legal Guardian (If applicable)	**Date**	**Signature**

Appendix 5:

To: Mr Thinyane Mollele

Head of Learning Academy

National Health Laboratory Services

I, Melini Baruth, would like to do my Masters in Biomedical Technology at the Durban University of Technology and would like permission to conduct my research study at your National Health Laboratory Services, Kwa Zulu Natal Region where I am currently permanently employed.

The research study I would like to pursue focuses on the assessment of technical competence of candidates within a Clinical Pathology discipline who attempted the National Board Examination in March 2015. The data I would like to obtain are the elements of technical competence according to modified SANAS F15 witnessing tool by directly observing participants. I will also need information regarding the accredited training laboratories approach to competency.

By granting me permission to conduct this research study I will be able to provide more information to the NHLS and hopefully the information will result in changes in the current practice of writing Board Examinations only which may be able to benefit the participants in the future.

I have attached my research proposal for you to go through.

I will be awaiting your response.

Thanking you

Kind Regards

Melini Baruth

Contact No's: Work- 0313276705

Cell- 0834680556

Supervisor for research study: Prof J K Adam

Contact No’s: Work- 0313735291

Appendix 6:

STATISTICIAN DECLARATION FOR CONSULTATION:

I, Deepak Singh have read Melini Baruth's M.Tech proposal (student no: **19150936**) and given her appropriate recommendations.

Signed.....  ..... **Date** **24 August 2015**

Appendix 7:

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

14 January 2016

IREC Reference Number: **REC 138/15**

Ms M Baruth
Cluster Box 24551
Westmount Drive
Broadlands
4068

Dear Ms Baruth

Assessment of technical competence of candidates within a Clinical pathology discipline

The Institutional Research Ethics Committee acknowledges receipt of your notification regarding the piloting of your data collection tool.

Kindly ensure that participants used for the pilot study are not part of the main study.

In addition, the IREC acknowledges receipt of your gatekeeper permission letter.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Yours Sincerely,

[redacted]

Professor M N Sibiya
Deputy Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2016 -01- 14
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

Appendix 8

Academic Affairs and Research
Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 386 6142
Fax: +27 (0)11 386 6296
Email: babatyi.kgokong@nhls.ac.za
Web: www.nhls.ac.za

11 December 2015

Applicant: Melini Baruth
Institution: National Health Laboratory Service
Department: Regional Training Department
Email Address: Melini.baruth@nhls.ac.za
Contact Number: 031 327 6705 / 083 468 0556

Re: Approval to conduct a study at the National Health Laboratory Service (NHLS) – KZN Region

Your application to undertake a research project titled "**Assessment of Technical Competence of Intern Medical Technologists in Haematology within a Clinical Pathology Laboratory**" has been reviewed. This letter serves to advise that the application has been approved.

Please note that the approval is granted on your compliance with the NHLS conditions of service and that the study can only be undertaken provided that the following conditions have been met.

- Full Ethics clearance have been obtained from an approved local Ethics Committee
- Processes are discussed with the laboratory manager and/or the pathologist and are agreed upon
- Confidentiality is maintained at participant and institutional level and there is no disclosure of personal information or confidential information as described by the NHLS policy.
- A final report of the research study and any published paper resulting from this study are submitted and addresses to the NHLS Academic Affairs and Research office and the NHLS has been acknowledged appropriately.

Please note that this letter constitutes approval by the NHLS Academic Affairs and Research. Once all requirements have been met, please contact the Business Manager Frank Phiri on 013 781 0632 and Laboratory Manager Isaac Mofokeng on 013 741 1014 who will provide approval and communicate with the relevant people. For Data requests, please complete and sign the attached data request form. This should be submitted to Helpdesk4@nhls.ac.za for processing by the Corporate Data Warehouse. Any data related queries may be directed to Sue Candy, Manager NHLS Corporate Data Warehouse, Tel: (011) 386 6036 Email: sue.candy@nhls.ac.za

Yours sincerely,

[redacted]

Dr Babatyi Malope-Kgokong
National Manager: Academic Affairs and Research