

**ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF ALLIED HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCES**



Competency Assessment on Gram Stain Examination and Interpretation among Medical Laboratory Professionals working in selected Hospitals of Addis Ababa, Ethiopia

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Abstract

Background: Laboratory test results are the cornerstone for patient diagnosis and treatment. Gram staining is one of the classic laboratory test method actively used to differentiate bacteria. However, gram stain examination and interpretation is difficult for medical laboratory professionals as it requires multiple observations and years of experience. In Ethiopia, no published evidence about competency assessment of medical laboratory professionals' gram staining technique was available. Such kind of information could help to identify gaps and make suggestions to academicians, researchers and policy makers to address competency gaps.

Objective: To assess the competency of medical laboratory professionals on gram stain examination and interpretation in selected hospitals of Addis Ababa, Ethiopia

Methods: A cross-sectional study was conducted to assess competency of medical laboratory professionals on gram stain examination and interpretation from September 2015 to December 2017. Purposive sampling method was used and panel slides were prepared from Known bacterial strains in American Type Culture Collection (ATCC). Data were collected from 190 participants based on examination and interpretation of six gram stained panel slides and response for 15 multiple questions. When then entered data into a *REDCap software* and analysis was performed by *R software*. The study used Bloom's cut off point to describe knowledge and skill of the respondents.

Results: From 190 participants, 55(28.9%) participants scored low knowledge, 131(68.9%) scored medium knowledge and only 4(2.1%) respondents scored high knowledge. Forty eight (25.3%), 78(41%) and 64(33.7%) participants scored low, medium and high skill level from a total of 190 participants, respectively.

Conclusion: Most Medical laboratory professionals are working without supervision and refresher training on gram stain examination and interpretation. Hence, the knowledge level and skill level of medical laboratory professionals are not satisfactory. Regular competence assessment, training and follow up are necessary to improve Medical Laboratory Professional competence.

Keywords: Knowledge and skill, Competence, Gram stain, Medical laboratory professionals, Addis Ababa, Ethiopia

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Abbreviations

AAU: Addis Ababa University

AHRI: Armauer Hansen Research Institute

ALERT: All African Leprosy Rehabilitation and Training Center

ASCP: American Society of Clinical Pathology

CFR: Code of Federal Regulations (U.S.)

CLIA: Clinical Laboratory Improvement Amendments

CM: Cytoplasmic Membrane

LPS: Lipopolysaccharide

MTB: Mycobacterium Tuberculosis

CPD: Continuing Professional Development

DRERC: Departmental Research and Ethics Review Committee

OM: Outer Membrane

PaL: Peptidoglycan-associated Lipoproteins

PI: Principal Investigator

PM: Peptidoglycan Mesh

QC: Quality Control

SLMTA: Strengthening Laboratory Management Towards Accreditation

U.S.: United States

UTI: Urinary Tract Infection

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1. Introduction

1.1. Background

Laboratory test results are the cornerstone for patient diagnosis and treatment. In the United States, according to data from the Centers for Medicare & Medicaid Services Medicare database, laboratory testing occurs for 98% of hospital admissions(1). Gram staining is one of the laboratory test methods which is named after the Danish bacteriologist Hans Christian Gram who originally devised it in 1882 and published in 1884 to discriminate between *Pneumococci* and *Klebsiella pneumoniae* bacteria in lung tissue (2, 3). Gram stain is a classic biological protocol that is still actively used to differentiate bacteria into two possible classifications: Gram-positive cells, in which the primary stain is retained and Gram-negative cells, in which the primary stain is lost (2, 4).

Gram stain is used routinely as requested in the clinical specimens submitted for smear and culture. It may be used to characterize any specimen. Cerebrospinal fluid, other sterile body fluids, expectorated sputum or bronchoalveolar lavages, wounds and exudates are routinely stained directly in which bacterial infections are strongly suspected (5, 6, 7). Gram stain interpretation gives immediate information regarding the presence or absence of bacterial infection and morphotypes of bacteria involved in infection. This can be ground for hospitalization and initiation of treatment and also initial choice of antibiotic therapy (8, 9).

In Ethiopia, most medical laboratories in health care facilities-cannot perform microbial culture for the diagnosis of microorganisms. Microbial culture for the diagnosis of microorganisms is a limited service. This was due to lack of skilled-man power, infrastructure, or cost of culture diagnostic materials and other issues (10). Hence, Gram stain is a method of choice for the diagnosis of microorganisms in most health care facilities, as microbial culture is impossible or not accessible in most of these facilities.

In spite of its importance, interpretation of Gram stain is difficult for medical laboratory professionals because such interpretation requires multiple observations and the judgment that comes with years of experience (11). For gram stain interpretation, minor error may report the presence of polymorph when not present, major error may report the presence of an organism not

present or fail to report the presence of 1⁺ to 2⁺ polymorphs, and very major error may fail to report the presence of an organism and fail to report the presence of 3+ to 4+ polymorphs (8, 12).

Competency defines the ability to carry out the total performance responsibilities of the given practitioner's generic position or competency as the combined knowledge and skill factors necessary to fulfill work obligations adequately. In other words, competency is the ability to carry out a specific task within given parameters of control (1, 13). The competency required for clinical laboratory personnel reflects performance in many dimensions such as knowledge, intelligence, technical skills, problem solving abilities, interpersonal skills, and skills in oral and written expression (1, 13,14).

In United States (U.S.), competency assessment in the clinical laboratory is mandated in U.S. law since 1988 as part of CLIA '88 and, published in the Federal Register as part of the Code of Federal Regulations (CFR). The CFR defines the requirements for initial training verification, initial competency assessment, and ongoing competency assessments of laboratory personnel (15). According to CLIA '88, medical laboratory technologists must be assessed for competency semiannually during the first year of employment and annually thereafter. This assessment must include all of the following: direct observation, review of intermediate results, blind testing using proficiency testing samples or internal samples, assessment of problem-solving skills, and monitoring (13, 15, 16). It would be the responsibility of the technical supervisor to assure that medical technologists are competent. However, some of the challenges clinical laboratories face today is the design and implementation of competency assessment programs (13).

In Africa, including Ethiopia, there was no accessible mandated law how competency of medical laboratory professionals should be assessed in each country.

1.2. Statement of the problem

Studies conducted in the U.S. and Canada reported that there were gaps on Gram stain interpretation between Medical Laboratory Professionals (8, 17, 18). These gaps occurred in countries with advanced Medical Laboratory Technologies, high level of higher institution education quality, and high level of skilled man-power, accessible health information resources, adequate training and other facilities.

In Ethiopia, even though gram stain is the method of choice for diagnosis of microorganisms to guide initial choice of antibiotic therapy as stated above, there was a gap between higher institutions to produce medical laboratory professionals with usable knowledge and practical skills (19), lack of health information resources (20), no evidence of refresher training and supervision on gram stain examination and interpretation, low level but progressive Strengthening Laboratory Management Towards Accreditation (SLMTA) practice (16, 21) and lack of continuing professional development(CPD) program. Hence, due to these gaps Gram stain examination and interpretation by medical laboratory professionals is low quality and inconsistent. Lack of proper gram stains examination and interpretation could lead clinicians to miss diagnose and miss treat patients, which could cause drug resistance, resource-wastage, and suffering and possibly death of patients and others (17, 22, 23).

In Ethiopia, there were also no accessible studies in the scientific literature that reported competency of medical laboratory professionals on gram stain examination and interpretation. This indicates that the area was not examined by both researchers and responsible bodies for continuing professional development and quality medical laboratory services. Therefore, there was lack of scientific evidence on competency of medical laboratory professionals on Gram stain examination and interpretation in Ethiopia and in the study area in particular.

1.3. Significance of the study

High quality Gram stain examination and interpretation cannot be achieved without competent medical laboratory professionals. Medical Laboratory Professionals can be competent on gram stain examination and interpretation, if there are studies to show knowledge and practice gaps and generate appropriate recommendations such as training and supervision. Despite the importance, there were no accessible studies that examined competency on gram stain examination and interpretation in Africa. Hence, competency assessment of Medical Laboratory Professionals on gram stain examination and interpretation was necessary to identify gaps about competency of Medical Laboratory Professionals during gram stain examination and interpretation and to assess associated factors.

Scientific evidence from competency assessment of Medical Laboratory Professionals will deliver important information for planning continuous professional development, training and supervision. It also provides important evidence to higher institutions to better align their training and produce knowledgeable and skilled man power. Generally, study in this area would be valuable for Medical Laboratory Professional associations, higher institutions, government bodies, stakeholders, participating hospitals and other health care facilities by showing addressable competency gaps in gram stain examination and interpretation.

2. Literature review

There are several studies about the importance of Gram stain examination in diagnosis of diseases using different body fluids and other specimens (24 - 26). A study in the U.S. reported that gram stain for bacteriuria appears to have more sensitivity, specificity and positive predictive value than routine urinalysis in detecting UTI in infants. In addition, the study suggested that doing gram stain is helpful when the amount of urine obtained is insufficient for routine urinalysis. Urine Gram stain can be adequate screening for UTI and early identification of mixed organisms, which could help to alert the clinician to a possibility of contaminated specimen (5).

In another study, various rates of sensitivity and specificity have been reported for different samples obtained from the human body in different countries (25, 27, 28). Sensitivity of over 90% and specificity of 73% have been documented for bronchoalveolar lavage fluid and intraocular samples (6). Gram stain study of specimens taken from artificial joints in orthopedic surgery has been found to be not reliable for determining the presence of infection in patients who are having revision surgery of the arthroplasty. While gram stain may be specific, it lacks acceptable level of sensitivity (range 0 to 23%) (6).

Another study also showed that the Gram stain is not suitable for microbiological analysis of burn wound surfaces (7, 29). However, in the U.S., Gram stain of a deep tissue biopsy of an ulcer is largely predictive of the microorganism causing underlying infection and likely sustainable because of the considerably lower costs when compared with cultures (30). In another study, results after processing fifty pus samples, direct smear examination by Gram staining was found to be better than culture in 5 pus samples and out of the total fifty samples or swabs processed, 74% were positive by Gram's staining whereas only 64% were positive by culture (7).

Although different studies indicated Gram stain may be the oldest, most entrenched and an important technique still in use in the microbiology laboratory, there were very few studies reported competency assessment of medical laboratory professionals on gram stain examination and interpretation (31).

In the U.S., a study surveyed a total of 552 institutions and, showed that 89.2% of institutions had a written competency plan and of those, 90.3% used their plan for microbiology. The study reported that approximately 98% of institutions review employee competency at least annually. Of all laboratories surveyed, 87.5% perform direct supervision, 77.4% review test or QC results, 60% review instrument preventive maintenance, 52.2% conduct written testing, and 20.8% perform other methods of assessment as a competency tool. For this study, measuring of adherence to the laboratory's own competency plan found that 89.7% assessed using direct observation, 85.8% assessed by reviewing QC and patient test results, 78% assessed by reviewing instrument records, and 74% assessed using written testing; 90.4% of new employees were assessed as indicated per policy, and 90% of employees were found to have responded satisfactorily to a written competency assessment regarding specimen processing. In these institutions failure to comply with the laboratory's own competency plan ranged from 1 to 6.4%, and employees who failed competency assessment were not allowed to continue their usual work in 8.6% of institutions (15).

In Ontario, Canada, a study reported that licensed clinical laboratories participate in external quality assessment (proficiency testing) and perform competency evaluation of their staff. The study was done on competency assessment practices. The Quality Management Program-Laboratory Services (QMP-LS) surveyed all 112 licensed Ontario microbiology laboratories. Of the 111 responding laboratories, 6 indicated they did not have a formal evaluation program since they perform only limited bacteriology testing. Of the remaining 105 respondents, 87% perform evaluations at least annually or every 2 years, and 61% include any test or task performed, whereas 16% and 10% focus only on problem areas and high-volume complex tasks, respectively. A survey respondents indicated that the most common competency issue requiring remediation was associated with Gram staining and interpretation (22).

An assessment of medical laboratory professionals was done in the U.S. by using sets of direct Gram stained smears for which the culture results were known. For this study accuracy of identification of *Pseudomonas aeruginosa* was 60% for the first survey conducted in 1987 but improved progressively to over 80% in 1988 and 1989 until a decline was observed in 1990(18). According to the study, this was correlated with an increase in the number of untrained personnel and indicated a greater need for in-service education in interpretation of gram-stained smears (18). The study reported that enteric bacilli were easier to categorize correctly, and the accuracy ranged from 80 to 100% throughout the period of the study survey while accuracy of identification of the "*Bacteroides-Haemophilus*" group also has remained in the 90 to 100% range since 1987. The assessment result indicated accuracy of identification of *staphylococci* has never been less than 80% and usually has been in the 90 to 100% range rather *Streptococcus pneumoniae* in sputum specimens had been correctly recognized 80 to 100% of the time during most of the survey but fell to 50% early in 1990. The study showed this was during a period of intensive training of new employees and the accuracy reached 90 to 100% later in 1990. For this study , *Neisseria* species recognition always has fallen in the 95 to 100% range but dropped to 50% early in 1988(18).

Another study was conducted in the U.S., by reviewing major errors in Gram stain reports from positive blood cultures during a 23-month period. The study reported that blood cultures were misread for 57 (0.7%) of 8,253 patients. Of 5,885 read as gram-positive cocci, 6 (0.1%) had only gram-negative organisms by culture, 3 of which were *Acinetobacter* species. Of 1,959 read as gram-negative bacilli, 25 (1.3%) had only gram positive organisms by culture. Of these, 9 were *Bacillus* and 2 were *Clostridium* species. Non recognition of mixed Gram stains accounted for 28 errors that most often were associated with a reading of gram-positive cocci(23).

Furthermore, a different study in the U.S., reported using computer based Gram stain competency assessment on 278 users. Overall, users correctly identified approximately 90% of the Gram stain items. When questions were categorized by cell type, users attained the highest scores in host cells (93%) followed by other cells (92%), gram-positive cells (90%), and gram-negative cells (88%). When categorized by type of interpretation, users attained the highest scores in the other category (92%), followed by identify by structure (91%), and identify by name (87%) (16). On the other hand from 40 Gram stain items, 6 were answered correctly by

99% or more of users, suggesting that these items were easy. When categorized by cell type, these questions were spread across all 4 categories: host cells, 3; gram-negative, 3; other cells, 2; and gram-positive, 1 (note that 3 questions were classified into more than 1 category). When categorized by type of interpretation, only 1 question was identified by name category, 5 were identified by structure category, and none were in the other category. There were 6 items that were answered correctly by fewer than 75% of the users, suggesting that these items were difficult. Five items were in the gram-negative category (range, 67%-74%), and 1 was in the host cells category. When classified by type of interpretation, 2 of the difficult items were classified as identify by structure and 4 as identify by name (17).

In the U.S., a study conducted to assess Gram stain interpretation proficiency of technologists reported that the overall Gram stain interpretation proficiency rate for 70 satellite laboratory technologists was 94%. In this study, host cells were interpreted with a higher success rate than bacteria (98% versus 89%; $P < 0.0001$) (32).

In other study in the U.S., gram stain results were discrepant from culture for 5% of all specimens. Fifty-eight percent of discrepant results were specimens with no organisms reported on Gram stain but significant growth on culture while 42% of discrepant results had reported organisms on Gram stain that were not recovered in culture. Upon review of available slides, 24% (63/263) of discrepant results were due to reader error, which varied significantly based on site (9%-45%). The Gram stain error rate also varied among sites, ranging from 0.4% to 2.7%. (33).

In Ethiopia a study conducted on 12 hospital laboratories participated on the national PT program from 6 cycles of 2012 and 2013 G.C., Gram stain had high PT failure rates from 20 test parameters. In this study Gram stain failure rate were 88.9% (34).

3. Objectives

3.1 General Objectives

- ❖ To assess the competency of Medical Laboratory Professionals on gram stain examination and interpretation in selected hospitals of Addis Ababa, Ethiopia

3.2 Specific Objectives

- ❖ To determine the knowledge of Medical Laboratory Professionals on gram stain examination and interpretation.
- ❖ To determine the skill of Medical Laboratory Professionals on gram stain examination and interpretation.
- ❖ To identify competency associated factors with gram stain examination and interpretation

3.3. Hypothesis

The knowledge of Medical Laboratory Professionals on gram stain examination and interpretation will be similar to knowledge of Medical Laboratory Professionals studied by computer based competence assessment on 278 participants in the U.S. (17).

4. Materials and methods

4.1 Study design

A cross-sectional study was conducted to assess competency of Medical Laboratory Professionals on gram stain examination and interpretation.

4.2. Study area, Study period and Study population

4.2.1. Study area

Addis Ababa is the capital city of Ethiopia with a population of 2,739,551 people, according to the 2007 census (35). It has around 42 Hospitals, from which 30 hospitals are private hospitals. The study was conducted in four federal hospitals (All Africa Leprosy Rehabilitation and Training Center(ALERT), St. Paul's Hospital Millennium Medical College, Amanuel Mental and Specialized Hospital and Black Lion Specialized and Referral Hospital), six hospitals under Addis Ababa City Administration Health Bureau (Minilik II Hospital, Zewditu Memorial Hospital ,Yekatit 12 Hospital Medical College, Gandhi Memorial Hospital, Turnesh Beijing Hospital and Ras Desta Damtew Memorial Hospital); two Uniformed hospitals(Armed Force Referral and Teaching Hospital and Police Hospital) and eight private hospitals(Kadisco General Hospital, St. Gebreal General Hospital, Addis Hiwot General Hospital, Amin General Hospital , Hayat General Hospital, Myung Sung Christian Medical Center, Yerer Primary Hospital and Tzna General Hospital) in Addis Ababa, Ethiopia. Tekele Haymanot General Hospital and St.Yared General Hospital replaced by Amanuel Mental and Specialized Hospital and Tzna General Hospital and excluded from this study because of Laboratory heads were not interested to participate. Landmark hospital was not included in the study because of staff shortage and work load.

4.2.2 Study period

The study was conducted from September 2015 to December 2017

4.2.3 Population

4.2.3.1 Source population

All Medical Laboratory Professionals who were working in Medical Laboratories of hospitals in Addis Ababa, Ethiopia.

4.2.3.1 Study population

Medical Laboratory Professionals who were working Medical Laboratories of Hospitals in Addis Ababa and fulfilled the inclusion criteria.

4.3 Subjects requirements

4.3.1 Inclusion criteria

All Medical Laboratory Professionals who were working in selected Medical Laboratories of Addis Ababa hospitals and who were on their job during the study period were included.

4.3.2 Exclusion criteria

Medical Laboratory Professionals who were absent during the study period

4.4 Variables

4.4.1 Independent Variables

- ❖ Sex(M/F),
- ❖ Age in years,
- ❖ Qualification(Categories),
- ❖ Service year(years),
- ❖ Previous training(yes or no),
- ❖ Hospitals(governmental ,Private and Uniformed),
- ❖ Higher Institutions
- ❖ Supervision (by regional or national laboratories)(yes or no),
- ❖ Health information resources (Categories)
- ❖ Employment status (i.e. full-time or part-time)
- ❖ Shift (day, night, etc.)
- ❖ Type of microscope

4.4.2 Dependent Variables

- ❖ Competency level of Medical Laboratory Professionals on examination and interpretation of gram stained panel slides
- ❖ Score of Medical Laboratory Professionals on theoretical questions

4.5. Sample size determination

In Addis Ababa there were around 42 Hospitals, from which 30 hospitals were private hospitals. This study included all government hospitals (both federal and Addis Ababa city Administration Health Bureau), uniformed hospitals and private hospitals. Preliminary assessment was done about number of medical laboratory professionals in each hospital before data collection. In private hospitals there were 5 medical laboratory professionals on average and the total number of medical laboratory professionals working in private hospitals in Addis Ababa was around 150. In Government hospitals there were around 288 and in uniformed hospitals 43 medical laboratory professionals from the preliminary assessment. Total numbers of medical laboratory professionals working in hospitals in Addis Ababa were around 481. Nancy G et al included 278 participants for computer based competence assessment study on gram stain in the U.S. While similar studies in Ethiopia by Ayalew et al on Malaria and by Hailemariam et al on TB included 80 and 81 participants, respectively. In this study, based on the above studies as bench mark; 190 participants were included.

4.6. Sampling methods

Sampling methods for this study was Purposive. All government, uniformed and ten private Hospitals in Addis Ababa were selected by Principal Investigator purposively for this study.

4.7 Data collection

4.7.1 Data collection tools and procedure

Gram stained panel slides and structured knowledge questions with background questionnaire were used to conduct this study. One stained slide from graded and interpreted stained slides was provided to each participant and then each participant was graded when interpreting one stained slide within five minutes. Participants were also provided 15 structured knowledge questions with background questionnaire to fill their response within 20 minutes. The questionnaire had sub-components for socio-demographic characteristics, educational background, service year, in service training, shift (day, night, etc.), employment status (i.e. full-time or part-time), type of hospital, supervision background, use of health information resources, and frequency of health information resources usage.

Microscopes used for the study were checked for their proper functionality by a senior Medical Laboratory Technologists at each laboratory and by the principal investigator as well. The whole procedure for data collection was administered by the principal investigator.

Finally, the data from gram stained slide interpretation and 15 structured knowledge questions with background questionnaire for each study participant were collected by the principal investigator. Generally, gram stain grading can be reported as

(8, 12, 36) :

- ❖ **1+ (very rare)**
 - Less than 10 in all fields examined
- ❖ **2+ (few)**
 - More than 10 in all fields but less than 1/field
- ❖ **3+ (moderate)**
 - More than 1/field but less than 25/field
- ❖ **4+ (many)**
 - More than 25 in one field

4.7.2 Panel Slide Preparation and Distribution

Bacteriology laboratory experts at the Armauer Hansen Research Institute (AHRI) and the principal investigator prepared and validated the gram stained panel slides. Both patient sample and samples from American Type Culture Collection (ATCC) were used for preparation of gram stained panel slides. Panel slides were prepared from known bacterial strains known as American Type Culture Collection (ATCC). The known bacterial strains were sub cultured on blood agar. From growth on blood agar, gram stained panel slides were prepared and no organism slides were prepared from patient sample. All slides were stained by gram staining procedure. Experts interpreted the prepared gram stain smears using investigative criteria for the presence or absence of gram stain findings (bacteria, yeasts and cells) and also quantification of findings (few, moderate and many)(5,12,13). Experts were validated the gram stain interpretation agreement with the culture growth on blood agar. The validated gram stain panel slides were panel slides interpretation agreed with Culture growth. For this study, six gram stained panel

slide types were used and the composition of test panels prepared in AHRI Bacteriology Laboratory Department. The panel slides that were prepared included Gram positive cocci in cluster(*S.aureus*), Gram positive cocci in chain(*S.pyogenes*), Gram negative diplococcic(*N.gonorrhoeae*), Gram positive diplococcic(*S.pneumoniae*) and Gram positive rods(*L.monocytogenes*) from ATCC, and no microorganisms with many pus cells from patient sample. Panel of slides were graded as few, moderate and many with different interpretation. Next to preparation and validation, the slides were arranged, packed and distributed to the participant by the principal investigator. The reporting formats and orders of how to perform the tests were packed separately.

4.7.3 Data Management and Quality Assurance

Data quality was assured through use of standardized data collection materials, pretesting of the questionnaires, and intensive supervision during data collection by the principal investigator.

4.7.4 Data Entry and Analysis

After completing data collection, the data were entered in to *RED Cap software* and analysis was performed by *R software*. The study used Bloom's cut off point to measure knowledge and skill of the respondents. Percent of correct response to a set of 15 knowledge questions was graded as follows: 59 % or below (8/15) as low, 60-80 % (9-12/15) as medium and above 80 % (>12/15): as high knowledge level. Similarly, percent of correct responses to a set of 6 skill related questions was graded as follows: those who were performed correctly in 3 or below 59 % (3/6) as low, 60-80 % (3-4.8/6) as medium and above 80 % (>4.8/6) as high skill level (37). A logistic regression analysis was used to determine associations with dependent and independent variables. Statistical significance was determined based on two-sided P value < 0.05. Median, very major error, major error, minor error, maximum score, minimum score and others errors were analyzed for skill tests. For 15 knowledge questions the analyses was also performed for median, maximum score and minimum score of exam answers.

4.8 Ethical consideration

The study was approved by the departmental research and ethics review committee (DRERC) of Department of Medical Laboratory Sciences, School of Allied Health Sciences, College of Health Sciences, Addis Ababa University and Armauer Hansen Research Institute Ethics Review Committee. Official letter was written to the participating hospitals from Department of Medical Laboratory Sciences, School of Allied Health Sciences, College of Health Sciences, Addis Ababa University. Information sheets were prepared in English and Amharic and it was read for participants. Consent forms were prepared in Amharic and English and it was read and signed (if agreed) by the participating medical laboratory professionals

Information that was obtained about the medical laboratory professionals from the questionnaires and the pane slides were kept totally anonymous. Participants had the right not to participate or to withdraw from the study at any time.

4.9 Operational definitions

Gram stain interpretation minor error: report the presence of polymorph when not present (5).

Gram stain interpretation major error: report the presence of an organism not present or failure to report the presence of 1+ to 2+ polymorphs (5).

Gram stain interpretation very major error: failure to report the presence of an organism and failure to report the presence of 3+ to 4+ polymorphs (5).

Competency: the ability to carry out the total performance responsibilities of the given practitioner's generic position or the combined knowledge and skill factors necessary to fulfill work obligations adequately(14).

Uniformed Hospitals: Armed Force Referral and Teaching Hospital and Police Hospital

4.10 Dissemination of Results

The result of this study will be reported to or shared with all those who are responsible for continuous professional development of medical laboratory professionals. The results will also be presented to the scientific community and policy-makers at different venues such as scientific conferences and publication in peer-reviewed journals.

5. Results

5.1 Background characteristics of respondents

A total of 190 Medical Laboratory Professionals were included in this study. The median age of the respondents was 28 years with the Interquartile (IQR) range of 8 years. The median experience of participant was 5 years with IQR range of 6 years while the median of experience in bacteriology was 0.5 years with IQR range of 3 years. Most of the study respondents were males 103 (55.1%) and regarding education, the majority of the respondents 98(52.1%) were had first degree education status. One hundred thirty eight 138(75%) participants were from government hospitals and the majority of participants 142(78.5%) studied in government higher institutions (Table 1).

Table 1 Socio demographic characteristics of Medical Laboratory Professionals working in selected Hospitals of Addis Ababa, Ethiopia, 2017

Background Variables	Characteristics	Number	Percent (%)
Age in years(n=186)	19-25	37	19.9%
	26-30	83	44.6%
	31-35	30	16.1%
	>=36	36	19.4%
	Unknown	4	2%
Sex(n=187)	Male	103	55.1%
	Female	84	44.9%
	Unknown	3	1.6
Hospital type(n=184)	Government	138	75%
	Private	40	21.7%
	Uniformed	6	3.2%
	Unknown	6	3.1

Higher Institution type(n=181)	Government	142	78.5%
	Private	39	21.5%
	Unknown	9	4.7
Education level (n=188)	Masters	16	8.5%
	First degree	98	52.1%
	Diploma	74	39.4%
	Unknown	2	1

Eighty one 81(42.6%) of study participants used similar type of microscope. During the study time, most of participants worked in Hematology 29 (15.4%), Microbiology 25(13.3%), Phlebotomy 23(12.2%), Clinical Chemistry 24(12.77%) and Parasitology 20(10.6%) laboratory sections. Most of the study participants 139(73.16%) were working without supervision on Gram stain examination and interpretation from regional or federal institutions. One hundred sixty two (85.7%) of respondents were working without training on gram stain examination and interpretation. Majority of the study participants 123 (65.4%) accessed health information resources and most of respondents 102(68%) used these health information resources sometimes (Table 2).

Table 2 Other background characteristics of Medical Laboratory Professionals working in selected Hospitals of Addis Ababa, Ethiopia, 2017

Background Variables	Characteristics	Number	Percent (%)
Microscope type (n=190)	Tensido	3	1.6%
	Labomad	13	6.8%
	HumaScop	22	11.6%
	LEICA	14	7.4%
	Ecoline	4	2.1%
	Olympus	81	42.6%
	PrimoStar	53	27.9%
	Parasitology	20	10.6%
	Serology	9	4.8%
	Clinical Chemistry	24	12.8%
	Phlebotomy	23	12.2%
	Micro Biology	25	13.3%
	Management	7	3.7%
		18	9.6%

Working department (n=188)	All section		
	Blood Bank	10	15.4%
	Hematology	29	15.4%
	Urine Analysis	2	1.1%
	Others	21	11.2%
	Unknown	2	1
Supervision (n=190)	Yes	51	26.8%
	No	139	73.2%
Training on Gram stain(n=189)	Yes	27	14.3%
	No	162	85.7%
	Unknown	1	0.5
Health information resources(n=188)	Yes	123	65.4%
	No	65	34.6%
	Unknown	2	1
Frequency of health information used as resources	Always	26	17.3%
	Some times	102	68%
	Never	22	14.7%

5.2 Knowledge of Medical Laboratory Professionals in selected Hospitals in Addis Ababa, Ethiopia, 2017(n=190)

For the 15 theoretical knowledge questions administered to participants, minimum score was 3(20%) and maximum score was 13(86.7%). From 190 participants, 55(28.9%) participants scored with low knowledge level, 131(68.9%) scored medium knowledge level and only 4(2.1%) respondents were scored high knowledge level.

Analyses were carried out to examine the association between different factors and knowledge of study participants on gram stain examination and interpretation. Education level, Supervision by regional or federal government body and training about gram stain had significant association with knowledge level of study participants (p value = 0.0000006, 0.004 and 0.002 respectively). From all study participants with high knowledge level (4), 3(75%) of them had masters' level and one (25%) had first degree level. Respondents with diploma education level had no high knowledge level.

All participants who were supervised by regional or federal government body had high knowledge level and all participants with high knowledge level had supervision. However, participants working without supervision had no high knowledge level. From study respondents with low knowledge level, most of the respondents 41(74.6%) with low knowledge level were those who had no supervision. From all study participants, there were 41(21.6%) participants who had no supervision and low knowledge level. Of all high knowledge level participants, the majority 3(75%) had training on gram stain whereas of all participants with low knowledge level, most of them 49(89.1%) had no training on gram stain. Of all study participants, 25.9% had no training on gram stain and had low knowledge level.

Age, higher institution type, microscope type, sex, working department, hospital type, health information resources and frequency of health information resources use had no significant association with knowledge level of medical laboratory professionals on Gram stain examination and interpretation. Even though, age groups 19-25 years and 31-35 years had no high knowledge level. For this study, female participants, participants working in private hospitals, learned in private higher institutions, used microscope type Tensido, Labomad, HumaScop, LEICA and

Ecoline and participants who had no access of health information resources do not have high knowledge level (Table 3).

Table 3 The level of the knowledge of the medical laboratory professionals on gram stain examination and interpretation associated with background characteristics in hospitals in Addis Ababa, Ethiopia, 2017

Independent Variables	Characteristic	Knowledge level			Total N (%)	χ^2	P value
		Low N (%)	Medium N (%)	High N (%)			
Age	19-25	11(5.9%)	26(13.98%)	0(0%)	37(19.89%)	2.9	0.8
	26-30	26(13.9%)	54(29%)	3(1.6%)	83(44.6%)		
	31-35	9(4.84%)	21(11.3%)	0(0%)	30(16.1%)		
	>=36	9(4.84%)	26(13.98%)	1(0.5%)	36(19.4%)		
	Total N (%)	55(29.6%)	127(68.3%)	4(2.2%)	186		
Sex	Male	26 (13.9%)	73(39.1%)	4 (2.1%)	103 (55.1%)	4.4	0.1
	Female	28 (14.9%)	56(29.95%)	0(0%)	84(44.9%)		
	Total N (%)	54 (28.9%)	129(68.9%)	4 (2.1%)	187		
	Government	42(22.8%)	92(50%)	4 (2.2%)	138(75%)		
	Private	10(5.4%)	30(16.3%)	0(0%)	40(21.7%)		

Hospital Type	Uniformed	3 (1.6%)	3(1.6%)	0(0%)	6(3.3%)	3.1	0.5
	Total N (%)	55(29.9%)	125(67.9%)	4(2.2%)	184		
Higher Institution Type	Government	47(25.9%)	92(50.8%)	3(1.7%)	142(78.5%)	3.4	0.2
	Private	8(4.4%)	31(17.1%)	0(0%)	39(21.6%)		
	Total N (%)	55(30.4%)	123(67.9%)	3 (1.7%)	181		
Microscope Type	Tensido	0(0%)	3(1.6%)	0(0%)	3(1.6%)	7.2	0.8
	Labomad	3(1.6%)	10(5.3%)	0(0%)	13(6.8%)		
	HumaScop	6(3.2%)	16(8.4%)	0(0%)	22(11.6%)		
	LEICA	3(1.6%)	11(5.8%)	0(0%)	14(7.4%)		
	Ecoline	0(0%)	4(2.1%)	0(0%)	4(2.1%)		
	Olympus	24(12.6%)	55(28.9%)	2(1.1%)	81(42.6%)		
	PrimoStar	19(10%)	32(16.8%)	2 (1.1%)	53(27.9%)		
	Total N (%)	55(28.9%)	131(68.9%)	4(2.1%)	190		
Education level	Masters	2 (1.1%)	11(5.9%)	3(1.6%)	16(8.5%)	24.6	0.000006
	First Degree	29(15.4%)	68(36.2%)	1(0.5%)	98(52.1%)		
	Diploma	23(12.2%)	51(27.1%)	0(0%)	74(39.36%)		
	Total N (%)	54(28.7%)	130(69.2%)	4 (2.1%)	188		
Working Department	Parasitology	6(3.2%)	14(7.5%)	0(0%)	20(10.6%)	14.8	0.79
	Serology	3(1.6%)	5(2.7%)	1(0.5%)	9(4.8%)		

	Clinical Chemistry	6(3.2%)	17(9%)	1(0.5%)	24(12.8%)		
	Phlebotomy	6(3.2%)	17(9%)	0(0%)	23(12.2%)		
	Micro Biology	9(4.8%)	14(7.5%)	2(1.1%)	25(13.3%)		
	Management	1(0.5%)	6(3.2%)	0(0%)	7(3.7%)		
	All section	5(2.7%)	13(6.9%)	0(0%)	18(9.6%)		
	Blood Bank	2(1.1%)	8(4.3%)	0(0%)	10(5.3%)		
	Hematology	10(5.3%)	19(10.1%)	0(0%)	29(15.4%)		
	Urine Analysis	1(0.5%)	1(0.5%)	0(0%)	2(1.1%)		
	Others	5(2.7%)	16(8.5%)	0(0%)	21(11.2%)		
	Total N (%)	54(28.7%)	130(69.2%)	4(2.1%)	188		
Supervision	Yes	14(7.4%)	33(17.4%)	4(2.1%)	51(26.8%)	11.	0.00
By Federal	No	41(21.6%)	98(51.6%)	0(0%)	139(73.2%)	1	4
(Regional) institution	Total N (%)	55(28.9%)	131(68.9%)	4(2.1%)	190		
Training on	Yes	6(3.2%)	18(9.5%)	3(1.6%)	27(14.3%)		
	No	49(25.9%)	112(59.3%)	1(0.5%)	162(85.7%)		
	Total N (%)	55(29.1%)	130(68.8%)	4(2.1%)	189	2.1	0.00

Gram stain						%	2
Health Information resources	Yes	35(18.6%)	84(44.7%)	4(2.1%)	123(65.4%)	2.2	0.3
	No	19(10.1%)	46(24.5%)	0(0%)	65(34.6%)		
	Total N (%)	52(28.7%)	130(69.1%)	4(2.1%)	190		
How much Times use the health information resources	Always	8(5.3%)	16(10.7%)	2(1.3%)	26(17.3%)	3.9	0.4
	Some times	29(19.3%)	71(47.3%)	2(1.3%)	102(68%)		
	Never	5(3.3%)	17(11.3%)	0(0%)	22(14.7%)		
	Total N (%)	42(28%)	104(69%)	4(2.7%)	150		

5.3 Skill of Medical Laboratory Professionals on gram stain examination and interpretation

From all 190 participants high score for skill test was 6(100%) and low score was 0(0%) from 6 skill related tests. Forty eight (25.3%), 78(41%) and 64(33.7%) participants scored low, medium and high skill level respectively. Hospital type, microscope type and health information resources availability were significantly associated with skill level (p value 0.0009, 0.04 and 0.01 respectively). However, age, sex, frequency of health information resources use, training on gram stain, supervision, working department type, education level and higher institution type did not show statistically significant association with skill level of respondents.

All study subjects from uniformed hospitals had high skill level on gram stain examination and interpretation. Among participants with low skill level and medium skill level, most of the respondents were from government hospitals (43(89.6%) and 52(70.3%) respectively). Participants used microscope type Labomad and Ecoline had no low skill on gram stain examination and interpretation. However, participants used microscope type Tensido had no high skill level on gram stain examination and interpretation. Of the respondent who had access for health information resources, most of them scored medium and high skill level on gram stain examination and interpretation (49(39.9%) and 50(40.7%) respectively). Furthermore, the majority of those who had no access of health information resources on gram stain scored low and medium skill level on gram stain examination and interpretation (23(35.4%)and 28(43.1%) respectively) (Table 4).

Table 4. The level of the skill of the Medical Laboratory Professionals on gram stain examination and interpretation associated with background characteristics in hospitals in Addis Ababa, Ethiopia, 2017

Independent Variable	Characteristic	Skill Level			Total N (%)	χ^2	P value
		Low	Medium	High			
		N (%)	N (%)	N (%)			
Age	19-25	9(4.8%)	15(8.1%)	13(6.9%)	37(19.9%)	3.4	0.8
	26-30	23(12.4%)	34(18.3%)	26(13.9%)	83(44.6%)		
	31-35	4(2.2%)	14(7.5%)	12(6.45%)	30(16.1%)		
	>=36	11(5.9%)	15(8.1%)	10(5.4%)	36(19.4%)		
	Total N (%)	47(25.3%)	78(41.9%)	61(32.8%)	186		
Sex	Male	23(12.3%)	41(21.9%)	39(20.9%)	103(55.1%)	1.47	0.5
	Female	23(12.3%)	36(19.3%)	25(13.4%)	84(44.9%)		
	Total N (%)	46(24.6%)	77(41.2%)	64(34.2%)	187		
Hospital Type	Government	43(23.4%)	52(28.3%)	43(23.4%)	138(75%)	18.7	0.009
	Private	5(2.7%)	22(11.9%)	13(7.1%)	40(21.7%)		
	Uniformed	0(0%)	0(0%)	6(3.3%)	6(3.3%)		
	Total N (%)	48(26.1%)	74(40.2%)	62(33.7%)	184		
Higher Institution	Government	38(20.9%)	58(32%)	46(25%)	142(78%)	0.54	0.8
	Private	9(4.9%)	15(8.3%)	15(8.3%)	39(21.6%)		

Type	Total N (%)	47(25.9%)	73(40%)	61(33.7%)	181		
Microscope Type	Tensido	2(1%)	1(0.5%)	0(0%)	3(1.6%)	21.6	0.04
	Labomad	0(0%)	4(2%)	9(4.7%)	13(6.8%)		
	HumaScop	6(3.2%)	11(5.8%)	5(2.6%)	22(11.6%)		
	LEICA	1(0.53%)	9(4.7%)	4(2%)	14(7.4%)		
	Ecoline	0(0%)	3(1.6%)	1(0.5%)	4(2%)		
	Olympus	21(11%)	30(15.8%)	30(15.8%)	81(42.6%)		
	PrimoStar	18(9.5%)	20(10.5%)	15(7.9%)	53(27.9%)		
	Total N (%)	48(25.3%)	78(41.1%)	64(33.7%)	190		
Education level	Masters	4(2.1%)	4(2.1%)	8(4.3%)	16(8.5%)	4.2	0.4
	First Degree	24(12.8%)	46(24.5%)	28(14.9%)	98(52.13%)		
	Diploma	19(10.1%)	28(14.9%)	27(14.4%)	74(39.4%)		
	Total N (%)	47(25%)	78(41.5%)	63(33.5%)	188		
	Parasitology	3(1.6%)	11(5.9%)	6(3.2%)	20(10.6%)		
	Serology	3(1.6%)	1(0.5%)	5(2.7%)	9(4.8%)		
	Clinical Chemistry	7(3.7%)	11(5.9%)	6(3.2%)	24(12.8%)		

Working Department	Phlebotomy	5(2.7%)	14(7.5%)	4(2.1%)	23(12.2%)	25.5	0.2
	Micro Biology	5(2.7%)	9(4.8%)	11(5.9%)	25(13.3%)		
	Management	3(1.6%)	4(2.1%)	0(0%)	7(3.7%)		
	All section	4(2.1%)	6(3.2%)	8(4.3%)	18(9.6%)		
	Blood Bank	1(0.5%)	2(1.1%)	7(3.7%)	10(5.3%)		
	Hematology	8(4.3%)	9(4.8%)	12(6.4%)	29(15.4%)		
	Urine Analysis	1(0.5%)	1(0.5%)	0(0%)	2(1.1%)		
	Others	7(3.7%)	9(4.8%)	5(2.7%)	21(11.2%)		
	Total N (%)	47(25%)	77(40.9%)	64(34.1%)	188		
Supervision	Yes	10(5.3%)	20(10.5%)	21(11%)	51(26.8%)	2.10	0.3
By Federal (Regional) institution	No	38(20%)	58(30.5%)	43(22.6%)	139(3.1%)		
	Total N (%)	48(25.3%)	78(41.05 %)	64(33.7%)	190		
Training on Gram stain	Yes	7(3.7%)	13(6.9%)	7(3.7%)	27(14.3%)	1.01	0.6
	No	41(21.7%)	64(33.9%)	57(30.2%)	162(85.7%)		
	Total N (%)	48(25.4%)	77(40.7%)	64(33.9%)	189		
Health Information	Yes	24(12.8%)	49(26.1%)	50(26.6%)	123(65.4%)	8.95	0.01
	No	23(12.2%)	28(14.9%)	14(7.5%)	65(34.6%)		

resources	Total N (%)	47(25%)	77(40.9%)	64(34.1%)	188		
How much Times use the health information resources	Always	7(4.7%)	6(4%)	13(8.7%)	26(17.3%)	5.6	0.2
	Some times	17(11.3%)	47(31.3%)	38(25.3%)	102(68%)		
	Never	6(4%)	9(6%)	7(4.7%)	22(14.7%)		
	Total N (%)	30(20%)	62(41.3%)	58(38.7%)	150		

5.4 Errors of Medical Laboratory Professionals on gram stain examination and interpretation

There were 44 observations (4%) with major errors and 321 observations (28%) with very major errors from all 1140 observations. Of all observations 321(28.2%) reported without grading, 39 observations (3.4%) reported gram positive bacteria as gram negative bacteria and 15 observations (1.4%) reported gram negative bacteria as gram positive bacteria. One hundred forty eight observations (12.9%) also reported without grading with gram positive bacteria reported as gram negative bacteria and forty three observations (3.7%) reported without grading with gram negative bacteria reported as gram positive bacteria (Table 5).

Table 5. The level of the Error of the medical laboratory professionals on gram stain examination and interpretation for skill test in hospitals in Addis Ababa, Ethiopia, 2017

Error type	Slides Cod	Characteristics	Number	Percent
Errors	GSS-01	Very major error	15	7.9%
		No error	175	92.1%
	GSS-02	Very major error	22	11.6%
		No error	168	88.4%
	GSS-03	Very major error	20	10.5%
		No error	170	89.5%
	GSS-04	Very major error	131	68.9%
		No error	59	31.1%
	GSS-05	Very major error	32	16.8%
		No error	158	83.2%
	GSS-06	Major error	44	23.1%
		Very major error	101	53.1%
		No error	45	23.7%
	All(N=190×6=1140)	Major error	44	4%
		Very major error	321	28%
		No error	775	68%

	GSS-01	No grading	63	33.2%
		Gram positive reported as Gram Negative	19	10%
		Both	59	31%
		No Error	49	25.9%
	GSS-02	No grading	70	36.8%
		Gram positive reported as Gram Negative	15	7.9%
		Both	60	31.6%
		No Error	45	23.7%
	GSS-03	No grading	96	50.5%
		No grading and Gram positive reported as Gram Negative	14	7.4%
		No Error	80	42.1%
		No grading	26	13.7%
		Gram positive reported as	5	2.6%

	GSS-04	Gram Negative		
		Both	15	7.9%
		No Error	144	75.8%
	GSS-05	No grading	62	32.6%
		Gram Negative reported as Gram positive	15	7.9%
		Both	43	22.7%
		No Error	70	36.8%
	GSS-06	No grading	4	2.1%
		No error	186	97.9%
		No grading	321	28.2%
		Gram positive reported as Gram Negative	39	3.4%
		No grading and Gram positive reported as Gram Negative	148	12.9%
		Gram Negative reported as Gram positive	15	1.4%

Other Error Types	All(N=190×6=1140)	No grading and Gram Negative reported as Gram positive	43	3.7%
		No error	574	50.4%

5.5 Knowledge and skill of Medical Laboratory Professionals by median age, general experience and experience in bacteriology laboratory in years

Participants with low knowledge and skill, medium knowledge and skill and high knowledge and skill had median age of 29, 30 and 29.5 years respectively. Medical laboratory professionals with low knowledge and skill, medium knowledge and skill, high knowledge and skill had median experience of 5, 6 and 7.5 years respectively. Participants with 0.16, 0.665 and 2.15 median years experience in bacteriology laboratory also had low knowledge and skill, medium knowledge and skill and high knowledge and skill respectively (Table 6).

Table 6. The level of the knowledge and skill of Medical Laboratory Professionals on gram stain examination and interpretation by median age, experience and experience in bacteriology laboratory in years in Hospitals of Addis Ababa, Ethiopia, 2017

Variables	Median	Skill level	Knowledge level
Age	29	Low	Low
	27	Medium	Low
	29.5	High	Low
	26.5	Low	Medium
	30	Medium	Medium
	27	High	Medium
	29.5	High	High
Experience in years	5	Low	Low
	4	Medium	Low
	7.5	High	Low
	4	Low	Medium
	6	Medium	Medium
	5	High	Medium
	7.5	High	High
Experience in bacteriology	0.16	Low	Low
	1	Medium	Low

laboratory	0.375	High	Low
	0	Low	Medium
	0.665	Medium	Medium
	1	High	Medium
	2.15	High	High

5.6 Association of knowledge and skill level of Medical Laboratory Professionals on gram stain examination

There was statistically significant association knowledge and skill level of study participants on gram stain examination and interpretation (p value= 0.006). Those who had high knowledge level scored high skill level on Gram stain examination and interpretation and they had no low and medium skill level. Of all study participants 21(11%) scored low knowledge level and low skill level, 60(31.6%) had medium knowledge level and medium skill level and 4(2.1%) was with high knowledge and skill level (Table 7).

Table7.Association of knowledge level and skill level of the Medical Laboratory Professionals on gram stain examination and interpretation in Hospitals in Addis Ababa, Ethiopia, 2017

Knowledge Vs skill Level	Low skill level	Medium skill level	High skill Level	Total	χ^2	P value
Low knowledge level	21(11%)	18(9.5%)	16(8.4%)	55(28.9%)	14.6	0.006
Medium knowledge level	27(14.2%)	60(31.6%)	44(23.2%)	131(68.9%)		
High knowledge level	0(0%)	0(0%)	4(2.1%)	4(2%)		
Total	48(25.3%)	78(41%)	64(33.7%)	190		

6. Discussion

This study may be the first to assess competence of Medical Laboratory Professionals on gram stain examination and interpretation using both knowledge and skill tests. Although, no similar studies were published to compare our findings, we found that most of the study participants were working without supervision 139(73.2%) and refreshers training 162(85.7%) on gram stain examination and interpretation. However, according to CLIA'88, Medical Laboratory Professionals must be assessed for competence semiannually during the first year of employment and annually thereafter (15). The study also showed that the majority of study participants 123(65.4%) had access health information resources and most of the respondents 102(68%) used these health information resources sometimes while also 22(14.7%) of the respondents never used health information resources. Further, our results showed that competence of Medical Laboratory Professionals on gram stain examination and interpretation lacks attention from responsible bodies. A survey study conducted in Canada by Desjardins M et al., also indicated that the most common competency issue requiring remediation was associated with gram staining and interpretation (22).

In the study, we used both knowledge and skill tests to assess competence of medical laboratory professionals on gram stain examination and interpretation. For the 15 theory knowledge test questions administered to the participants, the minimum and maximum score results were 3(20%) and 13(86.7%) respectively. Of the total 190 participants, 55(28.9%), 131(68.9%) and 4(2.1%) participants scored with low, medium and high knowledge level respectively. Thus, this finding revealed that participants with high knowledge level were very few. This may be due to lack of supervision and training. However, a study in the U.S., using computer based gram stain competency assessment on 278 study subjects reported that overall users correctly identified approximately 90% of the gram stain items (16). This may be due to appropriate supervision, training and access to advanced laboratory setting (1).

We found that education level, supervision and training on gram stain had statistically significant association with knowledge level of study participants. From all study participants with high knowledge level, 3(75%) of them had masters' level and one (25%) had first degree level educational status. Respondents with diploma education level had no high knowledge level. Participants who were supervised had high knowledge level and all participants with high

knowledge level had supervision. However, participants working without supervision had no high knowledge level. From study respondents with low knowledge level, most of the respondents (74.6%) with low knowledge level were those who had no supervision. From all study participant 21.6% participants were who had no supervision and low knowledge level. Generally, the study showed that education level and supervision have an impact on gram stain knowledge level of medical laboratory professionals.

In our study, from all high knowledge level participants, majority 4(75%) were participants who had training on gram stain while from all participants with low knowledge level, most of them 49(89.1%) were who had no training on gram stain. From all study participants 49(25.9%) were participants with no training on gram stain and low knowledge level. In spite of, most of participants are working without training; we found that training had an impact on gram stain knowledge level of study participants. However, in this study training had not affect skill level of the study participants. A previous study in the U.S., reported that training and in-service education was correlated with skill of medical laboratory professionals on interpretation of gram-stained smears. It showed that those who had training had high level skill level compared with those who had no training on gram stain interpretation (26). The difference with the U.S. study may due to different factors that affect knowledge and skill level of Medical Laboratory Professionals on gram stain interpretation. Moreover, our panels of slides are live true slides unlike the U.S one which could have its own impact on the difference.

The study indicated that, from all 190 participants, high and low score for skill was 6(100%) and 0(0%) from all 6 skill tests. About 48(25.3%), 78(41%) and 64(33.7%) participants scored low, medium and high skill level from all 190 participants respectively. The result showed that hospital type, microscope type and health information resources availability affects skill level of participants on gram stain interpretation. In this study, subjects from uniformed hospitals had high skill on gram stain examination and interpretation. From all participants with low skill, most of the respondents 43(89.6%) were found from government hospitals and also from all subjects with medium skill most 52 (70.3%) of them were from government hospitals. In our study, skill level of the study participants was different in different sites and statistically significantly associated with type of hospitals. Similarly, a study conducted in the U.S. indicated that gram stain error rate were varied significantly based on sites (33).

Although related literature was not accessed, we found also that participants who used microscope type Labomad and Ecoline had no low skill on gram stain examination and interpretation. However, participants used Tensido microscope had no high skill on gram stain examination and interpretation. This significant association of skill level of participants and microscope type showed that microscope type can affect gram stain examination and interpretation and mislead for incorrect interpretation of the result. However, it is difficult to comment on the true quality or functionality of any of the microscope used by participant laboratory personnel.

Most of respondents of our study had access for health information resources and most of them scored medium and high skill level on gram stain examination and interpretation. Furthermore the, majority of those who had no access of health information resources on gram stain scored low and medium skill level on gram stain examination and interpretation. Our results also indicated that health information resources availability can improve the skill of medical laboratory professionals on gram stain examination and interpretation. However, if the health information resources are not available, it leads to low skill on gram stain examination and interpretation.

In our study, from all 1140 observations for skill of medical laboratory professionals on gram stain examination and interpretation, we found, 44 observations (4%) with major errors and 321 observations (28%) with very major errors. Of all observations, 321(28.2%) reported without grading, 39 (3.4%) reported gram positive bacteria as gram negative bacteria and 15(1.4%) reported gram negative bacteria as gram positive bacteria. One hundred forty eight observations (12.9%) also reported without grading with gram positive bacteria reported as gram negative bacteria while 43 observations (3.7%) reported without grading with gram negative bacteria reported as gram positive bacteria. Similarly in Ethiopia a study conducted on 12 hospital laboratories participated on the national PT program from 6 cycles of 2012 and 2013 G.C., Gram stain had high PT failure rates from 20 test parameters. For this study Gram stain failure rate were 88.9% (34). However, a study done in U.S., from 5,885 observations read as gram-positive cocci, 6 (0.1%) had only gram-negative organisms by culture and from 1,959 read as gram-negative bacilli, 25 (1.3%) had only gram positive organisms by culture (27). Lack of proper Gram stain examination and interpretation could lead clinicians to misdiagnose and mistreat

patients, which could cause drug resistance, resource-wastage, and suffering and death of patients (16, 17, 27).

All in all to the best of our knowledge, we did not find similar type of study tools and methods to compare and contrast our findings. Thus, such kind of studies is required across the world in order to assess the competency of laboratory professionals and design continuous professional development. Having competency assessment definitely improve the quality of the laboratory services provided using gram staining methods.

7. Limitation

Although this study was the first of its kind to be conducted, it had a number of weaknesses.

1. From six stained panel slides, 5 stained slide types prepared from ATCC known bacterial strain and one slide type from patient sample. Because of ATCC strain was not available, from five stained panel slide types prepared from ATCC, only one stained slide was from Gram negative bacterial strain.

8. Conclusion

Based on the findings of this study, the following conclusions can be drawn:

Education level, supervision and training may negatively affect knowledge level of medical laboratory professionals on gram stain examination and interpretation. Most of study participants were working without supervision and training on gram stain. Medical laboratory professionals working without supervision and training had low knowledge level on gram stain examination and interpretation and this could be affecting their skill level on examination and interpretation of gram stain.

Hospital type, microscope type and availability of health information resources may affect skill of medical laboratory professionals. Medical laboratory professionals working in uniformed hospitals had high skill level and those working with some type of microscope had no high skill level on gram stain examination and interpretation. The study participants who had access to health information had improved skill level on gram stain examination and interpretation.

Knowledge level was found to be associated with skill level of medical laboratory professionals on gram stain examination and interpretation. Participants who had high knowledge can have high skill on gram stain examination and interpretation.

Most of study participant medical laboratory professionals were not including grading level when reporting gram stain result. There was also misinterpretation of gram stain result; including major error, very major error, reporting gram positive bacteria as gram negative bacteria and gram negative bacteria as gram positive bacteria. This type of lack of proper Gram stain examination and interpretation could lead to misdiagnosis and mistreatment of patients by clinicians, which could cause drug resistance, resource-wastage, and suffering and death of patients.

9. Recommendation

- Practice focused training is needed to reduce error rate of gram stain examination and interpretation and to improve knowledge and skill level of medical laboratory professionals on gram stain examination and interpretation.
- Supervision by regional or federal institutions and stakeholders' is necessary to improve knowledge and skill of medical laboratory professionals on gram stain examination and interpretation.
- Improving and encouraging access to health information resources is important to improve knowledge and skill level on gram stain examination and interpretation.
- Equipping laboratories with appropriate microscope type used for gram stain examination and interpretation may improve the examination and interpretation. It should be purchased with care for its power and quality.
- It is necessary to conduct nationwide study about Medical Laboratory Professionals competence assessment on gram stain examination and interpretation.
- Guidelines of competence assessment on Gram stain examination and interpretation has to be prepared by the responsible authorities

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11. Annexes

Annex I: Information Sheet (English Version)

Title of the project: Medical Laboratory Professionals Competency Assessment on Gram stain Examination and Interpretation in Hospitals in Addis Ababa, Ethiopia

Name of Principal Investigator: Adugna Tsehay

Organization: Addis Ababa University

Name of sponsor: Armauer Hansen Research institute

This information sheet was prepared for Medical laboratory professionals who will be involved in project entitled above. I will tell them about the whole processes that have been undertaken in the study and requesting them to participate voluntarily.

Description and Purpose of the study

The Gram stain is a classic biological protocol that is still actively used to differentiate bacteria into two possible classifications: Gram-positive cells, in which the stain is primary retained and Gram-negative cells, in which the primary stain is lost. Gram stain is one of the most frequently performed laboratory diagnostic procedures. Gram stain interpretation gives immediate information regarding the presence or absence of bacterial infection and morphotypes of bacteria involved in infection. This can be ground for hospitalization and initiation of treatment and also initial choice of antibiotic therapy. However, the competency of medical laboratory professionals is not well known in this study area. Therefore, this study was designed to determine the competency of medical laboratory professionals on Gram stain examination and interpretation in Hospitals in Addis Ababa. This study will be identified lower competency and associated factors of medical laboratory professionals on Gram stain examination and interpretation and provide scientific evidence to responsible bodies for continues professional development.

Procedures

In order to undertake the above-mentioned study, theoretical examination questions related with the topic; socio demographic characteristics, six Gram stained panel slides examination and interpretation will be taken from each study participants for analysis. Written consent will

obtain from each study participants and they will be kindly asked to give required information related with the study. The analysis of the data will be done by principal investigator.

Time Allowed: You should grade and interpret one slide within five minutes. You will be also provided 15 structured knowledge questions and background questionnaires to be answered and filled within 20 minutes.

Risks and discomforts: There will have not any possible risks during examination and interpretation of panel slides and answering of exam questions. It might be a possibility of discomfort during examination and interpretation of panel slides and answering of exam questions. Please feel free to ask which is not comfortable to you.

Benefits and Compensation: Participants in this study will be paid 50 birr for lunch.

Confidentiality: The information obtained during this study will be remained confidential. Disclosure of any of the data to third parties other than those allowed in the informed consent will not permit. Records will remain confidential. To maintain confidentiality, the investigator will keep records in locked cabinets and the results will be coded to prevent identification of the volunteers. However, you can find out the competence results of your own.

Right to refuse or withdraw: I assure them that, they will be free to withdraw from the study at any time and that they will be not discriminated in any form for education or other services.

Whom to Contact: The following contact addresses will be given to contact investigators at any time.

Name of investigator: **AdugnaTsehay** Phone No: **251929135819**

Email: delmemorise@yahoo.com

Department of Medical Laboratory Sciences, CHS, AAU, Tel. 0112 75 51 70

Sponsor Address: **AHRI Ethics Review Committee Tel. 0113481289**

Name of advisors: **KassuDesta (BSc, MSc, PhD Candidate, AAU)**

AdaneMihret (DVM, MSc, PhD, Armauer Hansen Research Institute

Co-advisors; HelmnehSineshaw (MD, MPH, Director, Treatment Patterns and Outcomes Research, American Cancer Society's)

KirubelEshetu (BSc, MSc, Regional Operations Director, International Clinical Laboratories)

AddisuGize (BSc, MSc, Immunologist, St Paul's Hospital Millennium Medical College)

Annex II: Informed Consent form (English Version)

I am informed fully in the language I understand about the aim of above mentioned research. I understood the purpose of the study entitled with “Medical laboratory professional competency assessment on Gram stain examination and interpretation in Hospitals in Addis Ababa, Ethiopia”. I have been informed that I will be done examination and interpretation of gram stain and also written examination. In addition I have been told all the information collected throughout the research process will be kept confidential. I understood my current and future medical services and others will not be affected if I refused to participate or with draw from the study.

Agree _____ Not agree _____

Therefore I give my consent freely for my participation in this study.

Code of participant: _____

Signature: _____ Date _____

Name of researcher: _____ Signature: _____

Date _____

Annex III: Background Questionnaire

1. Participant Code-----

Age: -----

Sex: Male Female

2. Hospital Code -----

3. Hospital type:

Government Private med

4. Where did you study your higher Education?

Government College University College University

Private College University College University

5. Type and condition of Microscope-----

6. Qualification of medical laboratory professional

Masters First Degree Diploma Certificate

7. Service year of medical laboratory professional -----

8. Employment status (i.e. full-time or part-time) -----

9. Shift (day, night, etc.)-----

10. Where do you work now (In which section)? -----

11. Your service year in bacteriology laboratory or section-----

12. Have you ever been supervised by regional or national laboratories about competence of examination and interpretation of gram stain?

Yes No

13. Did you have any training about gram stain technique?

Yes No

14. Are there health information resources available in your work area or nearby? (For gram staining technique)

Yes No

If your answer is yes, which one is available circle it.

A. books

B. Internet

C. journals

D. Guidelines

Others specify-----

15. How much times you use these health information resources?

A. Always B. sometimes C. Never

Annex IV: Media preparation for blood agar

Purpose: Blood agar is blood agar base II enriched with 5-10 % sheep blood. Blood agar is used for isolation and cultivation of many types of fastidious bacteria. It is also used to differentiate bacteria based on their hemolytic characteristics, especially within the genera Streptococcus, Enterococcus, and Aerococcus. It is appropriate for culturing almost all specimens for bacteriology.

Principle: Several species of Gram-positive cocci produce exotoxins called hemolysins able to destroy red blood cells (RBCs) and hemoglobin. Blood agar, which is a mixture of tryptic soy agar and sheep blood, allows differentiation of bacteria based on their ability to hemolyze RBCs.

Procedure

1. Add 40 gm Blood agar powder in 1000 ml of distilled water
3. Heat until completely dissolved on the water boil
4. Autoclave at 121 c⁰ for 15 minutes
6. Cool until 45-50 c⁰
7. Aseptically add sheep blood 5% (7%) and mix well
8. Dispense 15-20 ml of the ready media on to the petridish
9. Wait until solidify or Dry
10. Check sterility at 37c⁰ incubators for 24 hours with positive control
11. Inoculate or subculture
12. Check growth within 24 -48 hours

Annex V: Gram stain smear preparation procedure

1. Labeling slides: - Every slide must be labeled clearly with codes by a lead pencil
2. Smears should be spread evenly covering an area of about 15–20 mm diameter on a slide.
3. After making a smear, leave the slide in a safe place for the smear to air-dry, protected from dust, flies, cockroaches, ants, and direct sunlight.
4. To fix the smear, rapidly pass the slide; smear uppermost, three times through the flame of a spirit lamp or pilot flame of a Bunsen burner.
5. Allow the smear to cool before staining it.

Note: this study used five slides prepared from known bacterial strains (ATCC) and one slide prepared from patient sample. The ATCC was first took from Deep freezer and allow to room temperature in the hood. Then it was subculture on blood agar and after 24 hours, the smear was done from growth culture. To get different grading smear, there was serial dilution by normal saline. To prepare slide smear with few number of bacteria by using 0.5 ul loop, one loopful colony can emulsify with 2000 and more ul of normal saline, for moderate: 1000-2000ul of normal saline with one loopful colony and to prepare slide with many number of bacteria; less than 1000 ul of normal saline with one loopful colony(using 0.5 ul loop). But it may differ based on the growth of the colony. Slides coded as GSS (Gram Stain Slide) 001, GSS002, GSS003, GSS004, GSS005 and GSS006. GSS01 slides prepared from *S.aurous*, GSS002 slides prepared from *S.pyogen*, GSS003 slides prepared from *L.monocytogen*, GSS004 slides prepared from *S, pneumonia* and GSS005 slides prepared from *N. gonoreau* ATTC. GSS006 prepared from pus patient sample with no microorganism and many pus cells.

Annex VI: Gram Stain Procedure

1. Fix the dried smear.

Note: When the smear is for the detection of gonococci or meningococcal, it should be fixed with methanol for 2 minutes (avoids damaging pus cells).

2 Cover the fixed smear with crystal violet stain for 30–60 seconds.

3 Rapidly wash off the stain with clean water.

Note: When the tap water is not clean, use filtered water or clean boiled rainwater.

4 Tip of all the water, and cover the smear with Gram's iodine for 30–60 seconds.

5 Wash off the iodine with clean water.

6. Decolorize rapidly (few seconds) with acetone–alcohol. Wash immediately with clean water.

Caution: Acetone–alcohol is highly flammable therefore use it well away from an open flame.

7. Cover the smear with Safranin for 30 sec to 1 min.

8. Wash off the stain with clean water.

9. Wipe the back of the slide clean, and place it in a draining rack for the smear to air-dry.

10 Examine the smear microscopically, first with the 40 × objective to check the staining and to

See the distribution of material, and then with the oil immersion objective to report the bacteria and cells.

Annex VII: Gram stained panel slides result report form

Participant code: -----

To be filled by Laboratory personnel		To be filled by Principal Investigator		Remark
Slide number	Result	Expected Result	Error type	
GSS-01				
GSS-02				
GSS-03				
GSS-04				
GSS-05				
GSS-06				

Annex VIII: Competence assessment for theoretical bases in Gram staining for medical laboratory professionals working in Addis Ababa Hospitals, Addis Ababa, Ethiopia

1. Gram stain is a:

a) Simple stain b) Differential stain c) Special stains D. All

2. Using gram staining method, Gram positive organisms appear:

a) Pink. b) Violet c) Orange D) None

3. Using gram staining method, Gram negative organisms appear:

a) Pink. b) Violet. c) Orange. D) None

4. Organisms which are decolorized by Acetone alcohol & stained by the color of the counter stain are called:

a) Gram positive b) Gram negative c) Acid fast. D. A and B

5. Organisms which resist decolourization & retain the color of the primary stain (Crystal violet) are called:

a) Gram positive b) Gram negative c) Alcohol fast D. All

6. The counter stain in Gram stain is:

a) Crystal violet b) Safranin. c) Concentrated carbol fuchsin D. All E. None

7. Decolourization in Gram stain is done by:

a) Acetone Alcohol. b) Acid alcohol c) Safranin. D. None

8. All cocci are Gram positive except:

a) Staphylococci. b) Neisseria. c) Streptococci. D. Streptococcus pneumoniae

9. The different reaction to Gram stain is due to the following except:

- a) Thicker peptidoglycan layer in Gram negative bacteria.
- b) Protoplasm of Gram positive bacteria is strong acidic.
- c) Permeability in Gram positive bacteria is less than in Gram negative bacteria.

D. All

10. Which of the following is true about structure of Gram positive cell wall?

- a) Is composed of thick peptidoglycan layer
- b) periplasmic space is absent
- c) Include significant amount of teichoic and lipoteichoic acids
- d) All of the above

11. Which of the following is true about structure of gram negative cell wall?

- a) Thick peptidoglycan layer
- b) periplasmic space is absent
- c) Include outer membrane
- d) All of the above

12. Gram's staining consists of:

- a) 2 stages
- b) 4 stages
- c) 3 stages
- d) 5 stages

13. The purpose of iodine in gram staining methods is:

- a) Decolonization
- b) Fixative (mordant)
- c) Counter stain
- d) Primary stain
- e) None of above

14. The gram stain

- a) Classifies bacteria according to the structure of the cell envelope.

- b) Is an alternative to the acid-fast stain; a positive reaction for each stain will mean the same thing.
- c) Gives the best results when an old culture (grown 2 or more days) is used.
- d) should be performed on an extremely thick smear, such that the gram reaction can be seen by the naked eye

15. "Gram-variability"

- a) Is a term which can be used where two gram reactions are seen due to an error in the staining procedure?
- b) Applies to an organism which changes its cell wall structure from the gram-positive type to the gram-negative type as the culture ages.
- c) Applies to what is ultimately seen when cells in a culture of gram-positive bacteria lose the ability to retain the primary stain during the decolorization process
- D) Indicates a mixed (i.e., impure) culture.

አባሪ(Annex) IX : የስምምነት-ቅጽ(Consent form) የአማርኛው-ቅጽ.(Amharic version)

ሙሉ ለሙሉ በምረዳው ቋንቋ ከፍ ብሎ ስለተመለከተው ጥናታዊ ስራ አላማ መረጃዎች ተሰጥቶኛል። ርእሱ “በአዲስ አበባ ኢትዮጵያ በሚገኙ ሆስፒታሎች ውስጥ የሚሰሩ የህክምና ላብራቶሪ ባለሙያዎች በግራም እስቴይን ምርመራ እና ትርጓሜ ላይ ያላቸው ብቃት መመዘን” የተሰኘውን ጥናት አላማ ተረድቼዋለሁ። ምርመራ እና የግራም እስቴይን ትርጓሜን እንደማድረግ ተነግሮኛል እንዲሁም የጽሁፍ ምርመራም እንደሚደረግ ተነግሮኛል ። በተጨማሪም በጥናት ሂደቱ ውስጥ በሙሉ የተሰበሰቡ መረጃዎችን ሁሉ ሚስጥራዊ በመሆን እንደሚጠበቁ ተነግሮኛል። የወቅቱ እና የወደፊት የህክምና አገልግሎቶች ከጥናቱ ብወጣ ወይም ለመሳተፍ ፍላጎቱ ባይኖረኝ ተጽኖ እንደማይደርስባቸው ተረድቻለሁ ።

እስማማለሁ _____ አልስማም _____

ስለዚህ በዚህ ጥናት ላይ እንድሳተፍ በነጻነት ፍቃዴን ሰጥቻለሁ።

የተሳታፊው ኮድ : _____

ፊርማ: _____ ቀን : _____

የተመራማሪው ስም: _____ ፊርማ : _____

ቀን : _____

አባረ(Annex)X: የመረጃቅጽ(Information Sheet) የአማርኛው ቅጂ(Amharic Version)

የፕሮጀክቱ ርዕስ : በአዲስ አበባ ኢትዮጵያ በሚገኙ ሆስፒታሎች ውስጥ የሚሰሩ የህክምና ላብራቶሪ ባለሙያዎች በግራም ስቴይን ምርመራ እና ትርጓሜ ላይ ያላቸው ብቃት መመዘን

የዋነኛ ተመራማሪው ስም: አዱኛ ፀሃይ

ተቋም : አዲስ አበባ ዩኒቨርሲቲ

የአስፖንሰሩ ስም: አርማወር ሃሰን ሪሰርች ኢንስቲትዩት

ይህ የመጀረጃ ቅጽ ከፍ ብሎ ርዕሱ በተመለከተው ፕሮጀክት ውስጥ ተሳታፊ ለሚሆኑ የህክምና ላብራቶሪ ባለሙያዎች የተዘጋጀ ነው። በበጎ ፍቃደኝነት እንዲሰታፉ በመጠየቅ እና በጥናቱ ስለተከናወነው ሙሉ ሂደት የምንገባችሁ ይሆናል።

መግለጫ እና የጥናቱ አላማ

ግራም ስቴይን ባክቴሪያን በሁለት ክፍሎች ለመለያየት አሁንም በከፍተኛ ሁኔታ በንቃት ጥቅም ላይ እየዋለ ያለ ክላሲክ ባይሎጂካል አካሄድ ነው። ግራም - ፖዘቲቭ ሴሎች ቀለም በዋነኛነት ተይዘባቸው የሚቆይ ሲሆን ግራም ኔጌቲቭ ሴሎች ዋና ቀለማቸው የጠፋ ናቸው። ግራም ስቴይን አንዱ በተደጋጋሚ ሁኔታ የሚከናወን የላብራቶሪ ምርመራ ቅደም ተከተል ነው። የግራም ስቴይን ትርጓሜ የባክቴሪያ ቁስለትን መኖር ወይም አለመኖር በተመለከተ እና በቁስለት ሂደት ላይ ተሳታፊ የሆኑ የባክቴሪያ ሞርኮ ታይፕስ ላይ ፈጣን የሆነ መረጃን ይሰጣል። ይህም ወደ ሆስፒታል ገብቶ ለመታከም እና ህክምና ለማስጀመር እንደ መሰረት ሆኖ ሊያገለግል የሚችል ሲሆን እንዲሁም የአንቲ ባዮቲክ ህክምናን የመነሻ ምርጫ ሊሆን ይችላል። ይሁን እና በዚህ የጥናት አካባቢ የህክምና ላብራቶሪ ባለሙያዎች ብቃት በሚገባ አይታወቅም። ስለዚህ ይህ ጥናት በአዲስ አበባ በሚገኙ ሆስፒታሎች ውስጥ የሚገኙ የህክምና ላብራቶሪ ባለሙያዎች በግራ ስቴይን ምርመራ እና ትርጓሜ ምርመራ ላይ ያላቸውን ብቃት ለመወሰን የተነደፈ ነው።

የአካሄድ ቅደም ተከተሎች

ከፍ ብሎ የተመለከተውን ጥናት ለማከናወን ከርዕሱ ጋር ተጓዳኝ የሆኑ የተወሰኑ የምርመራ ጥያቄዎች፣ ሶሻዊ ምግብ-ፊክ ባህሪዎች፣ ባለ 6 ፓኔል እስላይድ ምርመራ እና ትርጓሜ ለምርመራ ከአያንዳንዱ የጥናት ተሳታፊዎች የሚሰድ ይሆናል። የጽሁፍ ስምምነት ከአያንዳንዱ የጥናቱ ተሳታፊዎች ተወስዶ ተገቢውን ከጥናቱ ጋር የተገናኙ መረጃዎች እንዲሰጡ ይጠየቃሉ። የመረጃው ትንተና በአባይት ተመራማሪው የሚደረግ ይሆናል።

አደጋዎች እና ተግዳሮቶች : በምርመራው ወቅት እና በፓኔል አስላይዶቹ ትግበራ ወቅት እንዲሁም የምርመራ ጥያቄዎቹ መልስ በሚሰጣቸው ወቅት ምንም አይነት አደጋዎች ወይም ተግዳሮቶች የማይኖሩ ይሆናል።

ጥቅማ ጥቅሞች እና ካሳዎች : በዚህ ጥናት ላይ ተሳታፊ የሆኑ ለምሳ 50 ብር የሚከፈላቸው ይሆናል ። በተጨማሪም በጥናቱ ህግ መሰረት በሚመለከታቸው አካላት በክፍተቶች ላይ ስልጠና የሚወስዱ ይሆናል ።

ሚስጥራዊነት : በዚህ ጥናት ወቅት የተገኙ መረጃዎች ሚስጥራዊ እንደሆኑ ይቀጥላሉ። መረጃ ከተሰጠበት ስምምነት ውስጥ ካልተፈቀደላቸው አካላት በስተቀር ለማናቸውም ሶስተኛ ወገኖች መረጃ ይፋ ማድረግ አይፈቀድም። ሪከርዶች ሚስጥራዊ እንሆኑ ይቀጥላሉ። ሚስጥራዊነትን ለመጠበቅ ተመራማሪው ሪከርዶቹን በሚቆለፉ መደርደሪያዎች ውስጥ የሚያስቀምጣቸው ሲሆን ውጤቶችም በበጎ ፍቃደኞች መለየት እንዳይችሉ በኮድ ምልክት ይደረግባቸዋል። የሚተወ መብቶች፣ ለእነርሱ ከጥናቱ በማንኛውም ጊዜ መውጣት እንደሚችሉ ነጻነቱ እንዳላቸው እንዲሁም ለትምህርት ወይም ለሌላ አገልግሎቶች መገለል እንደማይደረግባቸው አረጋግጬላቸዋለሁ።

ማንን ማግኘት ይችላሉ። የሚከተሉት የግንኙነት አድራሻዎች በማንኛውም ጊዜ ተመራማሪዎችን ማግኘት እንዲቻል ተስጥቷል።

የተመራማሪዎች ስም: አዱኛ ፀሃይ የስልክ ቁጥር: 09 29 1358 19

ኢሜይል : delmemorise@yahoo.com

የአማካሪው ስም : ካሱ ደስታ (ቢኤስሲ፣ ኤምኤስሲ፣ ፒኤችዲ እጩ፣ አአዩ)

አዳነ ምህረት(ዲቪም ፣ኤምኤስሲ ፣ፒኤችዲ ፣ አርማወር ሃንሰን የምርምር ተቋም)

ሀልምነህ ስንሻው (ኤምዲ፣ ኤምፒኤች፣ ዳይሬክተር፣ የህክምና አካሄድ እና ውጤት ምርምር፣ የአሜሪካ ካንሰር ማህበረሰብ)

ኪሩቤል እሸቱ (ቢኤስሲ፣ ኤምኤስሲ፣ የተሰማሚነት እና የጥራት ምዘና ስራ አስኪያጅ፣ አለም አቀፍ የክሊኒካል ላብራቶሪስ)

Annex XI: Declaration

Title of Project: Competency Assessment on Gram stain Examination and Interpretation among Medical Laboratory Professionals working in selected Hospitals of Addis Ababa, Ethiopia

I, the undersigned, declare that this MSc research project is my original work. It has not been presented for a degree in any other University. False statements could be cause for invalidating this research project and may lead to other administrative or legal action.

Principal investigator: Adugna Tsehay

Address: Department of Medical Laboratory Sciences, AAU

Signature: _____ Date: _____

Advisors: Kassu Desta (BSc, MSc, PhD Candidate)

Address: Department of Medical Laboratory Sciences, AAU

Signature: _____ Date: _____

Adane Mihret (DVM, MSc, PhD)

Address: Armauer Hansen Research Institute (AHRI)

Signature: _____ Date: _____