Addis Ababa University
College of Heath Science
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Assessment of Quality Assurance practice and proficiency of HIV rapid testing providers at point of care sites in selected public health facility of Addis Ababa, Ethiopia

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This is to testify that the thesis is prepared by Sisay Tulu, which is entitled "**Assessment of Quality Assurance practice and proficiency of HIV rapid testing providers at point of care sites in selected public health facility of Addis Ababa, Ethiopia"** and submitted in partial fulfillment of the requirements for the degree of Master of Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abbreviations

AAU	Addis Ababa University
ART	Antiretroviral Treatment
DTS	Dry Tube Sample
EDHS	Ethiopian Demographic Health Survey
EQA	External Quality Assurance
HIV	Human Immunodeficiency virus
IFRR	Internal Facility Report and Receipt
ISO	International Organization for Standardization
OPD	Outpatient Department
PHC	Public Health Clinic
PICT	Provider-Initiated Testing and Counseling
PMTCT	Prevention of Mother-To-Child Transmission
POCT	Point of Care Testing
PT	Proficiency Testing
QA	Quality Assurance
SNNPR	South Nation and Nationality People Region
SOP	Standard Operation Procedure
TAT	Turn-Around-Time
UNAIDS	Joint United Nations Program on HIV/AIDS
VCT	Voluntary HIV Counseling and Testing
WHO	World health organization

Abstract

Background: The implementation of HIV point-of-care testing technologies reduced turn-around-time (TAT), pre-analytical errors and sample transporting errors. But, it increased the complexity of QA implementation because it involves non laboratorians and outspread the testing sites to be covered by Proficiency testing.

Objectives: To assess quality assurance practice for HIV rapid testing services at point of care sites in public health facilities in Addis Ababa, Ethiopia

Methods: A cross-sectional prospective study was conducted based on random sampling technique in 3 hospitals and 41 health centers which included 265 point of care HIV rapid testing sites. Conveniently 310 HIV Rapid Test providers were also included. Standardized Checklists were used for the assessment. Data were captured, cleaned and analyzed using SPSS version 20.

Results: HIV rapid testing sites had 65.59% performance score. Of the 265 point of care HIV rapid testing sites that were evaluated On-site, 0.4% of them have Zero level performance which Needs improvement in all areas and immediate remediation. One level performance was noted in 27.2% of testing points which needs improvement in specific areas; and 64.2% of testing points have level two performance which means partly eligible for HIV rapid testing. Three level performances that is close to national site certification is seen in 7.9% of testing points. Among 310 HIV rapid testing providers, 302 (97.4%) could correctly detect negative and positive panel samples. Eight (2.6%) had discordant result during screening test (test one) among these 3(37.5%) had false positive reports that corrected through the algorithm on the final result; 4 (50%) had false negative reports and 1(10%) was report as invalid. In the onsite checklist, lack of SOP for safety, use of expired Kits, lack of clean water for hand washing at testing sites, data management of quality elements of Registrations book contents and lack of personnel training on internal quality control and External quality assurance, lack of timer, were mentioned as a major bottle neck for quality performance.

Conclusion: HIV rapid testing sites had 65.59% performance score which is below 80 %. HIV rapid testing providers scored 99.40% for proficiency panel testing which is below acceptable score of 100%. False negative results need attention since positives are released to the community due to misdiagnosis. Immediate intervention is needed on the identified findings.

Key words: External Quality Assurance, proficiency testing, onsite evaluation, HIV Point of care testing

1. Introduction

1.1. Background

According WHO 2017 report, from early 1980's more than 70 million people have been infected with human immunodeficiency virus (HIV) and about 35 million people have died of HIV. Globally, 36.7 million [30.8–42.9 million] people were living with HIV until the end of 2017. About 0.8% [0.7-0.9%] of adults aged 15–49 years worldwide are living with HIV, although the epidemic burden has continued to vary considerably in the Number countries and regions. Sub-Saharan Africa remains most severely affected, with nearly 1 in every 25 adults (4.2%) living with HIV (1).

With regards to Ethiopia, HIV/AIDS continues to be characterized by a low-intensity, mixed epidemic with significant heterogeneity across geographic areas and defined by independent self-sustaining HIV transmission streams within different population groups (2). According to single point HIV related estimates and projections for Ethiopia 2017, the national HIV prevalence is 1.16%. The recent 2011 Ethiopian demographic and health survey (EDHS) have shown that the urban prevalence is 4.2% which is seven times higher than that of the rural (0.6%). The 2011 EDHS also shows that the HIV prevalence varies from region to region ranging from 0.9% in SNNPR to 6.5% in Gambela. Furthermore, the HIV related estimates and projections indicate that the 2017 HIV prevalence in regions ranges from 0.57 % Southern nations and nationalities people (SNNP) to 5.0% Adds Ababa (3).

HIV rapid testing is a key tool in the fight against the HIV/AIDS epidemic. It enables the rapid expansion of prevention and treatment programs in resource limited countries. HIV testing sites include national and regional laboratories, blood donation centers, hospitals and health centers at antenatal clinics (mother and child health facilities), tuberculosis (TB) clinic, out patient department (OPD), facility based and stand-alone counseling and testing centers and mobile facilities. Ensuring the quality of HIV rapid testing presents unique challenges in that testing is often performed in various settings by personnel without formal laboratory training (4). Quality assurance (QA) is the series of procedures employed to evaluate all systems and processes in order to identify problems, correct them, and continue to enhance the level of performance in all phases of testing. QA includes quality planning, implementation, monitoring, and assessment (5).

Quality standards are an integral part of any laboratory testing, but especially POC testing as meant to be performed by non-laboratory trained staff. Quality control (QC) testing and proficiency testing (PT) are integral components of a quality system to monitor analytical performance in the laboratory and at the point of care. These two processes check the quality of a device's performance by comparing observed results of QC testing or PT with a target with pre-set specifications. QC testing provides an immediate check of quality, while PT provides a delayed peer-reviewed, external assessment of quality (6).

Quality of the test results produced in any setting is critical to the success of HIV and AIDS programs. In order to ensure the quality of testing and minimize errors, a quality system that addresses all aspects of the testing (policies, processes, procedures and any other activities) is essential. Assessing quality assurance practice and competence performance in point of care HIV testing sites enables to identify gaps early and act accordingly to ensure quality of HIV testing by non-laboratory personnel.

1.2. Statement of the problem

Even though HIV-related point-of-care testing technologies have a potential to play a major role in achieving the UNAIDS 90–90–90 targets through increasing access to diagnostics in low- and middle-income countries, there are associated challenges regarding ensuring accurate patient results and maintaining a high quality of testing (7). Possibly inaccurate diagnoses can have devastating consequences for an individual, resulting in stigma, loss of family, loss of job and loss of other opportunities. Expanding point-of-care testing in resource-limited countries required sustainable quality assurance practices that lead to accurate, reliable patient results and improved public health outcomes (8).

The majority sites of HIV testing in resource-limited Number of testing sites were dependent on rapid tests performed by trained health-care professionals and resulting in an expanded need to monitor the quality of testing procedures and ensure the accuracy of the results (9).

External quality assurance (EQA) or proficiency testing for point-of-care (POC) testing is in principle similar to EQA for larger hospital laboratories, but the participants are different. The participants are usually health care personnel with little or no knowledge of laboratory medicine. Therefore, it is important to convince the participants that participation in EQA schemes needs capacity to circulate materials and provide feedback reports with reasonable time intervals and offer help and guidance to the participants when needed. EQA are important for POC testing to address the accuracy and reliability of the pre-examination, the examination and the post-examination processes (10).

Since the emerge of POC tests has the potential to improve health care services and patient centered outcomes in diverse settings, particularly those with limited health service or laboratory infrastructure. They improve patient care especially in outreach settings for hard to reach groups for preventing new HIV infections, reducing the number of HIV individuals who are unaware of their status, and promoting linkage of HIV-positive individuals to care. However, it has challenges in the implementation of quality assurance practices (11, 12).

POCT devices are affected by several environmental and operator-related factors also there are significant challenges on quality assurance. The pre-, intra-, and post-analytic processes of HIV POCT/PHICT quality assurance practice and test provider competence at all testing sites, just as centralized laboratories impose great challenge (13).

POCT has created new challenges, and sources of potential errors; moreover, while the upsurge in its use has generated concerns regarding the quality of test results, and the risk of errors in POCT based on all steps in the entire testing process, including test requesting and result utilization. (14) Quality control measures, which are routinely used in laboratories, have not been widely implemented for POCTs. The World Health Organization and US Centers for Disease Control and Prevention advocate the implementation of POCT with a quality assurance method in place (15). Therefore, it needs an urgent evaluation of errors and risks of error in POCT that is based on the entire testing process and uses well-designed studies aiming to improve clinical outcomes and increase patient safety.

Furthermore, in HIV programs there are large inaccurate result reports for instance in the Democratic Republic of Congo, Burundi, and Ethiopia, 10.3%, 2.6%, and 4.7% false positive HIV results, respectively, were given to participants with devastating consequences of abandonment by partners and inappropriate initiation on treatment (16). The implementation of point-of-care testing technologies involving the use of non-laboratorians in routine testing has further increased the complexity of QA. (17) Therefore, this study will be important to understand the limitation of quality assurance practice on HIV testing at point of service (POCT). The implementation of point-of-care testing technologies involving the use of non-laboratorians in routine testing has further increased the complexity of QA (16, 17). Also, it will be important to understand the limitation of external quality assurance practice on HIV testing at point of service (POCT).

1.3. Significance of the study

The aim of this study was to get some preliminary insights on the Quality assurance practice at HIV testing site by non-laboratory professional POCT provider. It helps to identify gaps and inspire health facilities as well as HIV test providers towards ensuring standardized diagnostic efficiencies. The finding is also helpful to create improvement on logistic management and testing site set up and safety.

In addition to these, identifying gaps associated with POCT quality for appropriate action plays essential role to grow public interest in the quality of health care, increasing public expectations from POCT providers, and increase client confidence. It also builds staff awareness quality service provision, improves HIV testing provider performance and competitiveness, establish strong proficiency testing and HIV POCT site supervision; and evaluating each HIV testing provision site based on WHO standards.

Ultimately it provides information to decision makers and program managers that could improve the implementation of 90-90-90 UNAIDS strategy goal, which are 90% of HIV-positive people are diagnosed by 2020, 90% of HIV-positive patients are on antiretroviral therapy, and 90% of HIV-positive patients achieve viral suppression at large(18). This kind of assessment is also considered as an excellent exercise for standardizing POCT for accreditation purpose at national and international levels as indicated by ISO 22870:2016.

2. Literature Review

2.1. Literature review on quality assurance of HIV rapid Testing at point of care

Implementation of POCTs demands strong quality assurance system at all phases (Pre-analytical, analytical and post analytical). Studies have revealed errors associated with POCTs with weak quality assurance mechanisms. For example, a study conducted in London by Sacks R., *et.al* on Rapid HIV testing using Determine TM HIV 1/2 antibody tests showed that HIV point-of-care tests (POCTs) give occasional false positive results, causing unnecessary patient anxiety. According to the researchers Seventeen false- and Seventeen true-positive serum samples were randomized into pairs, comprising one false- and one true-positive sample. Among the sample provided all true-positive samples were identified positive and 8/17 false-positive samples turned negative, on repeat testing of stored sera (19).

The pilot survey conducted by Centers for Medicare and Medicaid Services of USA in 2005 has been reviewed by Meier and Jones on the Point-of-care testing error sources , amplifiers, prevention strategies, and detection monitors summarized that 19% of testing personnel had been neither trained nor evaluated in the performance of the assays they carried out. Moreover,32% of the observed test operators could not locate test instructions when asked to refer to them, 25% of test operators failed to follow manufacturer's directions,7% of test operators did not perform required calibrations,32% of test operators failed to perform quality control (QC)" (as specified), 6% (of test operators) use expired reagent kits, whose integrity manufacturers would no longer guarantee (20).

Another study conducted in South India on External Quality Assurance Scheme in a National Reference Laboratory for HIV Testing indicated that out of 9419 samples tested for QC, 9371 (99.49%) reported correct results and 48 (0.50%) gave discordant results. Out of 48 samples 26 (0.27%) were false positives and 22 (0.23%) false negative. Mislabeling, sample contamination, leaking vials, transcriptional errors; tests that were not performed correctly were identified as main challenges. For proficiency testing, 91.8% reported back test results. Of them, 645 (97.13%) reported correct results and 19 (2.86%) reported incorrect results. Out of 465 samples, 7 (1.05%) were false positive and 12 (1.80%) were false negative (21).

Rapid assessment of quality and field performance of HIV Rapid Diagnostic Tests conducted in three African countries Kenya, Uganda, and Malawi, in 2012 showed the following

implementation and results of QA/QC. In Uganda, a few larger, better resourced, more central labs reported doing retesting with known positives/negatives on a regular basis (e.g., with each new batch of test kits). PT was conducted on less than 10% of HIV testing facilities. Some reports of QA implementation in Uganda (including ten testing sites) reported a 3% to 18% discordance rate with average of 12% discordance. PT performance increased from 60% passing to 95% (with 10 sites participating) (22).

In Kenya, the same study reported that at lower-level facilities QC monitoring was done but was not conducted regularly, consistently, nor rigorously and PT participation rate has increased up to 50%. Results indicated 40% discordance in early efforts, reduced to 5% in the most recent rounds. Since October 2011, Kenya selects individual testers instead of facilities for EQA. Some failing grades may be attributed to users learning to conduct PT. For example, assessors heard from interviewees that they did not know they needed to reconstitute the panel specimens within 24 hours, store within certain temperatures, and conduct the tests on the panel samples according to the algorithm. In Malawi, QC is reported to be conducted on a daily or weekly basis depending on the volumes handled at the facility. In addition, facilities are instructed to conduct QC using predetermined control samples once a new batch will be used. Only central hospitals and testing centers with high demand use dry blood spots for QC. Malawi also reported only 60% PT following immediate training. Testers are paired with experienced counselors until they acquire proficiency. After testers go on their own, there were report of PT of 85% for lay workers and approximately 95% for trained health workers (22).

Another study conducted in Zambia on laboratory and non-laboratory personnel based on observations from the National HIV Proficiency Testing System indicated that, in PT exercises, lay counselors and nurses had more difficulties on interpreting results, with more occurrences of false-negative, false-positive and indeterminate results. Having received the standard HIV rapid testing training and adherence to the national HIV testing algorithm were positively associated with accuracy (23).

Whereas the evaluation of the HIV lay counseling and testing profession conducted in South Africa by Mwisongo *et al.* in 2015 revealed that almost all the lay counselors 31 (96.8 %) had received formal training in HIV testing and four of the six counselors had not received formal training in HIV testing. The majority of the lay counselors (24,75 %) had testing experience of between a few months and five years. Generally this study demonstrates that HCT counseling

and testing services in South Africa are mainly performed by lay counselors and testers. They are challenged by inadequate work space, a lack of standardized training policies (24).

According to experiences from a National Reference Hospital Zambia, most study participant performing an HIV rapid test reported the test to be easy. Some particularly lay counselors have difficulties in finger pricking and blood drawing as revealed by Mwangala *et al.* in 2015 on Task-Shifting and Quality of HIV Testing Services assessment study. Sometimes they have fault to adhere to certain procedures, partly due to non-availability of reagents such as the buffer and having to substitute with other test kit buffers or normal saline. Non-availability of test kits, particularly confirmatory test kits due to delays or inadequate supplies from the national distributor, Medical Stores Limited (MSL), was seen to lead to non-adherence to the testing algorithm, and participation in quality assurance programs. Though the providers reported to be carrying out internal quality control (IQC), i.e. a measure to ensure test precision is optimal, most and particularly non-laboratory providers reported that it was not being done consistently as per guidelines. All providers reported to be participating in the external quality assessment (EQA) program conducted by the Zambia National Quality Assurance Program (ZANQAP) of the NRL. Most providers expressed the importance of such activities to monitor their performance in HIV testing, but suggested more frequency to ensure proficiency. Generally this study concluded that Task-shifting coupled with policy shifts in service provision have challenged quality of testing service (25).

Despite its usefulness, funding limitations are challenges to sustain quality assurance programs for POCTs. One such example was a study which was conducted in Zimbabwe on Quality assurance for point-of-care testing in HIV and related testing. EQA implementation composed of proficiency testing panels were prepared in-house by Zimbabwe National Quality Assurance Program and distributed to participating sites on a monthly basis. However, less than 5% of sites are currently on the EQA program (26).

Study conducted in South Africa on evaluating quality management systems for HIV rapid testing services in primary healthcare clinics, showed that rural PHC clinics' average rating score for compliance to the WHO guidelines ranged between 64.4% and 89.2%. Ten out of eleven of the clinics were rated as moderate 70-89% based on WHO evaluation. All clinics have scored highest for the following audit component: equipment; process control and specimen management; and facility and safety, with 100%. Clinics obtained the lowest scores for the

assessment audit component followed by process improvement and organization, with 40.9%, 45.5% and 56.8% respectively, (27).

The Assessment of quality assurance program of *HIV* testing in Addis Ababa Hospitals and Clinics was conducted in 2012 by Regasa B. The study revealed that out of 20 assessed hospitals and clinics cases, 3(14%) laboratory personnel's who conduct HIV testing were found to have no training in HIV testing. Some laboratories 2 (10%) do not follow HIV testing algorithm and also 2 (10%) laboratory personnel's do not know what to do in case of indeterminate result. All laboratories use controls that are supplied with kit but 2 (10%) laboratories use external control (pooled sera) additionally. Seventeen (85%) uses manual (guidelines) supplied with kits but none of them uses SOPs (Standard operating procedures). There was poor participation in EQA (External Quality Assessment) program (50%). This study concluded that there is lack of qualified human resources, not following HIV testing algorithm and poor participation in External quality assessment program (28).

Even through Ethiopia states strategy for the implementation of point-of-care technologies through federal ministry of health, there is research gap on quality assurance, staff proficiency for testing and results interpretation. Therefore, this study will try to address the gap on practice of quality assurance and testing sites and staff performance of HIV rapid testing service provider in selected Addis Ababa health facilities.

2.2. Conceptual framework

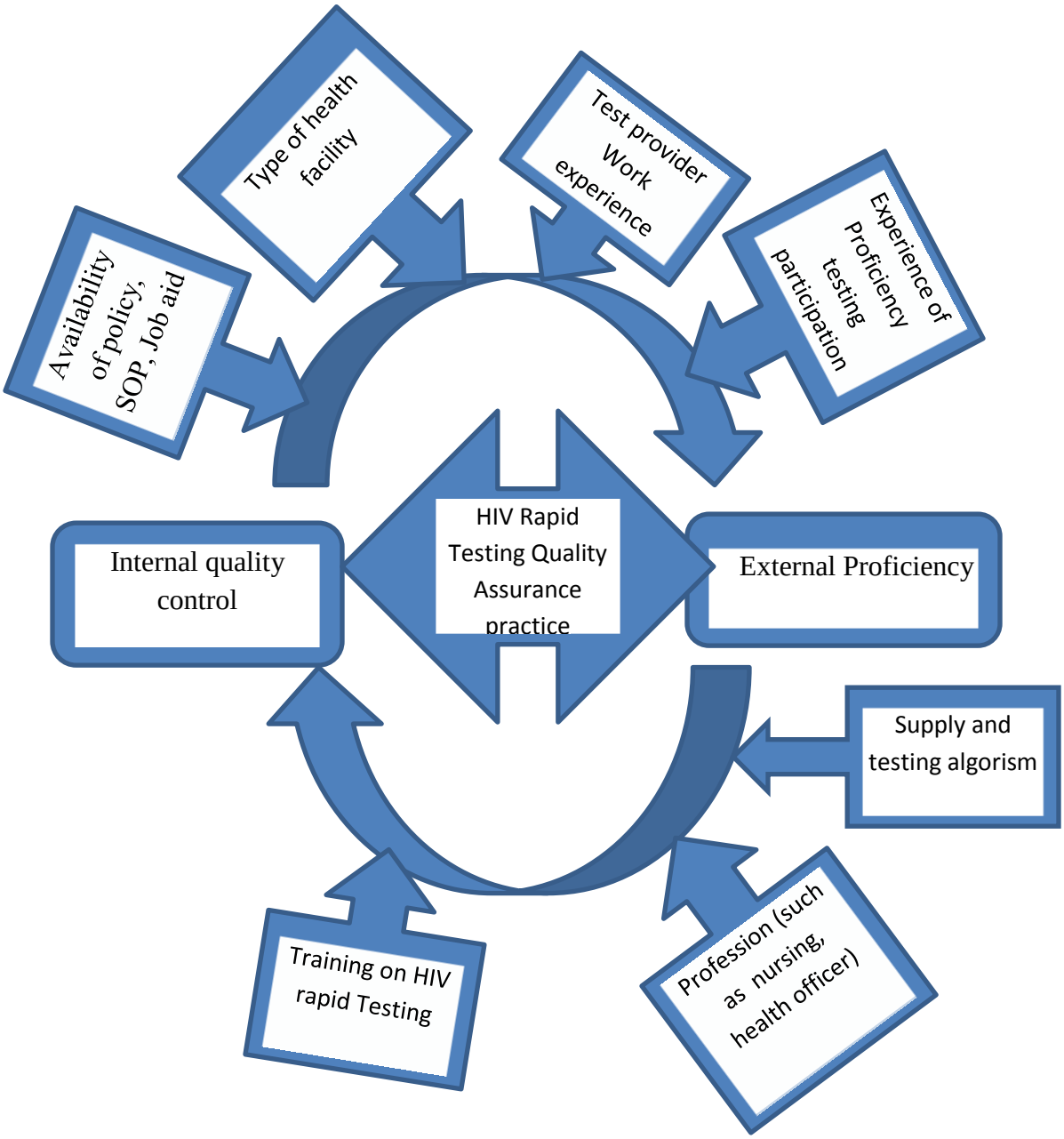

Figure 1; Conceptual framework (20, 21, 22, 23, 26, 27)

3. Objective

3.1. General objective

- To assess Quality Assurance practice and proficiency performance of HIV rapid testing provider at point of care in selected public health facility of Addis Ababa from January to April 2018

3.2. Specific objectives

- To assess quality assurance practice of HIV rapid testing at point of care site
- To evaluate proficiency performance of HIV rapid testing providers at point of care site

4. Hypothesis

- Alternative Hypothesis:- HIV rapid testing site at point of care in Addis Ababa public health facilities score below 80 %.
- Alternative Hypothesis:- Overall proficiency performance of HIV rapid testing services provider at point of care in Addis Ababa public health facilities is lower than 100%.

5. Materials and Methods

5.1. Study area

This study was conducted in Addis Ababa, a capital city of the Federal Republic of Ethiopia and seat for economic commission of Africa and the Africa Union. The city is divided for administrative purpose into 10 sub cities and 116 woreda in which above 3 million residents are residing.

There are about 500 health facilities in Addis Ababa which range from government specialized hospitals to privately owned ones, from higher clinics to lower clinics and health centers. There are 30 hospitals, 103 health centers, 94 special clinics, 99 higher clinics, 146 medium clinics, and 103 lower clinics. Among these health facilities, 6 hospitals and 103 health centers are ruled by Addis Ababa City administration health bureau and provide HIV rapid Test at least at, Voluntary testing and counseling (VCT), Provider-initiated testing and counseling (PICT), Services for preventing mother-to-child transmission (PMTCT), and at TB clinic. The study area of this research was public health facilities that are providing HIV rapid test service at point of cares sites and found in Kolfe Keranio,Gulele, Yerka , Kirkos , Arada , Addis Ketema and Akaki Kality sub cities of Addis Ababa city administration.

5.2. Study design and period

Cross-sectional study was conducted in Addis Ababa selected public health facilities that provide HIV rapid testing services at point of care sites from January-April, 2018.

5.3. Population:

5.3.1. Source population

Source populations were all Public health facilities in Addis Ababa which provide HIV rapid testing services at point of care sites and the service providers working at selected facilities..

5.3.2. Study population

Selected Public health facilities as well as test providers in Addis Ababa which provide HIV rapid testing services at point of care sites.

5.4. Inclusion criteria

All selected public health facilities that provide HIV rapid testing at point of care sites and health care provider who perform HIV test at POC and actively on duty during the study period and willing to participate.

5.5. Study variables

5.5.1. Dependent variables

- Level of Quality assurance practice
- Proficiency performance

5.5.2. Independent variables:

- Age
- Sex
- Profession (such as nursing, health officer, midwifery)
- Experience of Proficiency testing participation
- Types of testing point (e.g ANC, VCT)

5.6. Sample size calculation and Sampling technique

5.6.1. Sample size determination

A total of 3 hospitals and 41 health centers; totally 44 public health facilities were included. All HIV rapid testing points in selected participant facilities and all HIV rapid testing providers at point of care in the selected participant health facilities during the onsite evaluation were included.

On the other hand, in order to calculate the sample size for point of care testing provider, single population proportion formula was implemented, [n = (Z _/2)2 p (1-p) / d2], . Due to lack of previous such studies showing the proportion of competency performance evaluation, the following assumptions was made: proficiency testing proportion of HIV testing provider conceded as 50% (p = 0.5), , **Z** α**/2** = 1.96 and absolute precision or margin of error to be 5% (d

= 0.05). Computing with the above formula gives a total sample size of 384. However, 20% were not available for evaluation. Therefore, this study conveniently evaluated 310 HIV rapid testing provider at testing sites in the selected health facility during the onsite evaluation

$n = \underline{z\ (a/2)^2\ p\ (1-p)/}\ d^2$

Sample size =n

Level of significance =0.05

Marginal of error (d) = 5%

Z a/2 = Z-score at 95% confidence interval; which is 1.96

$n = \underline{z\ (a/2)^2 p\ (1-p)}$

d^2

$n = \underline{(1.96)^2\ 0.5(1-0.5)}\ = \underline{384}$

$(0.05)^2$

n=384-**0.2**(384) =310

5.6.2. Sampling Method

Simple random sampling technique was used in order to select the participating hospitals and health centers. On the other hand, convenient sampling technique was applied in order to select health professionals providing HIV rapid testing at POC testing sites from the selected hospitals and health centers.

5.7. Data collection procedure

Before data collection begins, letters of support from AAU, Department of Medical Laboratory Sciences were obtained and submitted to Addis Ababa city administration health bureau. After permission is secured from Addis Ababa city administration health bureau, it was presented to study participating facilities. After obtaining permission from the respective health facilities, data for this study were collected with well standard adopted WHO checklist through direct observation from HIV testing sites (VCT, PMTCT, PICT, and TB clinic, and others) and also during the onsite evaluation and consecutively questioning of skill of the service providers. Proficiency testing was conducted using proficiency testing panel samples that were presented

with standard report format evaluation to HIV rapid testing services provider at site. Thus, three methods namely panel testing, direct observation and questionnaire were employed.

5.7.1. Laboratory analyses

5.7.1.1. Testing Panel preparation

Serum or plasma or whole blood used to EQA panels preparation was obtained from Ethiopian Ministry of Health National Blood Bank/ pooled sample collected from left over of viral load test. Panel was then prepared locally at Addis Ababa Health Bureau Public health Research Laboratory (AAHBRL) based on WHO Standardized protocols for preparing proficiency testing samples at a national laboratory EQA through dry tube sample (DTS) panel preparation standard procedure.

Briefly, DTS samples were made in the AAHBRL laboratory by mixing to serum/plasma specimen 1:1001 dilutions. This means, 5 µl of green dye was added to 5 ml of positive or negative plasma specimen. After shaking well (vortexing) the specimen was mixed with the dye. Then 20 µl of colored serum or plasma specimen was transferred to each small tube ensuring that each specimen is aliquotted in properly labeled tubes. The tubes were uncapped in a biosafety cabinet and let to dry overnight at room temperature. Positive and negative specimens were kept in separate racks in a biosafety cabinet. On the following day, it was ensured that the specimens have dried completely before capping each tube and a visible colored pellet is formed at the bottom of the tube.

To ensure the quality of panel testing samples, it was verified by expert laboratory technologist based on National HIV rapid test algorism before and after DTS preparation. All safety precautions were taken because they are highly infectious. The DTS panel specimens are stable up to 37^{o}C, including during storage and transport, and can be transported at room temperature without the need for maintaining an expensive cold chain. Once received at the testing facility, the specimens can be stored at room temperature for up to 4 weeks without negatively affecting their integrity (24).

5.7.1.2. DTS Panel testing

EQA panels were distributed to participant testing sites to detect the presence or absence of a HIV1/2 Antibody in a panel. The panels were well characterized at AAHBRL by qualified laboratory scientists before being distributed to participants. Carefully five coded panel samples

with combination of three negative and two positive were blindly distributed to all participant health facility sites and provided to the respective study participants to check antibody reactivity for HIV.

These proficiency panels were sent to the sites from April 1, 2018 till April 15, 2018. At the point of care where HIV rapid testing is carried out, Laboratory personnel were expected to reconstitute the DTS with PBS-tween 20 buffer saline which was provided with panel samples and the reconstituted serum was used to test the HIV status of the serum. Results were recorded on prepared form and collected back by the principal investigator.

5.8. Data quality assurance

To assure data quality, proficiency testing panel material was prepared according to standard procedures developed by Addis Ababa Health Bureau Public Health Research Laboratory and national public health laboratory HIV external quality control team and WHO guideline. Onsite evaluation was conducted by senior laboratory technologist trained on quality management system by using standard national checklist and WHO Checklist for the stepwise process for improving the quality of HIV rapid testing which is adopted for this research.

Intensively Quality of the data was checked by reviewing for inconsistencies, irregularities and performing data cleaning of checklists, questionnaire and formats to improve data quality. Strong supervision was implemented during the process of onsite assessment, interview and DTS proficiency testing panel distribution under strong supervision of principal investigator. Data was entered twice, by different individuals independently. The two data files generated from this process was compared and any discrepancies were checked against the original data collection sheets or questionnaires. Training was provided including interviewing skills, processing procedures for DTS HIV proficiency testing, onsite assessments. Pre-testing was conducted in one federal governed hospital to evaluate flow of questions, presence of sensitive questions, appropriateness of categorization of variables, clarity of the questionnaire instructions to the interviewer and appropriate modification was made.

5.9. Data analyses and interpretation

We used standardized checklist adapted from WHO checklist to assess the status of quality assurance practice that included Personnel training related to HIV rapid testing, Physical facility, Safety, Pre-testing phase, Testing phase, Post-testing phase (documents and records) and external quality assurance to measure performance level of point of care HIV rapid testing sites in selected public health facility of Addis Ababa, Ethiopia.

The collected data was entered, cleaned and analyzed using SPSS statistical software version 20. Frequencies, proportions and mean comparison with 95% confidence interval was used to determine dependent and independent variables and Results were explained using absolute numbers, percentages.

Result interpretation was grounded on the WHO stepwise process for improving the quality of HIV rapid testing Scoring criteria and national guideline with each element being marked with an assigned point value. Items marked "yes" receive 1 point each. Items marked "partial" receive 0.5 points each. Items marked "no" receive 0 points each. The overall total points obtained by each HIV testing point audited was weighed to correspond to a specific performance level of WHO improving the quality of HIV-related point of- care testing 2015 guideline and Evaluation of HIV rapid test provider proficiency performance was scored as Satisfactory or Unsatisfactory based criteria, Correct result for each algorism have 1.0 score, document individual test result 0.5 score, invalid or wrong results or no results score 0 (If grade is 100% is Satisfactory (acceptable) and <100% is Satisfactory (unacceptable)(21).

5.10. Ethical considerations

The proposal was evaluated and cleared by Addis Ababa University, College of Health Science, School of Allied Health Science, Departmental Research and ethics review committee (DRERC), of Department of Medical Laboratory Science and a formal letter was written to the participant health facilities. The study protocol was also evaluated and approved by the Addis Ababa Health Bureau Research and Ethics committee. Moreover, privacy and confidentiality was assured for all interviewees. The right of any individual not to participate or withdraw from the study at any point was fully respected. Data collection from each study participants were started after informed consent is obtained. During data collection, there was a high degree of confidentiality. No name and other identifiers were indicated on the questionnaire. Health facilities list with codes was stored in a secured place locked and electronic files pass word protected. At the end of

the study, feedbacks were given from panel, direct observation and questionnaire findings for each health facility and AAHB.

5.11. Dissemination of results

The findings of this study will be presented to the Department of Medical Laboratory science and the result will be communicated to Addis Ababa public health Research and Emergency management core process. The result of this study will also disseminated to the scientific community through scientific presentation and publishing on different journal

5.12. Operational definitions

- **Dry tube sample:-** simple usable PT panels and quality control specimens prepared by transferring serum or plasma and mixed with green dye into tube dried at room temperature to be distributed for participants
- **HIV External Quality Assurance:** - is assessment conducted by an external laboratory to evaluate performance of HIV testing site and personnel frequently based on national quality assurance program.
- **HIV testing Algorism:-** Is the sequence of steps to follow to establish a person's HIV status that usually includes 2-3 different tests performed serially. In this case, Wantai Beijing (screening), Unigold (second test), Vikia as tie breaker
- **HIV testing process:** includes activities accomplished in pre-analytic, analytic and post-analytic procedure.
- **Non laboratory setting:-**designated area where HIV testing processed at the point of care.
- **POCT provider:** - a person provide HIV rapid testing at the site of care
- **Point of care testing:-**HIV testing performed near or at the site of a patient care
- **Point of care site:** designated unit in health facilities to provided health care service as well do HIV rapid testing
- **Proficiency performance:** is the Rate of ability to apply skills to correctly perform HIV rapid testing, transcribe and interpret correctly and evaluated by well characterized Panel sample.
- **Proficiency test:** - panels of well characterized specimens that distributed to testing sites for blind testing and the test results of the specimens are returned to reference laboratory Participants.

- **Public health facility**: - Health organization administrated by Addis Ababa city administration to provide medical service for the community
- **Quality assurance practice**: is the rate of implementing standards in testing process that designed to ensure, assess and confirm the quality tasting service provision based on standardized checklist.
- **Quality assurance practice level** :- based on overall total points obtained by each HIV testing point audited will be weighed form Level 0,Level 1,Level 2,Level 3 and Level 4 correspond to a specific performance scoring (less 40%),(41-59%),(60-79%),(80-89%) and more than 90%,respectively.

6. Results

In this study 3 hospitals and 41 health centers which are administered by Addis Ababa Health Bureau were included randomly. In addition, a total of 310 HIV Rapid Test providers who were active during the onsite assessment at their point of care sites were included conveniently.

6.1. Assessment of Quality assurance practice of health facilities

6.1.1. Types of point of cares HIV rapid testing sites

In this study, a total of 265 point of care HIV rapid testing sites were audited in a total of 44 health facilities (3 hospitals and 41 health centers). The majority of point of cares testing sites was PICT 135 (50.9%) followed by VCT 44 (16.6. Other point of care sites like operation room, recovery room, and intensive care unit accounted 1.1% (Figure 2).

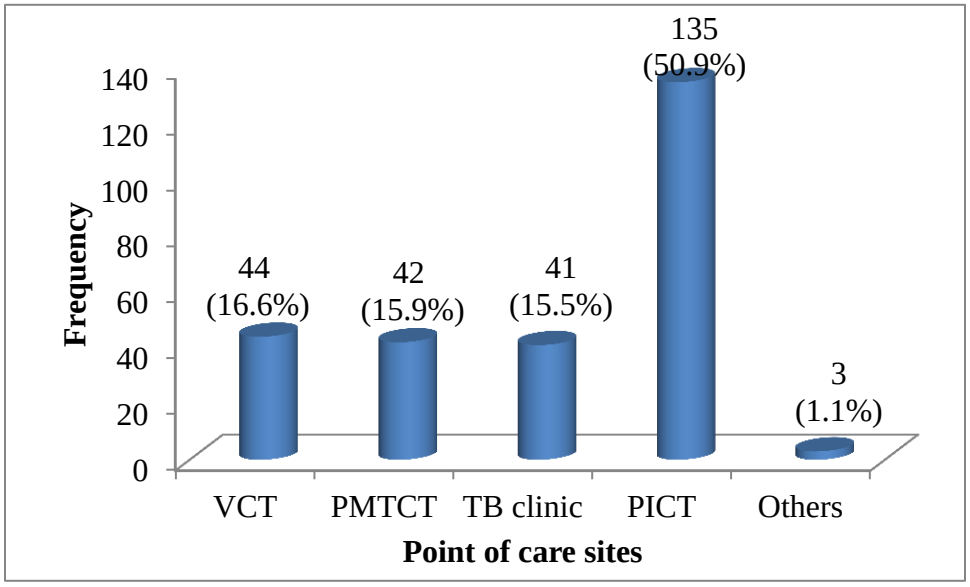

Figure 2.Types of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

6.1.2. Physical facility assessment, personnel training and safety

Based on the on-site evaluation, among the 265 point of cares HIV rapid testing sites assessed for Physical facility 29 (10.9%) did not have separate area HIV rapid testing, similar number (29, 10.9%) had no well clean and organized testing site while 250 (94.3%) had sufficient and secure storage space for test kits and other consumables and almost all point of care HIV rapid testing

site kept kits appropriately according to the manufacturer instruction at room temperature and in 255 (96.2%) point of testing area had sufficient lighting.

Table 1. Physical facilities of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Variables	Response	Number of testing sites	Percent (%)
Is there a designated area for HIV testing?	No	29	10.9
	Yes	233	87.9
	Partial	3	1.1
Is the testing area clean and organized for HIV rapid testing?	No	29	10.9
	Yes	236	89.1
	Partial	0	0.0
Is sufficient lighting available in the designated testing area?	No	10	3.8
	Yes	255	96.2
	Partial	0	0.0
Are the test kits kept appropriately according to the manufacturers' instructions?	No	2	0.8
	Yes	263	99.2
	Partial	0	0.0
Is there sufficient and secure storage space for test kits and other consumables?	No	15	5.7
	Yes	250	94.3
	Partial	0	0.0

Points of cares were also assessed for Personnel training because we expected that health care providers assigned at point of care HIV rapid testing sites were responsible for HIV rapid testing service, along with quality service. However, in 237 (89.4%) testing sites quality control training and in 40(90.6%) testing sites External quality assurance training were not provided for assigned testers. Only 66 (24.9%) testing sites had all staffs taking comprehensive training on HIV rapid testing using the nationally approved module. In 114 (44.3%) testing sites at least one of test provider had comprehensive training on HIV rapid testing using the nationally approved module among assigned staffs to provide testing. There were 26 (9.8%) staffs that perform HIV rapid testing without demonstration on new testing algorism and 63 (23.8%) point of care testing sites allowed only certified testers to perform HIV rapid testing, only 76(28.7%) point of care sites had staffs who have taken training on safety and waste management (Table 2).

Table 2. Personnel training of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Variables	Response	Number of testing sites	Percent (%)
Have all testers received comprehensive training on HIV rapid testing using the nationally approved curriculum and been certified?	No	85	32.1
	Yes	66	24.9
	Partial	114	43.0
Are the testers trained on external quality assessment or the proficiency testing process?	No	240	90.6
	Yes	1	0.4
	Partial (At Least One Of Test Provider Trained From The Site)	24	9.1
Are the testers trained on the quality control process?	No	237	89.4
	Yes	4	1.5
	Partial (At Least One Of Test Provider Trained From The Site)	24	9.1
Are the testers trained on safety and waste management procedures and practices?	No	93	35.1
	Yes	96	36.2
	Partial	76	28.7
Have testers received refresher training (demonstration) on new testing algorism?	No	26	9.8
	Yes	229	86.4
	Partial	10	3.8
Are only certified testers allowed to perform HIV testing?	No	202	76.2
	Yes	63	23.8

* Partial - at least one of test provider trained from the site

On-site evaluation of Safety issues revealed that among 265 assessed point of care HIV rapid testing sites 162(61.1%) had no standard operating procedures (SOP) and/or job aids how to dispose infectious and non-infectious waste and implement safety practices. No such documents were available in 181(68.3%) POC sites on how to manage spills of blood and other body fluids and in 162 (61.1%) on how to address accidental exposure (PEP) to potentially infectious body fluids through a needle-stick injury, splash or other sharps injury. Likewise, Clean water and soap for hand washing was not available at 94 (35.5%) sites and appropriate disinfectant to clean the work area and equipment was not available at 59 (22.3%) sites. Containers for infectious and non-infectious waste emptied regularly in accordance with the standard operating procedures and/or job aids in 251 (94.7%) and sharps, infectious and non-infectious waste handled properly in 244 (92.1%) point of care HIV rapid testing sites (Table 3).

Table 3. Safety practice of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Variables	Response	Number of testing sites	Percent (%)
Are standard operating procedures and/or job aids in place on how to dispose of infectious and non-infectious waste and implement safety practices?	No	162	61.1
	Yes	100	37.7
	Partial	3	1.1
Are standard operating procedures and/or job aids in place to manage spills of blood and other body fluids?	No	181	68.3
	Yes	84	31.7
	Partial	0	0.0
Are there standard operating procedures and/or job aids in place to address accidental exposure (PEP) to potentially infectious body fluids through a needle-stick injury, splash or other sharps injury?	No	162	61.1
	Yes	101	38.1
	Partial	2	0.8
Is personal protective equipment always available to the testers?	No	7	2.6
	Yes	258	97.4
	Partial	0	0.0
Do testers properly use personal protective equipment	No	6	2.3
	Yes	259	97.7
	Partial	0	0.0
Are clean water and soap available for hand washing?	No	94	35.5
	Yes	171	64.5
	Partial	0	0.0
Is an appropriate disinfectant available to clean the work area and equipment?	No	59	22.3
	Yes	195	73.9
	Partial	10	3.8
Are sharps and infectious and non-infectious waste handled properly?	No	8	3.0
	Yes	244	92.1
	Partial	13	4.9
Are containers for infectious and non-infectious waste emptied regularly in accordance with the standard operating procedures and/or job aids?	No	13	4.9
	Yes	251	94.7
	Partial	1	0.4

6.1.3. Assessment of pre testing, testing and post testing phases

Assessment of Pre-testing phase elements revealed that, 210 (79.2%) of points of care HIV rapid test sites had no national HIV testing guidelines/ policy manual/ that specific to the HIV rapid testing. However, 248 (93.6%) of 265 points of testing sites had HIV testing related guidelines like training manual, the mother-to-child transmission of HIV or HIV /TB, STI guidelines. In 240 (90.6%) sites standard operating procedures and/or job aids were available for each HIV rapid testing algorithm but 27 (10.2%) point of care HIV rapid testing sites did not use national HIV testing algorithm. Also alternative HIV testing algorithm was not available in case of expired test kits or shortages at 241 (90.9%) sites.

All assessed sites used only nationally approved HIV rapid testing kits. However, 45 (17.0%) sites were found while they use expired test kits during the assessment. Non labeled test kits with date and initials up on receiving were noted in191 (72.1%) points of care HIV rapid test sites. Two hundred four (77.0%) sites had a process of stocks managing and controlling system for supplies that monitors receipt, storage and use IFRR reporting system. Sufficient supplies were available to collect client samples at 260 (98.1%) testing sites during assessment but there is service interruption due to stock out in the last six month at 35 (13.2%) point of care testing sites.

Use of unique client identification system to record in the HIV testing register logbook was observed in 256 (96.6%) testing sites. Conversely, 144 (54.3%) sites were not using client unique identifiers labeled in accordance on test devices during testing up on the assessment moment (Table 4).

Table 4. Pre-testing phase of point of care HIV rapid testing sites in selected public health facilities, Addis Ababa, 2018

Variables	Response	Number of testing sites	Percent (%)
Are national testing guidelines/ policy manual/ specific to the HIV rapid testing available at the testing point?	No	210	79.2
	Yes	55	20.8
Are national HIV testing related guidelines (training manual, the mother-to-child transmission of HIV or HIV /TB, STI guideline) available at the testing point?	No	17	6.4
	Yes	248	93.6
Is the national HIV testing algorithm being used?	No	27	10.2
	Yes	234	88.3
	Partial	4	1.5
Is there a process in place for an alternative HIV testing algorithm in case of expired test kits or shortages?	No	241	90.9
	Yes	24	9.1
Are standard operating procedures and/or job aids in place for each HIV rapid test used in the testing algorithm?	No	25	9.4
	Yes	240	90.6
Are only nationally approved HIV rapid testing kits available for using currently?	No	1	0.4
	Yes	264	99.6
Are all the test kits in use within the expiration date currently?	No	45	17.0
	Yes	220	83.0
Are test kits labeled with the date received and initials?	No	191	72.1
	Yes	74	27.9
Is a process in place for managing stocks and controlling system control for supplies that monitors receipt, storage and use IFRR reporting system?	No	61	23.0
	Yes	204	77.0
Is there service interruption due to stock out last six month?	Yes	230	86.8
	No	35	13.2

Are job aids on client sample collection available and posted at the testing point?	No	36	13.6
	Yes	229	86.4
Are sufficient supplies available for collecting client samples?	No	5	1.9
	Yes	260	98.1
Are there unique client identification system recorded in the HIV testing register logbook?	No	9	3.4
	Yes	256	96.6
Are client unique identifiers recorded in the HIV testing labeled in accordance on test devices?	No	144	54.3
	Yes	121	45.7

Likewise, this study assessed testing sites for testing phase elements and found that 238 (89.8%) sites out of 265 had posted job aids on HIV testing procedures but timer was not available to be used routinely at 199 (75.1%) testing sites. Use of accurate sample collection devices such as capillary tubes, loops and disposable pipettes were practiced at 262 (98.90%) HIV testing points

Also, it was found that internal quality control processing for HIV rapid testing was practiced at 212 (80.0%) testing sites. In 156 (58.9%) testing sites internal quality control was run for HIV rapid testing by laboratory quality officer and in 51 (19.2%) by all laboratory staff but in 58 (21.8%) sites nobody had responsibility to do it. Positive and negative quality control specimens were performed when test kits opened and when new lot kits opened at 102 (38.5%) and 103 (38.9%), respectively. In the rest, Q.C were not performed (Table 5).

Table 5.Testing phase of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Variables	**Response**	**Number of testing sites**	**Percent (%)**
Are job aids on HIV testing procedures available and posted at the testing site?	No	27	10.2
	Yes	238	89.8
Are timers available and used routinely for HIV rapid testing?	No	199	75.1
	Yes	66	24.9
Are sample collection devices (such as capillary tubes, loops and disposable pipettes) used accurately?	No	3	1.1
	Yes	262	98.9
Is there internal quality control processing practice for HIV rapid testing in facilities?	No	52	19.6
	Yes	212	80.0
	Partial	1	0.4
Who is responsible to run internal quality control for HIV rapid testing?	No	58	21.9
	Laboratory quality officer	156	58.9
	All laboratory staff	51	19.2
How often positive and negative quality control specimens performed (such as daily, weekly, when new test kit open)?	No experience internal qc	60	22.6
	When test kits open	102	38.5
	When new lot purchase	103	38.9
Are quality control results properly recorded?	No	83	31.3
	Yes	171	64.5
	Partial	11	4.2
Does the person in charge routinely review quality control records?	No	84	31.7%
	Yes	177	66.8%
	Partial	4	1.5%

The 265 Points of cares HIV testing sites were audited for elements of Post-testing phase (documents and records) and we found that 250 (94.3%) testing sites had national standardized HIV rapid testing register or logbook. But, 216 (81.5%) testing sites logbooks did not have complete quality key elements like Serial No., Client or Specimen ID. Age, Sex, Date, each Kit Name, Lot No., Exp. Date, Final results, and Operator Name /Initial. Most of HIV testing register logbooks did not include Kit Name, Lot No., Exp., Final results, Operator Name /Initial. From these 265 studied sites only 35(13.2%) testing sites captured or recorded correctly all the elements such as client demographics, kit names, lot numbers, expiration dates, tester name and individual and final HIV results in the register or logbook. Large number of the sites 232 (87.5%) had their register or logbooks not having total summary at the end of each page. All registers or logbooks and other documents kept in a secure place in 217 (81.9%) point of care HIV rapid testing sites. All client documents and records securely kept throughout the testing process in 205 (77.4%) (Table 6).

This study found that 54 (20.4%) studied sites did not recorded invalid test results in the register or logbook and invalid tests were not repeated and the results were not properly recorded in the register or logbook in16 (6.0%) testing sites (Table 6).

Table 6. Post-testing phase of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa,2018

Variables	Response	Number of testing sites	Percent %
Is there a national standardized HIV rapid testing register or logbook available and in use?	No	15	5.7
	Yes	250	94.3
Does the HIV testing register or logbook include all the key quality elements like Serial No., Client or Specimen ID. Age, Sex, Date, each Kit Name, Lot No., Exp. Date, Final results, Operator Name /Initials?	No	4	1.5
	Yes	45	17.0
	Partial	216	81.5
Are all the elements in the register or logbook recorded or captured correctly (such as client demographics, kit names, lot numbers, expiration dates, tester name and individual and final HIV results)?	No	4	1.5
	Yes	35	13.2
	Partial	226	85.3
Is the total summary at the end of each page of the register or logbooks completed accurately?	No	232	87.5
	Yes	28	10.6
	Partial	5	1.9
Are invalid test results recorded in the register or logbook?	No	54	20.4
	Yes	201	75.8
	Partial	10	3.8
Are invalid tests repeated and the results properly recorded in the register or logbook?	No	16	6.0
	Yes	224	84.5
	Partial	25	9.4

Are all client documents and records securely kept throughout the testing process?	No	43	16.2
	Yes	205	77.4
	Partial	17	6.4
Are all registers or logbooks and other documents kept in a secure place?	No	31	11.7
	Yes	222	83.8
	Partial	12	4.5
Are registers or logbooks properly labeled and archived when full?	No	34	12.8
	Yes	217	81.9
	Partial	14	5.3

6.1.4. Assessment of external quality assurance elements

This assessment addresses External quality assurance elements and ratifies that most 254 (95.8%) of testing points have received periodic supervisory visits. But there are large gap in External quality audit through proficiency testing by facility laboratory or regional laboratory that means 233 (87.9%) testing sites were not addressed by External quality assurance.

Also feedback provided during supervisory visit was documented only in 84 (31.7%) testing sites. Out of assessed 265 sites, 152 (57.4%) testing points partially implement corrective action in case of unsatisfactory results. Most testing sites184 (69.4%) have assigned responsible laboratory person for technical support if testers need to be supported.

User HIV testing confidentiality complaint receiving tools like suggestion box or Notebooks available, reviewed periodically and feedback provided in 208 (78.5%) out of total 265 participant testing sites. Finally, the presence of strong internal referral linkage system and feedback between POCT site and ART service was endorsed by 229 (86.4%) point of care HIV rapid testing sites (Table 7)

Table 7. External quality assurance phase of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Variables	Response	Number of testing sites	Percent %
Does the testing point receive periodic supervisory visits?	No	11	4.2
	Yes	254	95.8
Is there External quality audit through proficiency testing, or supervision by facility laboratory or regional laboratory?	No	233	87.9
	Yes	26	9.8
	2	6	2.3
Is the testing point enrolled in an external quality audit or proficiency testing of HIV rapid testing?	No	233	87.9
	Yes	32	12.1
Does the person in charge at the testing point review the external quality audit or proficiency testing results before submitting them to the national reference laboratory or designee?	No	229	86.4
	Yes	36	13.6
Does the testing point implement corrective action in case of unsatisfactory results?	No	53	20.0
	Yes	60	22.6
	Partial	152	57.4
Is feedback provided during supervisory visits documented?	No	62	23.4
	Yes	84	31.7
	Partial	119	44.9
If testers need to be supported, is there assigned responsible laboratory person for technical support?	No	70	26.4
	Yes	184	69.4
	Partial	11	4.2
Is user HIV testing confidentiality complaint receiving tools like suggestion box or Notebooks available, reviewed periodically and feedback provided?	No	34	12.8
	Yes	208	78.5
	Partial	23	8.7
Is there strong internal referral linkage system and feedback between POCT site and AART service?	No	20	7.5
	Yes	229	86.4
	Partial	16	6.0

6.1.5. Quality assurance practice performance

Based on assessed sections of checklists which are Personnel training, Physical facility, Safety, Pre-testing phase, Testing phase, Post-testing phase (documents and records) and external quality assurance phase, the study revealed that point of care HIV rapid testing sites of selected public health facilities in Addis Ababa had low performance score of 36.67% in Personnel training and had the highest performance score of 93.33% in Physical facility. The overall Quality assurance practice performance score was 65.59% (at 95% Confidence Interval 64.42-66.76). Therefore, we accept the Hypothesis that HIV rapid testing sites at point of care in Addis Ababa public health facilities score is below 80 %. Among assessed types of point of care HIV rapid testing sites VCT had highest performance and followed by PMTCT .While we compare the performance of testing sites with quality assurance elements VCT and PMTCT have comparable performance in physical facility and personnel training (Table 8).

Table 8. Comparison of Quality assurance practice performance between different point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

Quality assurance practice	**Overall Performance of point of care HIV rapid testing sites**					**Total performance**	**95% CI**	
	VCT	PMTCT	TB clinic	PICT	others		Lower	Upper
Total score of personnel training	61.74	38.1	26.83	31.23	27.78	36.67	34.57	38.76
Total score of physical facility	94.09	94.76	101.95	89.85	100	93.33	90.74	95.90
Total score elements safety	67.8	71.56	71.82	70.08	81.48	70.34	68.10	72.58
Total score pre-testing phase	76.05	69.47	66.73	62.38	64.29	66.47	64.95	67.99
Total score Testing phase	82.95	71.77	69.16	66.98	71.43	70.78	67.63	73.93
Total score of post testing	73.23	68.26	71.41	70.78	66.67	70.84	69.10	72.59
Total score of EQA	68.31	56.88	53.52	47.49	61.11	53.52	51.20	55.84
Overall performance of Quality assurance practice	74.12	67.07	65.46	62.36	66.95	65.59	64.42	66.76

Other * operation room, Recovery Room, intensive care unit

6.1.6. HIV rapid testing sites Performance Level

Based on the on-site evaluation, HIV rapid testing points were assessed for different elements incorporated in Physical facility, Personnel training, Safety, Pre-testing phase, Testing phase, Post-testing phase (documents and records) and external quality assurance have scores from level zero to four. On the basis of the overall total points obtained by each HIV testing point, the four levels are as follows Level 0=score<40%; Level 1=41-59%; Level 2=60-79%; Level 3=80-89% and score> 90%=Level 4. Accordingly, only 0.4% of testing points have Zero level performance which Needs improvement in all areas and immediate remediation, 27.2% of testing points have Level 1 performance which Needs improvement in specific areas and 64.2% of testing points had Level 2 performance which means partly eligible for HIV rapid testing whereas 7.9% of testing points have Level 3 performance that is close to national site certification. (Figure 3)

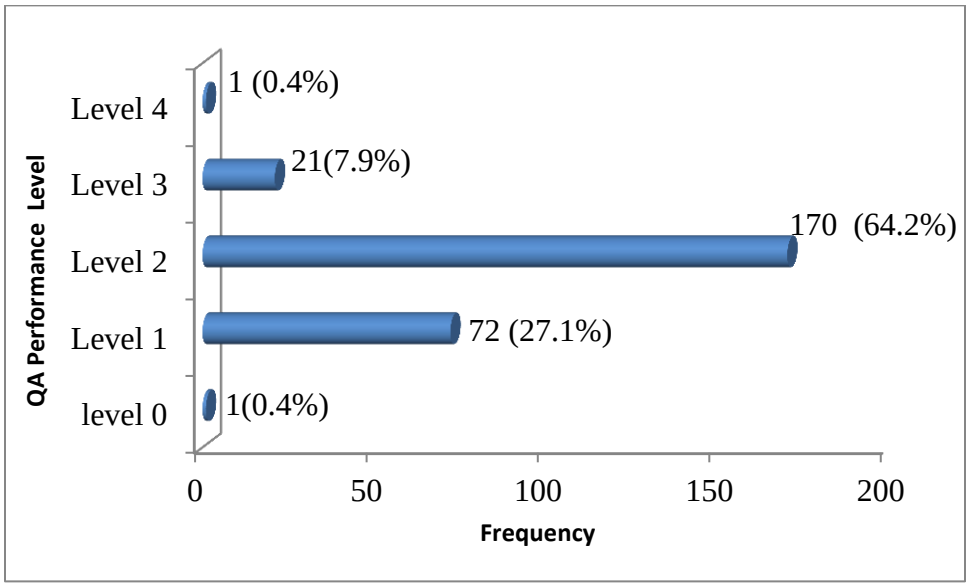

Figure 3. Quality assurance practice level of point of care HIV rapid testing sites in selected public health facilities in Addis Ababa, 2018

6.2. Proficiency of HIV rapid testing providers at point of care sites

6.2.1. Socio-demographic characteristics of HIV point of care test providers

There were a total of 619 care providers who perform HIV rapid testing at 265 points of care HIV rapid testing sites in the selected public health facilities (41 health centers and 3 hospitals). From these care providers, 310 (50.08%) who were actively on duty participated in this study

among study participants 197 (63.5%) were female, 124 (40.0%) had diploma in clinical nursing. The mean age of the study participants were 30.00 years. Most of them, (47.70%), were found between 26-30, age group. The mean years of health related experience and HIV rapid testing service was 6.18 and 3.61 years, respectively. Most participants, 183 (59%) had less than 5 years work experience. (Table 9)

Table 9. Socio demographic characteristics of HIV rapid testing providers in selected public health facilities in Addis Ababa, 2018

variables	Description	Frequency	%
Sex	Female	197	63.50
	Male	113	36.50
Age group in years	21-25	68	21.80
	26-30	148	47.70
	31-40	60	19.30
	36-40	25	8.30
	≥41	9	2.90
professionals level	MSC Nurse	1	0.30
	Nurse BSC (professional nurse)	43	13.90
	Nurse Level IV	124	40.00
	BSc midwifery	24	7.80
	Midwifery (Diploma)	37	11.90
	Public health	73	23.50
	community service provider	8	2.60
Experience in years	Grouped years	Frequency	Percent
Health related experience in years	<5	183	59.0
	5-10	80	25.8
	10-15	35	11.3
	>15	12	3.9
HIV rapid testing experiences in years	<3	73	23.5
	3-6	143	46.1
	6-10	10	3.2

	>10	84	27.1

6.2.2. Result of panel testing

Form the assessment of panel testing, a total of 220 samples which include 88 positives and 132 negatives were distributed and used to evaluate 310 HIV rapid testing providers. Among these HIV rapid testing providers', 302 (97.4%) were able to correctly detect negative and positive panel sample. A total of 8 (2.6%) participants have discordant result during screening test (test one); among these 3(37.5%) have false positive reports, 4 (50%) have false negative and 1(10%) report as invalid (Table 10). In general, in this study HIV rapid testing providers at point of care sites have 99.40% Proficiency of performance (at 95% Confidence Interval 99.09-99.80).

Table 10.Proficiency level of HIV rapid testing providers in selected public health facilities in Addis Ababa, 2018

Variables		Number of testing sites	Percent (%)
Proficiency result	Concordant result	302	97.4
	Discordant result	8	2.6
Types of discordant tests results	Test 1 false negative	4	50.0
	Test 1 false positive	3	37.5
	Test 1 Invalid	1	12.5

Finally, the study tried to assess whether rapid test providers are having specific trainings, their experience in EQA participation and what they do when they have shortages on one of the kit components. As displayed in Table 11, among 310 participants 136 (43.9%) had not been formally trained on HIV rapid testing, 273(88.1%) had no experience of participating in HIV rapid testing external quality assurance proficiency testing. However, 250 (80.6%) were willing to participate in HIV rapid testing external quality assurance and 27 (8.7%) participants responded that they used normal saline or distil water for injection in the case of test buffer lasts from the kits (Table 11).

Table 11. HIV rapid testing provider response to quality assurance practice in selected public health facilities in Addis Ababa, 2018

Variables	Response	Numbers testing providers	Percent (%)
Do you have formal training on HIV testing and proficiency testing?	No	136	43.9
	Yes	174	56.1
Have you participated on quality assurance related trainings?	No	273	88.1
	Yes	37	11.9
Do you have willingness to participate in HIV rapid testing EQA	No	60	19.4
	yes	250	80.6
Do you have any difficulties while collecting sample, perform test and interpret result?	no	280	90.3
	yes	30	9.7
If HIV testing buffer is lost/finished, what have you been doing?	Nothing	283	91.3
	Use normal saline or distilled water	27	8.7
PT result format completed properly	No	111	35.8
	Yes	199	64.2
PT result format completed properly	No	111	35.8
	Yes	199	64.2

6. Discussion

This study aimed to assess Quality Assurance practice of HIV rapid testing at point of care in 44 selected public health facilities of Addis Ababa (3 hospitals and 41 health centers). Based on assessed elements under the sections of Personnel training, Physical facility, Safety, Pre-testing phase, Testing phase, Post-testing phase (documents and records) and external quality assurance phase, the overall QA performance score of the facilities was 65.59%. VCT sites had the highest performance score followed by PMTCT sites. The highest performance score of 93.33% was obtained for Physical facility while low performance score of 36.67% was seen in Personnel training. Similarly, a study conducted in South Africa on evaluating quality management systems for HIV rapid testing services in primary healthcare clinics, showed that rural PHC clinics' average rating score for compliance to the WHO guidelines ranged between 64.4% and 89.2% and have scored highest for the following audit component: equipment; process control and specimen management; and facility and safety, with 100% score. Clinics obtained the lowest scores for the assessment audit component followed by process improvement and organization, with 40.9%, 45.5% and 56.8%, respectively (27).

WHO's 5Cs (Consent, Confidentiality, Counseling, Correct results and Connection Consolidated) guidelines has recommend that any HIV testing sites including facility-based testing (laboratories, clinical facilities), community-based testing and testing conducted at point of care should have national HIV testing policy that is regularly updated and linked to the national laboratory policy and strategic plan (29). However, in the current study it was found that national testing guidelines/ policy manual/ specific to the HIV rapid testing was not in place at 210 (79.2%) testing points, alternative HIV testing algorithm in case of expired test kits or shortages of kit components was not in place at 241 (90.9%) testing points, and 85 (32.1%) testing sites were operated by testers who have not received comprehensive training and certified on HIV rapid testing using the nationally approved curriculum and there was service interruption due to stock out last six month at 35 (13.2%) testing points.

In this study, 43.9% of the personnel have not been formally trained and evaluated to perform HIV rapid testing and 17.0% were found while they use expired test kits during the assessment. But our study is incomparable with a study conducted in USA by Centers for Medicare and Medicaid Services where 19% of testing personnel had been neither trained nor evaluated in the performance of the assays they carried and 6% use expired reagent kits. These clearly show more untrained and unevaluated personnel are performing HIV tests and used expired kits at the points

of care sites in our case; this variation as expected could be due to the strong quality assurance practice in USA (20).

There are large gap in External quality audit through proficiency testing by facility laboratory or regional laboratory in which 233 (87.9%) testing sites were not addressed by External quality assurance program in our study. This finding is in contrast to PT participation rate in Kenya that has increased up to 50%. Their results indicated that 40% discordance rate was noted in early phase but reduced to 5% according to the finding from three African testing sites (Kenya, Uganda, and Malawi) in 2012 (22). The observed decreased discordancy rate is due to consistent and frequent proficiency testing participation of testing sites.

The current study also evaluated proficiency of HIV rapid testing providers at point of care sites using DTS panel prepared in house using standard protocols. Of the total 310 participants, 302 (97.4%) were able to correctly detect negative and positive panel samples both for test one and test two according to the national algorithm. Whereas 8 (2.6%) participants had discordant result during screening test (test one); among these 3(37.5%) had false positive reports, 4 (50%) had false negative and 1(10%) report as invalid. The finding is below the required 100% proficiency for HIV testing (9). While false positive report is damaging for the tested individuals false negative reporting puts the population at risk by undetecting potentially infectious individuals and hence contributing to HIV transmission. This finding is slightly lower than the findings in a study conducted in South India that 99.49% of their participants reported correct results and 48 (0.50%) gave discordant results. Out of 48 samples 26 (0.27%) were false positives and 22 (0.23%) were false negative and for proficiency testing 91.8% reported test results. The variation between our study and south Indian study could be due to the large sample size enrolled in the Indian study (21).

Implementation of POCTs demands strong quality assurance system at all phases (Pre-analytical, analytical and post analytical). Studies have revealed errors associated with POCTs with weak quality assurance mechanisms. For example, a study conducted in London by Sacks R., *et.al* on Rapid HIV testing using Determine TM HIV 1/2 antibody tests showed that HIV point-of-care tests (POCTs) give occasional false positive results, causing unnecessary patient anxiety our again support that because there are 3(37.5%) false positive among discordant results (19). In this study, we found that (2.6%) discordant results in the screening tests that is not comparable with the finding of Rapid Assessment of Quality and Field Performance of HIV Rapid

Diagnostic Tests conducted in three African countries, Kenya, Uganda, and Malawi, 3% to 18% discordance rate with average of 12% discordance (22).

In this study, 30 (9.7%) of the participants have difficulties of collecting sample with pipette or capillary tubes or perform test or interpret result, while 136 (43.9%) of the participants also were not having formal training on HIV rapid testing and proficiency testing. Surprisingly, 27 (10.2%) of participants were not followed the national HIV testing algorithm. Likewise, the study conducted in Zambia on laboratory and non-laboratory personnel indicated that lay counselors and nurses had more difficulties on interpreting results that cause occurrences of false-negative, false-positive and indeterminate results. The Zambian study also showed that having the standard HIV rapid testing training and adherence to the national HIV testing algorithm were positively associated with accuracy (23).

The majority of participants 80 (84.8%) have less than 10 years in Health related experience. The training gap of testers is huge. Whereas the evaluation of the HIV lay counseling conducted in South Africa by Mwisongo *et al.* in 2015 revealed that almost all the lay counselors 31 (96.8 %) had received formal training in HIV testing and the majority of the lay counselors (24, 75 %) had testing experience of between a few months and five years (24).

8. Strength and Limitations of the study

8.1.Strength

- We have tried to reach 44 health facilities in order to make the study more representative

8.2.Limitation

- We did not use blinded rechecking quality assurance assessment system which would be better to identify the rates of false results release to communities.
- HIV rapid testing is a technique that has inherent errors, like any other technique, even when performed by the most experienced professionals. Thus, the results of one testing sites simply cannot be assumed to be more correct than another. This calls for referee reading of all discrepant results by a third reader under blind conditions. Any errors in the pre testing, – testing and post testing of the referee have to be accepted as inherent limitations of the rapid testing process.

9. Conclusion and recommendation

9.1. Conclusion

On-site evaluation indicated that low performance score 36.67% in Personnel training and have highest performance score of 93.32% in Physical facility with an overall Quality assurance practice performance score of 65.59% at 95% Confidence Interval. Among audited point of care HIV testing sites, 25% are score below 58.08% and also 25% are above 71.17%. Therefore, we accept the Hypothesis that HIV rapid testing sites at point of care sites in Addis Ababa public health facilities score below 80 %.

HIV rapid testing points of care have performance score from level zero to four that only 0.4% of testing points have Zero level performance, 27.2% of testing points have one level performance , 64.2% of testing points have level two performance and 7.9% of testing points have three level performance .

Among 310 study participants HIV rapid testing providers' 302 (97.4%) could correctly detect negative and positive panel sample both with test one and test two according to national algorithm. 8 (2.6%) have discordant result during screening test (test one) among these 3(37.5%) had reports false positive that were corrected through the algorithm on the final result. Four (50%) had false negative; 1(10%) was reported as invalid. In general, in this study HIV rapid testing providers at point of care sites had 99.40% proficiency of performance. Therefore, we are concluded that overall proficiency performance of HIV rapid testing services provider at point of care in Addis Ababa public health facilities is lower than 100% which means unsatisfactory.

9.2. Recommendations

Based on the finding, the following recommendations are forwarded:

- The regional health and research laboratory external quality assessment schemes implementation should improve and extend more to the HIV rapid point of care testing sites because our finding shows weak EQA participation at the testing sites.
- Stockholders have to be support public health facilities to expand and address HIV rapid testing training for all point of care testing providers at large Because there huge gap on HIV rapid testing quality assurance
- Regular onsite supervision program has to be strengthened and expand to address all point of care testing sites because we found discordant result leading to improper diagnosis.

- The region should develop appropriate communication channel and maintain a significant means of monitoring and evaluation system for all HIV Rapid testing point of cares at large; there is large gap in provision of feedback.
- Alternative HIV rapid Testing kits algorithm should be availed by national laboratory for current kits algorism because there is no backup system at all in the case of service interruption.

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Annexes

Annex I: Information sheet

Addis Ababa University, College of Health Sciences, School of Allied Health Science, Department of Medical Laboratory Science, Addis Ababa, Ethiopia

Title of the research: Assessment of Quality Assurance practice and proficiency of HIV rapid testing providers at point of care sites in selected public health facility of Addis Ababa, Ethiopia

First of all I would like to thank you in advance for your cooperation and consent to participate in this study. Please read or listen carefully about the general information of the study. If you have any question regarding the study please ask freely

Background

My name is Sisay Tulu and currently I am student of Addis Ababa University, Department of Medical Laboratory Sciences for masters degree in clinical laboratory science in the track Clinical Laboratory Management and Quality Assurance program. Now, I am working a research project. HIV rapid testing point care site assessment is a widely accepted process of evaluation of its' quality, performance, and reliability and efficiency, in which an authoritative independent body gives formal recognition that the it is competent to carry out specific tasks. It is a means to promote and enforce better quality HIV testing and to ultimately reduce testing errors. Accreditation also increases the credibility of the results and services delivered by a POCT through providing recognition through ISO 22870:2016. It is compliant with quality and competence standards considered necessary for accurate, reliable and safe testing. The value of accreditation lies in promoting the delivery of reliable results for patient management or generation of reliable data for critical public health interventions

Aim of the study

The aim of the study is to assess quality assurance practice of HIV rapid testing services at point of care site with panel testing and on-site evaluation by adopted WHO HIV rapid testing site checklist and EQA guidelines to determine quality assurance practice gaps and proficiency of the personnel performing the tests at POCT site in selected public health institution in Addis

Ababa, Ethiopia. The finding will help to identify gaps for action, which will further assist in the improvement of the diagnostic outcome. It is also important for government to make decision.

Benefits for participants

Study participants will not have any financial incentives or other inducements from participating on this study.

Risks for participant

The proposed research will not have any known harm, social discrimination, physiological trauma and economical loss on study participants.

Confidentiality

I assure that all the information you will provide during the interview and data collection process will be kept confidential by using codes instead of names. Your participation in this research is entirely voluntary. Your willingness to participate in this study is essential and answering all questions would be highly appreciated

Assurance of Principal Investigator

I put my signature below to confirm you that I take over the responsibility for the information that you give.

Sisay Tulu (PI): Signature: _____Date:_____

Note: If you have any questions about this study, feel free to ask now or anytime throughout data collection and the study period by contacting:

Principal investigator: The address of the principal investigator is: Sisay Tulu , BSc Department of Medical Laboratory Sciences, Clinical laboratory Management and Quality Assurance track

Tel: +251-0911-726068 E-mail:sisaytulu2011@gmail.com/sisay_tullu@yahoo.com

I hope that you will be frank and honest in providing answers to the following questions: -

Do you agree to answer the following questions to the best of your ability?

Yes ( ) No ( ); If you answer yes, please continue responding to the interviewer

Thank you in helping with this important study.

For any information you can contact

1. Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences

Annex II. Consent Form (English and Amharic)

I the undersigned name assure if the indicated title is performed in our institution for the sake of the sector's quality improvement and consistent laboratory quality assurance in terms of HIV rapid testing services at point of care.

Information sheet and Verbal Consent form (English version) Onsite evaluation: Evaluation of quality management systems implementation for HIV rapid testing services at point of care site in selected public health facility of Addis Ababa, Ethiopia, 2017

Name of the health facility _____HIV rapid testing site ----------
---------- Questionnaire identification number----------
Signature_____Date: ----------

Annex III: Amharic version of subject in formation sheet and consent form

ስሜ ሲሳይ ቱሉ ይባለል፣

ባሁኑ ሰዓት በአዲስ አባባ ዩኒቨርስቲ በክሊኒካል ላቦራቶሪ ሳይንስ የሁለተኛ ዲግሪ ፕሮግራም በክሊኒካል ላቦራቶሪ ማኔጅመንት እና ኳሊቲ አሹራንስ ትምህርት ክፍል እየተከታተልኩ እገኛለሁ፡፡ወደዚህ ተቋም የመጣሁበት ዋና ዓላማ ፈጣን የኤች አይ ቪ ደም ምርመራ ሂደት ለማየት እና ከስታንደርድ አሰራር አንፃር ለመገምገም ነው፡፡

በዚህ መጠይቅ ውስጥም ሆነ በሌላ አጠቃላይ የጥናቱ ውጤቶች በሚስጢር ተይዘው ለጥናቱ ብቻ አገልግሎት ላይ የሚውሉይ ሆናል፡፡ በቃለ መጠይቁም ሆነ በጥናቱ ላይ ለመሳተፍ በርስዎፈቃደኝነት ላይ የተመሰረተ ይሆናል፡፡ ነገር ግን የርስዎና የተቋምዎ በጥናቱ መሳተፍ የሚያስገኘው መረጃ የጥናቱን ዓላማ ለማሳካትና የየኤች አይ ቪ ደም ምርመራ ጥራት ከፍለ ማድረግ ለበሽተኞችም አስፈላጊና ተገቢ መድሓኒት በወቅቱ እንዲጠቀሙ ከማድረግ አኳያ የጥናዊ አሰሳው ያለው ሚና ከፍተኛ ነው፡፡

አድራሻ፡-

1. አዲስ አበባ ዩኒቨርስቲ በክሊኒካል ላቦራቶሪ ሳይንስ ትምህርት ክፍል

Annex IV: Adopted Checklist for assessment of quality assurance practice at HIV rapid testing sites

Date of assessment (dd/mm/yyyy):_____/____/_____

Testing facility name:_____

Level of facility's Laboratory of by WHO SLIPTA or accreditation organizations

_____

Testing facility ID (if applicable)_____

Type of testing point (circle one)

1. Voluntary testing and counseling or HIV testing and counseling
2. Provider-initiated testing and counseling
3. Services for preventing mother-to-child transmission (PMTCT)
4. TB clinic
5. Laboratory
6. Other (please specify):_____

Number of testers at testing point: _____

Average number test performed per month in average last three months:

_____

Part B. Checklist

Section	Yes/Partial/ No	Comments	Score
1.0 Personnel training and certification expected score 10			
1.1 Have all testers received comprehensive training on HIV rapid testing using the nationally approved curriculum?			
1.2 Are the testers trained on using standardized HIV testing registers or logbooks?			
1.3 Are the testers trained on external quality assessment or the proficiency testing process?			
1.4 Are the testers trained on the quality control process?			
1.5 Are the testers trained on safety and waste management procedures and practices?			
1.6 Have all testers received refresher training within the past two years?			
1.7 Are there records indicating that all testers have demonstrated competence in HIV rapid testing before testing client?			
1.8 Have all testers been certified through a national certification program?			
1.9 Are only certified testers allowed to perform HIV testing?			
1.10 Are all testers required to be recertified periodically (such as every two years)?			

1.Personnel training and certification total score			
2.0 Physical facility 5			
2.1 Is there a designated area for HIV testing?			
2.2 Is the testing area clean and organized for HIV rapid testing?			
2.3 Is sufficient lighting available in the designated testing area?			
2.4 Are the test kits kept in a temperature-controlled environment based on the manufacturers' instructions?			
2.5 Is there sufficient and secure storage space for test kits and other consumables?			
Physical facility total score			
3.0 Safety 11			
3.1 Are standard operating procedures and/or job aids in place to implement safety practices?			
3.2 Are standard operating procedures and/or job aids in place on how to dispose of infectious and non-infectious waste?			
3.3 Are standard operating procedures and/or job aids in place to manage spills of blood and other body fluids?			
3.4 Are there standard operating procedures and/or job aids in place to address accidental exposure to potentially infectious body fluids through a needle-stick injury, splash or other sharps injury?			
3.5 Is personal protective equipment always available to			

the testers?			
3.6 Do all testers consistently use personal protective equipment?			
3.7 Do all testers properly use personal protective equipment throughout the testing process?			
3.8 Are clean water and soap available for hand washing?			
3.9 Is an appropriate disinfectant available to clean the work area and equipment?			
3.10 Are sharps and infectious and non-infectious waste handled properly?			
3.11 Are containers for infectious and non-infectious waste emptied regularly in accordance with the standard operating procedures and/or job aids?			
Safety total score			
4.0 Pre-testing phase			
4.1 Are national testing guidelines specific to the program (such as on HIV testing services, preventing the mother-to-child transmission of HIV or TB) available at the testing point?			
4.2 Is the national HIV testing algorithm being used?			
4.3 Is there a process in place for an alternative HIV testing algorithm in case of expired test kits or shortages?			
4.4 Are standard operating procedures and/or job aids in place for each HIV rapid test used in the testing			

algorithm?			
4.5 Are only nationally approved HIV rapid testing kits available for use currently?			
4.6 Are all the test kits in use within the expiration date currently?			
4.7 Are test kits labelled with the date received and initials?			
4.8 Is a process in place for managing stocks?			
4.9 Are job aids on client sample collection available and posted at the testing point?			
4.10 Are sufficient supplies available for collecting client samples?			
4.11 Are there any system (national guidelines describing)how client identification should be recorded in the HIV testing register?			
4.12 Are client identifiers recorded in the HIV testing register in accordance with national guidelines and on test devices?			
Pre-testing phase total score			
5.0 Testing phase			
5.1 Are job aids on HIV testing procedures available and posted at the testing site?			
5.2 Are timers available and used routinely for HIV rapid testing?			
5.3 Are sample collection devices (such as capillary			

tubes, loops and disposable pipettes) used accurately?			
5.4 Are testing procedures adequately followed?			
5.5 Are positive and negative quality control specimens routinely used (such as daily or weekly) in accordance with Number of testing sites ry guidelines?			
5.6 Are quality control results properly recorded?			
5.7 Are incorrect or invalid quality control results properly recorded?			
5.8 Are appropriate steps taken and documented when quality control results are incorrect and/or invalid?			
5.9 Does the person in charge routinely review quality control records?			
Testing phase total score			
6.0 Post-testing phase – documents and records			
6.1 Is there a national standardized HIV rapid testing register or logbook available and in use?			
6.2 Does the HIV testing register or logbook include all the key quality elements like Serial No.,Client or Specimen ID.Age(Yrs),Sex ,Date, each Kit Name, Lot No., Exp. Date, Final results Operaton Name /Initials			
6.3 Are all the elements in the register or logbook recorded or captured correctly (such as client demographics, kit names, lot numbers, expiration dates, tester name and individual and final HIV results)?			
6.4 Is the total summary at the end of each page of the			

register or logbooks completed accurately?			
6.5 Are invalid test results recorded in the register or logbook?			
6.6 Are invalid tests repeated and the results properly recorded in the register or logbook?			
6.7 Are all client documents and records securely kept throughout all phases of the testing process?			
6.8 Are all registers or logbooks and other documents kept in a secure place			
6.9 Are registers or logbooks properly labeled and archived when full?			
Post-testing phase – documents and records total score			
7.0 External quality audit (proficiency testing, supervision and retesting)			
7.1 Is the testing point enrolled in an external quality audit or proficiency testing program?			
7.2 Do all testers at the testing point test the external quality audit or proficiency testing samples?			
7.3 Does the person in charge at the testing point review the external quality audit or proficiency testing results before submitting them to the national reference laboratory or designee?			
7.4 Is an external quality audit or proficiency testing report received from the national reference laboratory and reviewed by testers and/ or the person in charge at			

the testing point?			
7.5 Does the testing point implement corrective action in case of unsatisfactory results?			
7.6 Does the testing point receive periodic supervisory visits?			
7.7 Is feedback provided during supervisory visits documented?			
7.8 If testers need to be supported, is there assigned responsible laboratory person to being technical support?			
7.9 Is user HIV testing confidentiality complaint receiving tools like suggestion box or Notebooks available, reviewed periodically and feedback provided?			
7.10 Is there strong internal referral linkage system and feedback between POCT site and AART service?			

Annex V: Questionnaire for Socio demographic characteristics and theoretical knowledge evaluation of HIV rapid testing providers in public health facilities in Addis Ababa, 2017

Part I: Socio demographic characteristics

1. Gender _____
2. Age in years _____
3. Educational level_____
4. Professional _____
5. Years of experience in health or health related profession
6. _____
7. Did you have been trained and Evaluated in the performance of the HIV rapid testing _____
8. Years of experience in HIV rapid testing service _____
9. Do you have an Experience of participating HIV rapid test Proficiency testing (If yes how Often)_____
10. If Q. Number 9 "No", do you have willingness to participate in HIV rapid testing External quality assurance _____
11. Have any difficulties faced you while you collect sample, perform test and interpret HIV rapid result? Please explain it!
12. If the HIV testing buffer is lost, what you have been doing _____
13. Are Proficiency Testing Result Reporting Format completed properly_____

Annex VI: Proficiency Testing Results Reporting Form

Health Facility Name					
Facility Code					
Testing Site Name					
Date Samples Received					
Date Testing Performed					
Participant signature					
	Rapid HIV Test				
	Test 1	Test 2	Test 3		
Test Name					
Lot Number					
Expiration Date					
PT Panel Identifier	Results Test 1	Results Test 2	Results Test 3	Final Status	Comments
	NR R INV	NR R INV	NR R INV	NEG POS IND	
	NR R INV	NR R INV	NR R INV	NEG POS IND	

	NR R INV	NR R INV	NR R INV	NEG POS IND	
	NR R INV	NR R INV	NR R INV	NEG POS IND	
	NR R INV	NR R INV	NR R INV	NEG POS IND	
	NR R INV	NR R INV	NR R INV	NEG POS IND	

Circle the results of the individual test results and final status, once the testing is completed for each sample NR – Non reactive ,R – Reactive ,INV – Invalid, NEG – Negative, POS – Positive IND – Indeterminate

Annex VII: Standard operating procedures for DTS proficiency testing

Standardized protocols for preparing proficiency testing samples at a national laboratory

Standard operating procedures: proficiency testing program using dried tube specimens

HIV rapid diagnostic tests

1.0. Purpose

The purpose of this procedure is to provide guidance to setup a proficiency testing program using dried tube specimens to ensure the quality of HIV testing.

2.0. Equipment

- Biosafety cabinet
- Vacuum pump unit

3.0 Supplies

- 2.0-ml conical bottom tubes
- Green food colouring dye
- Pipettes that are capable of multi-dispensing pipette tips
- Disposable transfer pipettes
- Freezer boxes
- Tube racks
- Cryo labels
- Storage bottles
- Zipper storage bags
- Labels
- Disposable filter unit 0.2 µl

4.0. Special safety precautions

4.1 Wear protective clothing while handling dried tube specimens.

4.2 Handle dried tube specimens as if they are capable of transmitting an infectious agent.

4.3 Do not interchange vial caps; this will lead to cross contamination of specimens.

4.4 Leave the dried tube specimens in the biosafety cabinet for overnight drying of the specimen.

5.0. Procedure

5.1.Obtain rejected plasma units from the local blood bank of different HIV reactivity, including some HIV negatives. Initially acquire >10 units to build specimen inventory.

5.2.Transfer plasma from the bag to a clean storage bottle. Store plasma at 4°C untiln further testing has been conducted.

5.3.Regardless of the status given by the blood bank, the laboratory that is responsible for providing the proficiency testing panel should verify the specimen reactivity.

5.4. Plasma specimens should be characterized with respect to their HIV status by all HIV rapid tests, ELISA and Western blot (if available) based on a Number of testing sites ry-specific algorithm.

5.4.1. Rapid test: test plasma specimens with all commonly used HIV rapid tests in the Number of testing sites ry.

5.5. Preparing proficiency testing buffer (phosphate-buffered saline (PBS)/Tween-20)

5.5.1 PBS with Tween-20 pouches can be commercially purchased

5.5.2 Prepare 1.8-ml aliquots in prelabelled 2-ml screwcapped tubes.

5.5.3 The label on tube should include the following:

5.5.4 Identify the tube as “proficiency testing buffer”.

5.5.5 Set an expiration date of one year after you prepare.

5.6.Preparing dried tube specimens

5.6.1. Create a panel of six samples from the characterized specimens with a combination of negative and positive reactivity for HIV.

5.6.2. Carefully blind the panel, assigning a new ID to each of the six-member panel. For example, dried tube specimens A1 to dried tube specimens A6. Ensure that the original ID and new ID are linked.

5.6.3. Label each tube with an appropriate new ID.

5.6.4. Depending on the number of laboratories enrolled in the proficiency testing programme, prepare 10–20 extra sets.

5.6.5. Prepare a 1:100 dilution of green dye to specimen. For example, add 1 µl of dye (food colouring) to 1 ml of specimen. Vortex the specimen to mix the dye.

5.6.6. Prepare dried tube specimens by transferring 20 µl of coloured serum or plasma specimen to tube.

5.6.7. Ensure that each specimen is aliquotted in properly labelled tubes. Aliquot only one specimen at a time to avoid any possibility of mixing.

5.6.8. Leave the tubes uncapped in a biosafety cabinet and let it dry overnight at room temperature. Make sure different specimens are kept in separate racks in a biosafety cabinet.

5.6.9. The following day, ensure that the specimens have dried completely before capping each tube.

5.6.10. A visible coloured pellet is formed towards the bottom of the tube.

5.6.11. Capped dried tube specimens are kept at 4°C until ready for shipment to the participating laboratories.

5.7.Packaging proficiency testing panels

5.7.1. Prepare proficiency testing panels for shipments to include the following:

5.7.1.1.One member of each panel

5.7.1.2. One vial of proficiency testing buffer

5.7.1.3.Two plastic transfer pipettes (dropper)

5.7.1.4.One page of instruction sheet or handout

5.7.1.5. One page of reporting forms each (for rapid diagnostic tests and enzyme immunoassays)

5.7.2. Put all the contents in labeled zippered storage bags.

5.7.3. The bagged proficiency testing panels can be stored at 4°C until shipment or delivery to testing sites. Reconstitution of dried tube specimens.

5.7.4. Tap the tube gently to ensure that the coloured pellet falls to the bottom of the tube.

5.7.5. Antibodies are reconstituted one day before testing.

5.7.6. Using the dropper provided, add 7 drops of proficiency testing buffer to each dried tube specimen to be tested. Cover the tube, tap gently and incubate overnight at room temperature.

5.7.7. The next day, mix the specimen by gently tapping the tube.

5.7.8. Test the reconstituted dried tube specimens with the appropriate HIV rapid or enzyme immunoassay tests.

5.7.9. Report the results using the report form before the deadline.

5.8.Result analysis

5.8.1. Collect reports from all participating laboratories.

5.8.2. Enter data in the appropriate spreadsheet.

5.8.3. Send the final report to all the participating laboratories.

5.8.4. Follow up with a supervisor for the laboratories that do not receive a 100% passing grade.

Annex VIII: Dummy Tables: Socio demographic characteristics of HIV rapid testing providers in public health facilities in Addis Ababa, 2018

S/No.	Variable	Frequency	Percent (%)
1	Gender		
	1. Female		
	2. Male		
2	Age group in years ( )		
3	Professional level		
	1. MSC Nurse		
	2. Nurse BSC (professional nurse)		
	3. Nurse Level IV		
	4. MSC midwifery		
	5. Bsc midwifery		
	6. Midwifery		
	7. Public health		

	8. physician		
	9. other specify----------		
5	Years of experience in health or health related profession ( )		
6	Years of experience in HIV rapid testing service (-----)		
7	Experience in Proficiency testing		

Annex X. List assessed health facility

Randomly selected Addis Ababa health bureau health facilities assessed for Quality Assurance practice and proficiency of HIV rapid testing providers at point of care in Addis Ababa, Ethiopia, 2018

S/N	Facility name
I	**Kolfe Keranio S.C**
1.	Kolfe KeranioW-3
2.	Kolfe KeranioW-1
3.	Alem Bank/ W-4
4.	Kolfe KeranioW-9/ W-24
II	**Gulele**
5.	Shiromeda/W-3
6.	Hidassie/W-7
7.	Addisu Gebeya/W-8
8.	Selam/W-9
9.	Shegole/W-10
III	**Yerka S.C**
10.	Entoto No 2/ W-2
11.	Entoto No 1/ W-3
12.	Korean Veteran Memo/W-4
13.	Yeka/ W-5
14.	Yeka /W -6
15.	Yeka /W -7
IV	**Kirkos S.C**
16.	Gotera Masalecha/W-3
17.	Feresmeda/ W-5
18.	Kazanchis/ W-8
19.	Meshualekia/ W-9/ W-18
VI	**Arada S.C**
20.	Churchil/ W-1
21.	Semen/ W-4
22.	Afinchober/ W-5
23.	Janmeda/ W-6
24.	Kebena/ W-7
25.	Baeta/ W-8
26.	Arada/ W-10
VII	**Addis Ketema S.C**
27.	Abyssinia/ W-2
28.	Addis Ketema/ W-4
29.	Addis Raey/ W-7
30.	Millinium/ W-8
31.	KuasmedaW-9
VIII	Ne/Sil/Laf S.C

32.	Ne/Sil/Laf W-1
33.	Ne/Sil/Laf W-2
34.	Ne/Sil/Laf W-5
35.	Ne/Sil/Laf W-6
36.	Ne/Sil/Laf W-12
IX	Lideta S.C
37.	Lideta S.C W-1
38.	Lideta S.C W-2
39.	Lideta H.C
40.	Hidase fire
X	**Akaki Kality S.C**
41.	Saris/ W-6
42.	Yekatit 12 medical college hospital
43.	Menelik Referral hospital
44.	Zewuditu Memorial Hospital

Declaration

I, the undersigned, declare that this MSc thesis is my original work, has not been presented for a degree in Addis Ababa University or any other universities. I also declare that all sources of materials used for the thesis have been duly acknowledged.

Name of the student:

Sisay Tulu _____ _____

Name Signature Date

This thesis has been submitted for ethical review with our approval as university advisor. Name of the advisors:

Aster Tsegaye (BSc, MSc, PhD) _____ _____

Signature Date

Fatuma Hassen (Bsc, MPH, PhD fellow) _____ _____

Signature Date