Addis Ababa University

College of Heath Science

Department of Medical Laboratory Sciences

Performance of non-medical laboratory professionals on HIV rapid testing and associated factors in public health facilities of Adama , Oromia, Ethiopia.

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This is to certify that the thesis prepared by Gemechis Bulti, entitled: Performance evaluation and associated factors of non-medical laboratory professionals working on rapid HIV testing in Health centers and hospital of Adama city , Oromia, Ethiopia. and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (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

AAPHRI/EML	Addis Ababa Public Health Research and Emergency Management Laboratory
AIDS	Acquire immune deficiency syndrome
ART	Antiretroviral Treatment
DRERC	Departmental research and ethics review committee
DTS	Dry Tube Sample
EQA	External Quality Assurance
HIV	Human Immunodeficiency virus
ISO	International Organization for Standardization
LMIC	low and middle income countries
OPD	Outpatient Department
PBS	Phosphate buffer solution
PICT	Provider-Initiated Testing and Counseling
PLHIV	People living with Human Immune Virus
PMTCT	Prevention of Mother-To-Child Transmission
POC	point of care
POCT	Point of Care Testing
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality control
TB	Tuberculosis
UNAIDS	United Nations Program on HIV/AIDS
VCT	Voluntary Counseling and Testing
WHO	World health organization

Abstract

Background: The implementation of HIV point-of-care testing and upgrading of the service in a countries with highly HIV prevalent is mandatory. However, the studies related to accuracies are remaining limited. As a need to get HIV testing increases, the testing strategies and technology shift to rapid test (RT) and point of care test (POC) which were used to decentralize the testing and includes non laboratory professionals as the complexity of the testing method was resolved.

Objective: the aim of this study was to assess performance and associated factors of non medical laboratory professional working on rapid HIV testing in public health facilities of Adama, Oromia, Ethiopia.

Methods: Facility based cross-sectional study was conducted from February to April, 2020. A total of 348 non medical laboratory professionals were considered determining their performance and associated factors working on rapid HIV testing in health centers and hospital of Adama. Epidata version 3.1 was used for data entry and exported to SPSS version 23 for analysis and P-Value less than 0.05 was taken as statistically significant.

Results: Among 348 HIV rapid testing providers, 336 (96.6 %) could correctly detect negative and positive panel samples and the rest 12 (3.4%) had discordant result during performance test evaluation. From those who had discordant test result, 5(1.4%) had false positive reports and 7 (2%) had false negative reports that were corrected through the algorithm on the final result. In the onsite checklist, 93(26.7%) had safety Manual at their working area where 255(73.3%) lack of safety Manual at point of care. Regarding check up of expiry dates of the kits, 268(77.0%) doesn't checked expiry dates of test Kits where 80(23.0%) of them checked expiry dates of the kits. 308(88.5%) of non laboratory professionals were managed data of quality elements of Registrations book contents and 155(44.53) non laboratory professionals were lack of personnel trained on internal quality control and External quality assurance. Statistical analysis by multi variable logistic regression indicated that, profession AOR 0.057(0.006-0.570) (95% CI), P=0.015 and Transfer right amount of sample AOR 51.799 (6.929-387.235) (95%CI) P=0.001 were significantly associated with non-acceptable rapid HIV proficiency test result.

Conclusion: HIV rapid testing sites had (96.6%) performance score. False negative and false positive results need attention since misdiagnosis leads to psychological, social and economic disturbances to the community. Therefore, immediate intervention is needed based on identified findings. Less experience non laboratory professionals shown lower Proficiency performances so this gaps might be minimized by facilitating training on HIV rapid testing.

Key words: Evaluation, Performance, point of care testing, non laboratory profession

I. Introduction

1.1Background

The number of individuals infected with human immunodeficiency virus (HIV-1) continues as one of health problem based on the latest statistics; there were an estimated of 37.9 million HIV-positive people in the world, while 54% of these peoples living with HIV were from eastern and southern Africa. An estimated of 1.7 million individuals children and adults of all age groups were acquired HIV infection annually as well as AIDS related deaths were estimate 770 000 individuals by 2018 [1]. As a result, HIV/AIDS causing lots of damage and destructions throughout the world, especially in Sub-Saharan Africa [2]. The HIV/AIDS situation in Ethiopia 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 Key and Priority Populations (KP and PP), and in pockets of the general population. Per 2016 DHS estimate, adult HIV prevalence in Ethiopia is estimated to be 0.9%. There is substantial prevalence variation by region from 0.4% up to 4.8%. Based on 2017 Spectrum estimates, Ethiopia has 410,335 PLHIV and 13,556 AIDS deaths annually[3].Consequently, the low- and middle-income countries has subjected critically on a public health approach that relies on decentralization of primary health care facilities and lesser-trained health workers in primary care services to deliver HIV testing to the majority of HIV positive patients [4]. That leads the large scale of HIV testing task per year and to make sure accuracy of the test result primarily [5].

For countries with limited resources, HIV rapid testing is a primary concern in a fight against HIV epidemics which ensure the prevention and treatment programs. 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, outpatient department (OPD), facility based and stand-alone counselling and testing centers and mobile facilities. The main challenges in ensuring the quality of HIV testing is that, in many setting; the testing is performed by non-trained individuals and without laboratory back ground [6].

Nurses and counselors reported that limited spaces compromises confidentiality, difficulty in taking consent in both OP and IP setting. The quality of test is also affected due to in ability to follow the testing protocol, high work load, lack of training and poor supervision. That may happen in different groups of non laboratory professionals working on HIV testing and the effect ranges from in appropriate sample collection, testing performance and to wrong interpretation of the result [7].

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 [8]. 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 [9].

Therefore, the critical point since 1980's after accurate HIV testing become available, which was key to increase the number of PLHIV and initiate ART was HIV testing, PMTCT, PICT services[10-13].

As a need to get HIV testing increases, the testing strategies and technology shift to rapid test and(RT) and (POC) point of care test which is use to decentralize the testing and includes non laboratory professionals as the complexity of the testing method was resolved. Due to the increasing need for HIV testing, testing technologies have shifted from complex techniques performed by highly trained laboratory professionals, to rapid tests (RTs) or point of- care (POC) tests using the finger-prick method.

However the decentralization or expansion of the test affects the quality of testing in different ways. Which is even smaller error may cause change is a result and leads to miss-diagnosis. 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. [6, 7].

Even though there is limited information in Ethiopia; the aim of this study was to assess the Performance evaluation and associated factors of non medical laboratory professionals working on rapid HIV testing in Adama health centers and hospital Oromia Ethiopia.

1.2 Statement of the problem

In resource constrained countries like Ethiopia, a raid test for HIV is one of the most cost effective interventions, even though ensuring quality control is a challenge. Also lack of trained man power and qualification makes the challenge more complicated [14]. Additionally, 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 [15].

In spite of the major role played by HIV rapid tests in improving health outcomes, the results quality by Point of care testing remains doubtful since testing is generally conducted by non-laboratory trained personnel in resource-limited settings Studies highlight an increased risk of misdiagnosis by non-laboratory personnel conducting POC tests, due to their narrow knowledge and observation of quality measures for diagnostic testing. Also the reading of rapid test results is personal and may impact diagnostic outcomes especially when testing personnel are undertrained. Therefore, possibly inaccurate diagnoses can have devastating consequences for an individual, resulting in stigma, loss of family, loss of job and loss of other opportunities [16].

Besides the obvious negative impact of HIV misdiagnosis, rapid test results can also be false negative especially during the early stages of infection. Missed HIV diagnosis often leads to rapid health deterioration of the infected person and prevent early treatment initiation during the early stages of infection. In a world burdened by high HIV prevalence and poor healthcare access in LIMCs, the risk of poor quality testing have a negative effect on linkage to ART and on health outcomes as well as prevent the achievement of the UNAIDS '90/90/90' goals by 2020 [17, 18].

Even though the participants of EQA and POC are different, proficiency testing for point of care testing (POC) is similar with the EQA in principle. Therefore, convincing those health care personnel working on POCT were important to link in EQA schemes that is use to provide feedback and capacitate participants as needed. This increases the test quality, accuracy and reliability pre-examination, during examination and post-examination [20].

1.3 Significance of the study

The aim of the study was to get preface of the current status with evidences on the performance evaluation and associated factors of non medical laboratory professionals working on rapid HIV testing in Adama public health facility HIV testing corner outside laboratory sites.

It helps to facilitate identification of common mistakes and initiate health facilities as well as HIV test providers to ensure for consistent HIV testing practice through scale-upping the knowledge and skill of the testers. Moreover, identifying gaps related with POCT quality for proper execution surrogate essential role for promoting quality health care compliance with public interest, increase public outlook from POCT providers, and enhance confidence of service users to health facility services.

It also builds workforce understanding on quality service prerequisite, advances HIV testers competitiveness and performance, initiate HIV POCT site supervision and establish strong proficiency testing; and evaluating each HIV testing requirement based on standard sated by WHO.

Generally, the findings from the study is expected to present information to responsible bodies and upper managers that could help to achieve the improvement goals of quality service on HIV POCT as well as additional knowledge on POCT standard and purpose at national and international levels as indicated by ISO 22870:2016.

2. Literature Review

Performance evaluation of non-medical laboratory professionals HIV test used to admit point-of-care testing (POCT) to improve patient care, mainly in resource-limited settings where laboratory infrastructure is poor and the mass of population lives in rural settings. However, because of challenges in progressing the technology and weak quality assurance measures, the promise of human immunodeficiency virus (HIV)-related POCT in resource-limited settings has not been fully exploited to improve patient care and impact public health [20].

As a result of forced challenges task shifting describes the process of capacitating lesser-trained health workers to provide specific services previously delivered by specialists with higher levels of training. Lay provider HIV testing was recommended in the 2015 While WHO consolidated guidelines on HIV testing services following a systematic review of the evidence demonstrating non-inferiority. The severe shortage of health care workers including doctors, nurses, and laboratory professionals in high HIV burden countries led a number of countries in sub-Saharan Africa to pioneer task shifting and allow lay providers to conduct HIV rapid testing and nurses to deliver antiretroviral therapy, significantly expanding access to services[4].

One strategy for this expansion will be the introduction and scale-up of innovative approaches, including point-of-care (POC) technologies, while strengthening and improving efficiencies in existing conventional laboratory systems and the networks between laboratories and health facilities. POC testing may enable more clients to access the benefits of diagnostics, while also facilitating receipt of their results during the same visit. This faster turnaround time of results may allow for speedier clinical decisions (e.g., treatment initiation, treatment regimen switch, adherence and counseling, linkage to preventive services for HIV-negative patients, etc.), improved retention in care, and decreased loss to follow-up. While many considerations for planning and implementing POC testing are similar to those for laboratory-based diagnostic testing, POC testing involves unique challenges when it comes to product selection and placement, training and supervision, device monitoring, service and maintenance, safety and waste management, data management, clinic and patient pathways performance, quality assurance, and supply chain management [21].

2.1. Quality of POCT related factors.

The accomplishment of POCTs stress well-built quality assurance system at all phases (Pre analytical, analytical and post analytical). Studies have exposed errors connected with POCTs with weak quality assurance mechanisms. For instance, a pilot investigation conducted by Centers for Medicare Medicaid

Services of USA in 2005 has been reviewed by Meier and Jones on the POCT mistake sources, Magnifiers, avoidance strategies, and detection monitors summarized that 19% of testers had been neither qualified nor evaluated in the assays they performed. in addition,32% of practical test operators could not place test information when asked to refer to them, 25% of them failed to go behind manufacturer's instructions,7% of test operators can't perform calibrations,32% of test operators unsuccessful to carry out quality control, 6% of investigators used expired reagent kits, whose manufacturers integrity would no longer assure. [22]

Implementation of a quality system is critical to ensuring reliable testing results. Ensuring the quality of laboratory services requires a focus on all the components of laboratory operations, including organizational structure, documentation of policies and procedures, resource mobilization and management, management of laboratory data, internal and external quality control systems, preventive maintenance, procurement, inventory management, and safety. The implementation of quality systems in both laboratory and non-conventional laboratory environments is indispensable. The training program for those performing HIV tests must be competency and performance-based, and must include a focus on good laboratory practice, laboratory safety, specimen collection and handling, recording and transcription management, reporting and data management, and quality control. All testing algorithms must be validated in the country prior to implementation. Quality control specimens must be used to monitor the correct performance of HIV testing. Quality control traditionally involves the testing of specimens of a known value using the same reagents and equipment that are used for the specimens being measured. Since rapid/simple HIV test kits are single-use devices, this approach is not possible. Quality control specimens must therefore be used in a manner that monitors the correct performance of the test by the tester and the ability of the test kits to work properly. While it is not possible to test each kit, quality control specimens can be used to detect damage to an entire batch or lot of kits due to improper storage or handling, or through manufacturing defects [23].
A study conducted in London by Sucket *al* on Rapid HIV testing using Determine TM HIV 1/2 antibody tests, Rapid point-of-care tests (POCTs) for HIV enable clinicians to give either a negative or preliminary positive HIV result at the initial patient visit. POCTs are popular with many patients, as a rapid result can reduce anxieties associated with the longer waits for laboratory test results.1,2 False-positive results are, however, known to occur with HIV POCTs and inevitably cause patient anxiety.3 All positive HIV POCT results therefore need laboratory confirmation using a venous blood sample.[24]

Study conducted in South India in HIV Testing National Reference Laboratory on External Quality Assurance Scheme (EQAS) Showed that from 9419 samples tested for Quality Control, 9371 (99.49%)

reported right results and 48 (0.50%) gave unacceptable results. Out of 48 samples 22 (0.23%) false negative (FN) and 26 (0.27%) false positives (FP) results were reported. Because of Mislabeling 91.8% test results reported back, leaking vials, sample contamination and transcriptional errors were identified as major challenges for proficiency testing that were not performed correctly. Of them, 445 (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.[25]

African countries i.e., a Study conducted in South Africa on assessing quality management system for rapid HIV testing services in primary healthcare clinics, showed that rural PHC clinics' average rating score for fulfillment to the WHO guidelines laid between 64.4% and 89.2%. 10 out of 11 clinics were rated as moderate 70-89% based on WHO evaluation. All clinics have achieved highest for the following audit component such as; equipment, process control and specimen management, and facility and safety, with 100%. Clinics obtained the lowest scores for the 9 assessment audit component followed by process improvement and organization, with 40.9%, 45.5% and 56.8% accordingly [26].

2.2. Performance of non-laboratory professional relates factors.

Along with study review from Zambia National Reference Hospital, most study participant performing an HIV rapid test reported the test to be simple. Particularly, some lay counselors have complexity in finger puncture and blood drawing as revealed by Mwangalaet *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. Most contributors expressed the importance of such activities to supervise their performance in HIV rapid testing, but suggested more frequency to guarantee performances of proficiency. Generally this study concluded that service provision in Task-shifting joined with policy shifts have challenged quality of testing service.[17].

In spite of 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 [18].

In Kenya, the study was reported that at lower-level facilities QC monitoring was done but was not conducted regularly, consistently, and not rigorously. From the report indicated that, Eighty nine percent (89.0%) of the DTS panels were correctly detected by the participants as clear positive or negative, whereas 11.0% had an error in detection using any of the two kits or applying the NHTA requirement. The key reason of inaccuracy was inappropriate appliance of the kit user manual especially on the required time. The study participants interpret the results before the waiting time. In a continuous observation, there was progressive decline of the errors obtained by the participants with increase in the number of participation in the PT program [27].

The study revealed on HIV testing in Addis Ababa by Regasa B. in 2012 that out of 20 assessed hospitals and clinics cases, three or fourteen percent of laboratory personnel's who conduct HIV testing were have no training in HIV testing .a few laboratories 2 (10%) do not follow HIV testing standard and also 2 (10%) laboratory personnel's don't know what to do in case of imprecise outcome. 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 be short of of skilled human resources, not follow HIV testing standard and poor involvement in EQA [28].

Even though Ethiopia outlines the policy to apply point-of-care technologies (POCT) through federal ministry of health, there is study gap on quality assurance, employee's proficiency and results reading of rapid HIV testing. Thus, this study will add an input to get the gap of rapid HIV testing service giver on practice of quality assurance on testing sites and staff performance in selected Adama, public health facilities.

- Figure 1: Conceptual framework determine performance level of non medical laboratory professionals on Rapid HIV testing in Adama public Hospital and health centers Oromia, Ethiopia,2020.

3. Objective

3.1 General objective

- The general objective of this study was to assess performance and associated factors of all non-medical laboratory professionals working on rapid HIV testing in Public health facilities in Adama, Oromia, Ethiopia February- April, 2020.

3.2 Specific objectives

- To evaluate the performance of all non-medical laboratory professionals working on HIV rapid testing at point of care site in Adama Public health facilities Oromia, Ethiopia.
- To identify associated factors on non compliance of HIV rapid testing at point of care test in Adama Public health facilities Oromia, Ethiopia.

4. Materials and Methods

4.1 Study area

The study was conducted in oromia region Adama city administration. Adama city administration is one of a city located in East Shewa Zone. It is located at 8.54°N 39.27°E at an elevation of 1712 meters, 99 km southeast of Addis Ababa. The Adama city administration consisting of 14 urban and four rural kebeles with total population 388,257.[29]

In the city there are 1 public hospital and 7 public health centers: Adama health center,Gada health center, Anole health center, Biftu health center, Boku Shanan health center , Awash Health center and Dambala health center. Adama city provides health services including HIV rapid test, VCT, PICT, and PMTCT.

4.2 Study design and period

Facility based cross-sectional study was conducted to assess performance and associated factors of all non medical laboratory professional working on rapid HIV testing in Adama public Hospital and Health centers. The study was conducted from Febraury- April, 2020.

4.3 Population

4.3.1 Source population

All non-laboratory professionals working at Adama Public health facilities, who were providing HIV rapid testing/services at point of care site,

4.3.2. Study population

Non-laboratory health professionals who were working in Adama Public health center and Hospitals providing HIV rapid testing/services at point of care sites were included in this study.

4.4 Inclusion criteria and exclusion criteria

4.4.1 Inclusion criteria

- All governmental Health centers and hospital located at Adama city and provides HIV rapid testing services was included
- All non laboratory professionals at Adama Health centers and hospital who was working on HIV rapid testing.

4.4.2 Exclusion criteria

- Non laboratory professionals who were not willing to take part in the study were excluded.
- Non laboratory professionals on annual leave.

4.5 Study variables

4.5.1 Dependent variables

- Performance of non medical laboratory professional working on rapid HIV testing.

4.5.2Independent variables:

- Age
- Sex
- Profession
- Experience of Proficiency testing participation
- Types of testing point (e.g. PICT, VCT, and PMTCT)
- Training on HIV rapid test
- Test reading time
- Quality control practices
- Kit storage condition

4.6 Sample size calculation and Sampling technique

4.6.1 Sample size determination

In order to get a representative sample and to come up plausible finding of HIV test performance among Adama public hospital and health centers of non medical laboratory professionals was determined using single population proportion formula, [n = (Z _/2)2 p (1-p) / d2] , by using the proportion of competency performance evaluation(p) from previous research done on this topic in Addis Ababa.[30] the following assumptions was capture:

(p = 0.65),Z ω/2 = 1.96 and margin of error will be 5% (d = 0.05) .

n = z (α/2)2 p (1-p)
d2

n = Sample size
P =0.65
d=Marginal of error
n = (1.96)2 0.65(0.35) = 350
(0.05) 2

By adding (10 % non-responses, refusal and incomplete) = **385** the total sample size of 385 all non laboratory professionals was included in this study. Since the total number of all non laboratory professionals who working on rapid HIV testing in Adama public hospital and health centers were less than calculated total sample sizethat means in all health facility only 348 non laboratory professionals working on Rapid HIV test), all non laboratory professionals 348 of them was included in this study.

4.6.2 Sampling Method

The list of governmental health centers and hospital under Adama city administration was listed and number of non laboratory professional those working on rapid HIV test at POCT is obtained and all taken.

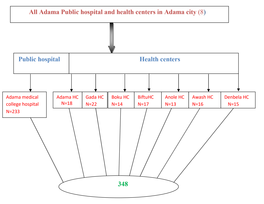

Figure 2: sampling procedure frame work for allocating study participants for performance and associated factors of all non-medical laboratory professionals working on rapid HIV testing in Adama health centers and hospital Oromia, Ethiopia,2020.

4.6.3 Data collection procedure

The letters of support from AAU, Department of Medical Laboratory Sciences was collected and permission was obtained from Oromia health bureau and respective hospital and health centers before data collection begins. Then data for this study was collected through direct observation [Annex VI] from HIV testing sites (VCT, PMTCT, PICT, and TB clinic, and others). Proficiency testing panel samples was performed using HIV rapid test by services provider at POCT. Data were collected by all health facility Laboratory quality officers.

4.6.4 Laboratory analyses

4.6.4.1 Source of proficiency testing sample and back ground

Known positive and negative DTS samples which were prepared for HIV proficiency testing (PT) collected from Addis Ababa Public Health Research and emergency Management Laboratory (AAPHREML). The PT samples were prepared at Addis Ababa Public Health Research and Emergency Management Laboratory (AAPHREML) based on Standardized operating procedure protocols of proficiency testing sample preparation.[Annex VII]

Addis Ababa Public Health Research and emergency Management Laboratory was founded in 1996 G.C in Addis Ababa, Ethiopia. Today the laboratory is providing laboratory testing service by receiving clinical samples from more than 120 private and government health facilities located in Addis Ababa on the following scope of tests: molecular (viral load, DNA PCR, Genexpert MTB/RIF) analysis, clinical microbiology analysis and Hematology. In addition to the testing service the laboratory provides External quality assessment (EQA) for HIV testing, TB and malaria microscopy. The laboratories also provide and facilitate training for laboratory professional, reagent preparation for TB. To improve the quality of the laboratory services the laboratory s participating in Accreditation process by ISO-15189 standards. So far it is granted an accreditation on two scopes of testing (HIV-1 Viral load and Genexpert MTB/RIF). The laboratory is also working to achieve full scope accreditation until the end of 2020. [31]

Briefly, the quality of the sample was verified by experts before and after Dry Tube Sample (DTS) preparation. All safety precautions will be taken because they are highly infectious. Look at [Annex VII].

4.6.4.2 Proficiency testing

Known PT sample was distributed to participant testing sites to determine performance evaluation and associated factors of non medical laboratory professionals working on rapid HIV testing the presence or absence of a HIV1/2 Antibody. The PT samples were well characterized at AAPHREML by qualified laboratory scientists before being distributed to study participants. The samples were carefully coded and each participant was ordered to perform the reconstituted sample or the serum test from the three negative and two positive samples that were blindly distributed to check reactivity. The

samples were distributed to the participant sites from February 2020 until April 2020. Then the result from each participant was recorded on preparations form and collections back by principal investigator.

4.7. Data quality assurance

Samples were prepared according to standard procedures developed by AAPHRELML and WHO guideline. And the-inter personal test result of the sample was cross checked b/n five laboratory professionals before DTS sample distribution. Onsite evaluation was conducted by principal investigator using checklist.

Prior to main data collection pre-testing was conducted in one non-governmental hospital (Adama General) and then clarity of the questionnaire, formats checked and appropriate modification was created. Then a carful implementation was undergone during the process of onsite assessment, interview and DTS proficiency testing sample distribution with strong supervision by principal investigator.

4.8 Data analysis and interpretation

Epidata version 3.1 was used for data entry and the data was exported to SPSS version 23 for analysis. Frequencies and proportions comparison with 95% confidence interval were used to determined dependent and independent variables and results was explain using numbers and percentages.. All variables, with p-value < 0.25 in bivariate logistic regression were taken to multivariate logistic regression. Multivariate logistic regression analysis was done to control for possible confounding variables. P-value < 0.05 and 95% confidence interval (CI) and AOR was used in judging the statistical significance of the associations.

4.9 Ethical considerations

Ethical clearance was obtained from Addis Ababa University, College of Health Science, Departmental Research and ethics review committee (DRERC), of Department of Medical Laboratory Science. Permission letters was obtained from Oromia Health Bureau, respective hospital and health centers. Moreover, privacy and confidentiality was assured for all study participants. The right of any individual not to participate or withdraw from the study was respected at any point. Data collection

from each study participants was beginning after written consent was obtained. No name and other identifiers were indicated on the questionnaire. Data collected from hospital, health centers and individuals was stored in a secure place.

4.10 Dissemination of results

The finding from this study will be presented Department of Medical Laboratory science, different seminars and distributed to Hospitals and other concerned bodies who are working on similar subject matter and also further effort will be employed to publish the findings in different scientific journals.

4.11 Operational definitions

Discordant result: - When any of participants report one false positive or false negative; that were considered as discordant.

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, Stat Pack (screening), Abon and SD BIOLINE as tie breaker

HIV testing process: includes activities accomplished in pre-analytic, analytic and post- analytic procedure.

Key population: people living with HIV

Non laboratory setting:-designated area where HIV testing processed out of laboratory.

Non Laboratory professionals:- peoples not graduated by medical laboratory profession.

Performance Evaluation:-Ability of non medical laboratory professional to follow appropriate procedure in conducting HIV rapid/ testing.

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

Poor performance: - that non laboratory professional that scored one mistake from the five samples given during the tests which were either false positive or false negative was considered as poor performance.

Priority population:-group of persons with mental illness or mental retardation

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 and validated specimens that distributed to testing sites for blind testing which is produced by AAPHRI/EMI, (Addis Ababa Public Health Research and Emergency Management Laboratory)

5. Result

5.1 Socio demographic Characteristics of study participants

In this study, a total of 348 non-medical laboratory professionals were participated. Most of participants, 188 (54.0%) were with age range from 20 -35 Years. In addition 192 (55.2%) of participants were females. In terms of professional categories, the highest study participants were clinical nurses, 230 (66.1%) followed by Health officer and Midwifes [73 (21.0%) and 32 (9.2%)] respectively. Regarding on working experiences higher percentage of study participants 167 (48.0%) had < 5 years working experience, 181 (52.01%) of the participants had training on HIV testing (Table1).

Table 1. Socio demographic characteristics of HIV rapid testing non-medical laboratory professionals working on in public Hospital and health centers in Adama, Oromia, 2020

variables	Description	Frequency N	Percent (%)
Age	20-35	188	54.0
	36-45	103	29.6
	46-65	57	16.4
	Total	348	100.0
Gender	Female	192	55.2
	Male	156	44.8
	Total	348	100.0
Profession	Nurse	230	66.1
	Midwifery	32	9.2
	Health Officer	73	21.0
	Others	13	3.7
	Total	348	100.0
Professional working Experience	≤ 5 Years	167	48.0
	6-10 Years	60	17.2
	11-15 Years	29	8.3
	>15 Years	92	26.4
	Total	348	100.0
Having HIV rapid test training	Yes	184	52.9
	No	164	47.1
	Total	348	100.0

5.2. HIV Proficiency testing Performance of non Medical laboratory professionals

In the present study, Proficiency test were performed correct in 336 (96.6%) test analysis. However, 12 (3.4%) were not accepted or discordant result in the performance evaluation, but there were no invalid testing performance during in the evaluation. Majority of errors 7 (2%) out of 12 (3.4%) were from reports of false negative non acceptable test performance; and the second most repeated error 5(1.4%) were from false positive (FP) reports. However, no invalid performance was identified in the evaluation (Table 2).

Table 2. Proficiency test Performance of HIV rapid testing on non Medical laboratory professionals in all governmental health centers and Hospital Adama, Oromia, Ethiopia, 2020.

Variable		Number of Participants N	Percent (%)
Proficiency result	Accepted	336	96.6
	Non Accepted	12	3.4
	Total	348	100.0
Discordant test result	FN	7	2.0
	FP	5	1.4
	Invalid	0	0

5.2 Quality assurance performance

5.3.1 Pre-analytical

Assessment of Pre-testing phase elements indicated that, 255 (73.3%) of points of care HIV rapid testers had not used national HIV testing manual and SOPs which are specific to HIV rapid testing. HIV test kits storage management were applied by 309 (88.8%) study participants during point of care testing evaluation. However, 39 (11.2%) non medical laboratory HIV testing professionals were not followed standard HIV test kit storage management according to guidelines. In addition to that, 268 (77.0%) participants were Checked and recorded HIV test kit Expiry date before running test procedures. The other main pre analytical steps of quality assurance sample ID Proper labeling were not practiced by 33(9,5%) participants (Table 3).

5.3.2 Analytical quality assurance Performances

Most of study participants 216 (62.1%) were not Applied job aids and testing algorithm during HIV testing at point of care evaluation. Among 348 (100%) study participants only 18(5.2%) were not transferred right amount of samples with provided test kit devices. The Proper handling of test strip, when prepared test and beginning time, had been seen in majority of participants 325 (93.4%). Moreover 311 (89.4%) participants were labeled immediately as buffer added and However, usage of proper buffer batches shown lowest performance 94 (27%) of study participants. Those study participants that used correct result interpretation accordingly were 336 (96.6%); and Recorded test results immediately at the end of waiting time without delay were 304 (87.4%), as shown in (Table 3).

5.3.3 Post analytical quality assurance Performances

Most of the participants 324 (93.1%) results recorded in HIV test log book as soon as the result released. In addition, 308 (88.5%) was recorded and captured all elements in the register book correctly. However, 24(6.9%) and 40(11.5%) results not Recorded in HIV test log book and miss elements in the HIV test register books accordingly (Table 3).

Table 3 HIV rapid testing quality assurance performance of non-medical laboratory professionals working on in public Hospital and health centers Adama city, Oromia, Ethiopia, 2020.

Quality assurance cycles	Variable	Description	Frequency	Percent (%)
Pre-Analytical	Available SOP and Manuals for HIV testing	Yes	93	26.7
		No	255	73.3
	Storing HIV test kit out of sun light and in proper area	Yes	309	88.8
		No	39	11.2
	Checked and recorded HIV test kit Expiry date	Yes	80	23.0
		No	268	77.0
	Properly label sample ID	Yes	315	90.5
		No	33	9.5
Analytical	Application of job aids and testing algorithms	Yes	132	37.9
		No	216	62.1
	Timers settled before proceeding with testing	Yes	266	76.4
		No	82	23.6
	Handling of test strip properly when prepared testing	Yes	325	93.4
		No	23	6.6
	Transferred right amount of samples with provided test kit devices	Yes	320	94.8
		No	18	5.2
	Usages of proper buffer batches	Yes	94	27.0
		No	254	73.0
	beginning time Labeled immediately as buffer added	Yes	311	89.4
		No	37	10.6
	Used correct result interpretation accordingly	Yes	336	96.6
		No	12	3.4
	Recorded test results immediately at the end of waiting time without delay	Yes	304	87.4
		No	44	12.6
Post-Analytical	Recorded results in HIV test log book	Yes	324	93.1
		No	24	6.9
	Are all elements in the register book was recorded and captured correctly	Yes	308	88.5
		No	40	11.5
	Invalid tests was repeated and properly recorded the results in the log book	Yes	302	86.8
		No	46	13.2

5.4 Assessment of factors Associated with non accepted Proficiency test performances

In this study, 11 out of 12 discordant Proficiency testing results were done by participants who had lower Professional work experiences (≤ 5 years), Moreover 9 (2.6 %) out of 12 (3.4%) discordant testing performances were seen on not supervised by facility / Regional laboratory even it was not shown significance association with binary logistic regression (P-value 0.45 at 95% CI), However significant association on professional AOR=0.057(0.006-0.579),p=0.015 and highly significant to transferring right amount of sample AOR= 51.799(6.929-387.233),p=0.001.

Generally, gender, sex, work experiences, Training, Application of job aid and testing algorithm, Supervision by facility and regional laboratory were tested with binary logistic regression. Discordant finding of 11 (3.1%) out of 12(3.4%) were found with not application of routine Participation in EQA. (Table 4).

Table 4 Possible associated factors with HIV rapid test proficiency on non-medical laboratory professional's performance at governmental health centers and hospital, Adama, Oromia, Ethiopia, 2020.

Variables those<0.25 in binary logistic regression were included for multivariate analysis, and then profession and Transfer right amount of samples was significant.

Variables	Categories	Proficiency test result		Total	COR (95% C.I)	P-value	AOR (95%C.I)	P-value
		Accepted N (%)	Non Accepted N (%)					
Gender	Female	183(52.3)	10(2.9)	193(55.2)	4.27(1.913-19.602)	0.063		
	Male	134(44.3)	20(5)	156(44.8)	1			
Age	20-35	171(58.9)	11(3.1)	186(54.8)	264.(68.1-026)	0.055		
	36-45	103(29.6)		103(29.6)	1			
	46-65	50(18.1)	2(0.5)	57(16.4)				
Profession	Nurse	219(62.9)	11(3.1)	230(66.1)	108(.016-.719)	0.023	.037(.004-0.379)	.015
	Midwifery	22(5.2)		22(5.2)				
	Health Officer	72(20.7)	1(0.3)	73(20.9)				
	Other	13(3.7)		13(3.7)	1			
Work Experiences	≥ 5 Years	136(44.8)	11(3.1)	147(47.1)	388(.138-.955)	.039		
	6-10 Years	69(17.2)		80(17.2)				
	11-15 Years	29(8.3)		29(8.3)				
	>15 Years	85(26.1)	2(0.3)	82(26.4)	1			
Training on HIV testing	Yes	181(52.01)	3(0.86)	184(52.87)	3.703(.932-13.168)	.063		
	No	135(44.55)	9(2.58)	164(47.13)	1			
Application of job aids and testing algorithm	Yes	131(37.64)	1(0.30)	132(37.94)	7.925(.897-35.084)	.063		
	No	205(58.90)	11(3.10)	216(62.06)	1			
Supervision by facility staff or Regional laboratory	Yes	128(34.3)	3(0.9)	123(35.4)	1.667(.443-6.274)	.450		
	No	214(62.1)	9(2.6)	225(64.6)	1			
Transfer right amount of samples	Yes	325(93.4)	5(1.4)	330(94.8)	81.384(13.223-151.082)	.000	51.798(6.929-387.235)	0.003
	No	12(3.2)	2(1.0)	18(5.2)	1			
Participating in EQA	Yes	134(38.5)	1(0.3)	135(38.8)	7.297(.931-57.198)	.058		
	No	203(58.0)	11(3.1)	213(61.2)	1			

5.5 Proficiency test performances of facility testing site

Aggregating the discordance findings of this study, among 12 non discordant testing performances at outpatient department (OPD) were, 6(1.8%) false negative and 5 (1.4%) False positive were identified. However, VCT and TB clinic not detected discordant performances in the study evaluation (Table 5).

Table 5: Proficiency performance by testing sites in all governmental health centers and Hospital Adama, Oromia, Ethiopia, 2020.

Site of testing	**Proficiency test performances**			
	Non discordant N (%)	FN N (%)	FP N (%)	Total N (%)
OPD	224 (64.4%)	6 (1.8%)	5 (1.4%)	235 (67.6%)
VCT	50 (14.3%)	0 (0%)	0 (0%)	50 (14.3%)
PMTCT	47 (13.5%)	1 (0.3%)	0 (0%)	48(13.8%)
TB clinic	15 (4.3%)	0(%)	0 (0%)	15 (4.3%)
Total	336 (96.5%)	7 (2.1)	5 (1.4%)	348 (100%)

5.6. Safety practice study professionals were not disinfected

Among 348 non laboratory professionals working at point of care HIV rapid testing sites 31 (8.9%) were not followed standard safety precautions. Observational assessment also shown as 64(18.4%) study participants working environments was not cleaned and organized for standard HIV testing working environments requirements. Likewise, 83 (23.9%) study participants were not disinfect and clean working space. Among 348 (100%) study participants 17(4.9%) were not practiced Proper waste disposal during the study evaluation (Table 6).

Table 6. Safety practice of point of care HIV rapid taste provider in selected government health facilities in Adama, Oromia, 2020.

variables	Description	Frequency N	Percent (%)
Follow all safety precaution	Yes	317	91.1
	No	31	8.9
Clean and organized working area	Yes	284	81.6
	No	64	18.4
Disinfect and clean working space accordingly	Yes	265	76.1
	No	83	23.9
Proper disposal of waste	Yes	331	95.1
	No	17	4.9

6. Discussion

In this study, all Governmental health centers and hospital administered under Oromia health Bureau Adama city (1 hospital and 7 health centers) were included. A total of 348 HIV Rapid Test providers who were active during the onsite assessment at their point of care sites were included conveniently. The significance of assuring quality of HIV rapid testing has been recognized as a key component towards confirming reliable result and has a core role in prevention and control HIV/AIDS, which was the main purpose of this study. With the introduction of point-of-care testing commonly referred as Voluntary Counseling and Testing (VCT), outpatient department (OPD), TB clinic, and prevention of mother to child transmission (PMTCT) involving the use of non-laboratory staff in routine testing has further increased the complexity of Quality Assurance.

The aim of the study was to evaluate Quality Assurance practice of HIV rapid testing at point of care Performance on non-laboratory professionals. The finding indicated that 336 (96.6%) were performed test analysis correctly. However, 12 (3.4%) were not accepted or discordant result.. Among 12 (3.4%) non discordant test performance 7 (2%) false negative (FN) and 5(1.4%) false positive (FP) were observed in the evaluation. The result is in line with the study conducted in India which indicates 48 (0.50%) gave discordant results. Out of 48 samples 28 (0.27%) were false positives and 22 (0.23%) false negative [25] Although there is improvement in test accuracy by non-laboratory professionals who are working on POCT, which is in line with study done in Zambia; our study shows there is a significant association as between proficiency test and profession [32]. This may be due to lack of sufficient training and frequent change in test algorism which may need frequent training & updates.

Depend on their profession, higher study participants 230 (66.1%) were nurse followed by 73 (21.0%) and 32 (9.2%) were Health officer and Midwifery respectively. In this study, Professional work experiences (< 5 years) accounts 11 out of 12 discordant Proficiency testing results. Higher number 167 (48.0%) of study participants work experiences ≥ 5 years' which In contrast with other study in South Africa that shows the majority of participants 80 (84.8%) have 5< 10 years in Health related experience. the majority of the lay counselors (24, 75 %) had testing experience of between a few months and five years (24). The reason might be in our country professional employment increased year to year compared with other country.

In this study professionals working on HIV rapid testing with having training on HIV testing were 184(52.9%). This is slightly different from a study conducted in north Ethiopia which was (56%) [33]. Additionally, it demonstrates low coverage when compared with the evaluation of the HIV counseling conducted in South Africa almost all the lay counselors 31 (96.8 %) had received formal training in HIV testing. This difference may be due to difference in sample size and characteristics of study participants, our study participants were below 5 years work experiences health professionals whom perform HIV rapid test in TB clinic, VCT, PMTCT and OPD but their study participants were laboratory and non-medical laboratory professional and their samples were only 128 participants. From the assessed testing points, 184(52.9%) health professionals' who conduct HIV testing were found to have no trained in HIV testing. This is incomparable with study conducted in Tigrey, Ethiopia, which reported only 64(44%) were found not trained in HIV testing [33].

In our study 216 (62.1%) study participants didn't follow national test algorithm. This is in line with study conducted in Ethiopia [28]; generally, our study results supported by the previous observational study made by others so as to work experience and training significantly affect the accuracy of rapid HIV test results [19].

Among 348 professionals 31 (8.9%) were assessed at point of care HIV rapid testing sites had not followed standard safety precautions. Observational assessment also shown as 64(18.4%) study participants were working environments not cleaned and organized for standard HIV testing working environments requirements. Likewise, 83 (23.9%) study professionals were not disinfected and clean working space accordingly in each quality assurance cycles due different reasons such as unavailability or shortage of soaps and disinfectants. Likewise, a study done in South Africa on evaluating quality management systems tQMS) for HIV rapid testing services in primary healthcare clinics, showed that rural public health clinics' average score for fulfillment to the World health organization strategy ranged between 64.4% and 89.2% and have attained uppermost for the following assessment element: equipment; process control and specimen management; and facility and safety, with 100% score. The lowest scores were gained from Clinics for audit assessment followed by process improvement and organization, with 40.9%, 45.5% and 56.8%, in the order. [26].

We believe the implementation of the EQA program for HIV testing had additional benefits for example, helping to strengthen the relationships of the point of care testing site with facility /regional/

laboratory supervisory network as well as improving communication between the networks and the regional/national/ referral laboratory, as it has been observed elsewhere.

In this study most of assessed non laboratory professional 255(73.3%) not used standard operating procedures (SOPs), but study conducted in South East Asia indicates only 1 out of 13 (7.7%) assessed laboratories did not have SOPs [34]. The low application of standard operating procedure might be due to lack of training on importance of SOPs and weakness of supportive supervision and supporting from facility and regional laboratory personnel's.

The average score of the proficiency testing were 96.6%.This is lower than survey conducted in South Africa by Solamawit Alemu Woldesenbet which indicated that 98.9% [13]. This deference may be due to study participant difference and method used for HIV testing. Because our study participants included all testing points and they performed HIV testing using HIV rapid test but their study participants' only laboratory professionals and they used HIV rapid test and ELISA to perform HIV rapid testing. Our findings demonstrated that 96.6% of testing points score which was quit supported with a study conducted by Jean Louis and his colleagues which was 97.5% [35].

7. Limitation

Due to time shortage we did not conduct interview for non laboratory profession which would be give more information about knowledge of professional on rapid HIV test.

8. Conclusion and recommendation

8.1 Conclusion

In our study, the overall HIV rapid testing sites had (96.6%) performance score. False negative and false positive results need attention since misdiagnosis leads socio economic disturbances to the community. Therefore, immediate intervention is needed based on identified findings. Less experience non laboratory professionals shown lower Proficiency performances so this gaps might be minimized by facilitating training on HIV rapid testing.

In general, this study concluded that overall proficiency performance of HIV rapid testing services provider at point of care sites in Adama governmental health centers and hospital should need further improvement to minimize or eliminate non acceptable HIV detection.

8.2 Recommendations

We recommended to:-

- Extend the EQA to more health worker point of care testing site; As this will improve the performance of non laboratory professional.
- Regular onsite supervision program has to be strengthened and expand to address all point of care testing sites because we found discordant test result leading to improper diagnosis.
- Outpatient department health workers in Adama governmental health center and hospital needs more support than other department b/c there is more or less observable gaps were seen on HIV rapid test performance at OPD testing site.
- It's better to avoid work experience gaps by providing training for fresh professional to cover the gaps before they start permanent regular work.

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Annexes

Annex I: Information sheet (English Version)

Title of the Research Project:

To assess performance and associated factors of non-medical laboratory professional working on rapid HIV testing in Adama public Hospital and health centers , Oromia, Ethiopia

Principal Investigator: Gemechis Bulti (BSc, MSc candidate)
Name of the Organization: Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University

Introduction: You are invited to participate as a study subject in a research conducted by MSc candidate, from Addis Ababa University. Your participation is voluntarily. The research teams will include one principal investigator and two advisors from Department of Medical Laboratory Sciences, College of Health SciencesAddis Ababa University.

. Please take as much time as you need to read or listen in the information sheet.

Purpose of the Research Project: We are asking you to take part in this study because we will try to evaluate performance of non medical laboratory professionals working on rapid HIV testing in Addis Ababa public hospitals. The aim of the study is 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 pleys 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. Therefore, we invite you to take part in this study and contribute your role to identify gaps and inspire health facilities as well as HIV test providers towards ensuring standardized diagnostic efficiencies. The values are needed for providing

quality laboratory service. Thus, result from this study is expected to improve performance of non laboratory professional at POCT.

Procedures and the expected participation: If you are willing to participate, you need to understand the purpose of the study and give your consent. Not only this but also you will be perform HIV rapid test by using proficiency test sample. The proficiency test sample will be distributed by principal investigator. Then, you are requested to give your consent to participate in the study for principal investigator. Moreover, there will be a face-to-face interview for additional questions.

Potential risks: There will be minimal risks, however, there might be some minimal risk when we perform HIV rapid test. Nevertheless, we will try to minimize the risk as much as possible, as the personal protective equipment will be used.

Confidentiality: We respect your privacy and confidentiality. Any information that identifies you will not be shared with anyone else outside the study team. The information we will collect from you as part of the study will be kept in a locked file cabinet, or be protected by a password on the computer only accessible to personnel involved in the study. There is no sensitive issue that you will be asked related with your social desirability but any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Potential benefits to subjects and/or to the society: You will not receive any payment for your participation in this research study as compensation. However, based on the study result you will be treated in view of that. In addition, the result of the study will be beneficial for the result from this study is expected to improve performance of non laboratory professional at POCT.

Participation and Withdrawal from the Study: The participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind. You may also reject to give any information and performing the test. You can ask any questions regarding to this study.

Contact information. If you have any questions about this study you can contact the following principal investigators and advisors for further information.

-Name: Gemechis Bulti -Phone: 251921560964 -E-mail:gemeki2014@gmail.com

በአዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ የሕክምና ላቦራቶሪ ሳይንስ ትምህርት በማስተርስ ድግሪ ተማሪ የመመረቂያ ጥናት ላይ እሳተፋቹ ቅ.ንዝዘየሸ፡፡ እባክዎ በዚህ ጥናት ይመሳተፍ ከመሳማትዎት በፊት ከዚህ ከዚህ የሚፃናጫን ንብዛ በተሞሮ ያንብቡና ገልጽ ያለሆነልዎትን ማንናጫዎ የባቱ ይጠይቁ ፡፡፡

መግቢያ: የጥናት ርዕስ' Performance evaluation and associated factors of non medical laboratory professionals working on rapid HIV testing in Adama public hospital and health centers, Oromia, Ethiopia.'የአርስዎ በዚህ ጥናት ላይ የማሳተፍዎት ተጎትር መሉ በመሉ በፀፃ ፈቃደኝነት ላይ የተመሰረተ ነዉ፡፡ በጥናቱ ይመሳተፉ ነዉ፡፡ በጥናቱ ይመሳተፍ ከወሰኑ የማስማሙ ከዚን የሰምምነት ቅፅ ላይ በጹሁፍ ፊርማ ማስቀመጥ ይጠበቅቦዎታል ፡፡

የጥናቱ ቁሳቁስ ይመሰገን የሚጠይቅበትኮ ምንድን ነው? በዚህ ጥናት ይመሳተፍ የማስማሙ ከሆነ የጥናቱ አሳማ ማውቅ እና የመማህየሃ ቅፅን በመፈረም መማማትት ይጠበቅብዎታል፡፡ ያደ ብቻ ሳይሆን ከዚፉት ከሰዛበት የመጫን ናመና በመጠየም የሌች አደ ሄ ምርመራ መስራት ይጠበቅብዎታል፡፡ ይዞን አንጅ ያደ አደነቱ መረጀ የርስዎን ማንነት የሚገልጨ መረጀዎችን ማስትም ስም፣ እድሌቸና የስልክቁጥር የመሳሰሉትን መረጀዎችን አደጨምርም፡፡ ያልዳንም ለዚህ አገልግሎ ብቻ የሚጨል እርስዎን ለማወቅ የሚያስችል መለያ ቁጥር ተቅም ላይ እንዲጨል ያደረጋል ፡፡

በዚህ ጥናት መሳተፍ የሚያስከትላቸዉ ቹቋሮች ምንድን ናቸዉ? ናመና በሚስደሰት ወቅት ምንም አደነት የስፋ ችግር አያጋዋምየት፡፡ሆኖም ገን ናመናዉ ስለር ልረዋ ስለምችል የደብንት መጠበቅ አሎ ስለ ምንም አደነት ጎዳት አደደርስም፡፡

መረጀ የማስወር የጠበቀ መቆየት የሚችለዉ እንደት ነዉ? ስለሰለም የስወት ማንናጫም መረጀ የሚጠበቁ ደጥናት ብቻ ነዉ፡፡ ይህን ማወደር ሊያገኙ የሚችሉት የተወሰኑ የጥናቱ ተባባሪ ሰዎች ብቻ ናችው፡፡ ከዚያም በላይ ስለ እርስዎ ያለውን ማንናጫም መረጀ የተዘደ የደለና ቃል ባለው የኮምፒውተር የመረጀ ማህደር ውስዋ እንዲቀመዋ ደደረጋል፡፡

በዚህ ጥናት መሳተፍ የሚያስገኛቸው ቅቅሞች ምንድን ናቸው ? ያዘ ጥናት የማስተናገ ዲንሄ መመረቂያ እንደመሆን መጠን በዚህ ጥናት በመሳፈልም በገበዘዘ የሚያገናኙት ቅቅም

ባለፕሮጀክ ከግዳቱ በሚገኘው ውጤት ገን ቀጠሮግ ንሶት፡፡ የእርስዎ ቀጥቅር ከላቦራቶሪ ባሉሥ ጨጭ ያሉት ሰዎች ምርመራጨን በቅክክል እንደሰና ከሰተኛ አስተዋጽዎ ያኖረሃል፡፡

በዚህ ዋናት ቀሲዲል የመማያ መብቶች ምንድን ናቸው ?

በዚህናናት መጠየቁመብቶችዎ ሊከበሩበትሥሊኖርዎትየተመሰረተከመሆኑበማንኛውምሰዓትናነሳት የማቋረጥመሉመብትዎንበማንኛውምምክንያትሳይሰጡ ሊሰጡምንከመፈለግዎንየመወሰንዎትመብ ምትምንአለሥንትእነኳንአነሳነሳሥ፣ከዚህምበተጨማሪሚናነሳንበተመስከተማንኛውንምል ደንትተታዳሮመጠየቅዎንከሕግአስማማንትንመብትአለዎት፡፡

ሚያዚ ካልቦት ወደዎ ችግር ቢደጋመጠውቅት ምን ማደረግ ያለበሰን ይጠበቅ ይሆናል ሚናት

በተመሰከተ ወደዎ ከፊህ ሚናት ጋር በተዛመደ መሰከ በሊሚያ,ግመሙ ሮንንተሮ አደ,ነዎች ወደዎ ግያቁ ካለዎት በሚመለከተው አሮሪዳ ደወዮሙ፡፡

ስም፡ኮመሮስ ቡልቂ **ሞባይል፡ +251-921569964** **ኢሜል፡ gomeki2014@gmail.com**

Annex III. Consent form (English version)

Id number_____

English version information sheet and concent form for the questionnaire developed for the assessment of Performance evaluation and associated factors of non-medical laboratory professionals working on rapid HIV testing in public Hospital and health centers of Adama city , Oromia, Ethiopia.

I had been informed that the objective of this study is to assess performance evaluation and associated factors of non-medical laboratory professional working on rapid HIV testing in public Hospital and health centers of Adama city, Oromia, Ethiopia. The results of this study have an importance to treat me and other health worker, and to be used as an input for the future development of strategies or guidelines for performance evaluation. I had been also informed about the confidentiality of this study. The principal investigator requested me to participate in the study that would require my willingness to provide the required data. Therefore, with full understanding of the importance of the study, I agreed voluntarily.

I_____ hereby give my consent for providing the requested information and specimens as the doctors find best for me.

Annex IV. Informed consent form (Amharic version)

የተሳታፊዎች ስምምነት ማረጋገጫ

የጥያቄር ቁጥር ----------

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ-"To assess performance and associated factors of non-medical laboratory professional working on rapid HIV testing in Adama public Hospital and health centers,Oromia Ethiopia" ዋናች ላይ በቂ ገለጻ ደርጎልኛል፡፡ለጥናቱም ከዋናው ቁጥር ተቁጥሬ የመጠጫን ናሙና መስራት እንደምጠበቅብኝ ተነግሮልኛል፡፡ የጥናቱንም አላማዎች ተረድቻለው፡፡

በቾስ መጠይቅ ላይ የገለጽኳቸው መረጀዎች በመሰ በጥያቄር የተጠየቁ እንደገባሁ ተገንዝቢያለሁ፡፡ ብቁናቁ ላይ ያለመጥየቄና ማንኛውንም መረጃ ያለ መሰጠት እንዳልም በማንኛውም ጊዜ ከዋናች ሪሰን የማገለል መብቱ የተጠበቀ እንደሆነ ተገልጾልኛል፡፡

ለዚህ ለዚህ ጥናት መረጀና የስምምነት ቃሴን

የሰጠሁት በአጠቃላይ ሀኔታውን በመረዳትና በነጻነም ፍቃደኝነት ነው፡፡ በቀጨሜሪም ማታው ለመጠየቅ ተፈቅዶልኝ ለማወቅ የፈለኩትን ያህል ማብራሪያ አግኝቻለው፡፡ የዚህ ጥናት ተሳታፊ በመሆን የማገኘው ቀጥም በምርመራ ግጨ የምፈልገትን ስህተት ማጨጣት እና የመፍትሄ ሀሳብ ማቅረብ እንደሆነ ተረድቻለሁ፡፡

በአጠቃላይ እኔ ከላይ በመተማመኛ ቅፅ የተጠቀሱትን ሁሉ በሚገባና በተረጋጋ መንፈስ አንብቤያለሁ፡፡ስለዚህ በዚህ ጥናት ለመሳተፍ ፈቃደኛ መሆኔን በፊርማዬ አረጋግጣለሁ፡፡

ፈርማ---------- ቀን ----/----/----------

(የስምምነት ቅጹን ማጋበብ ለማይችል ተሳታፊነው)

የአማካሪ ስሜ ስም ---------- ፈርማ ----------

ቀን----------

Annex V Questionnaire

To assess performance and associated factors of non-medical laboratory professional working on rapid HIV testing in Adama public Hospital and health centers Oromia, Ethiopia from Feb to April 2020

Study Area code _____date_____

Socio demographic characteristics

Sex: ◯Male ◯male

Marital status: ◯single ◯ married ◯her

Age: _____

Profession ◯ Nurse ◯ Midwifery ◯ Health officer ◯ other

Work experience _____

Specific questions

1. Did you train on current HIV test Algorism and has certificate? ☐Yes ☐No
2. Are standard operating procedures for all HIV testing process written, up-to-date, and acce☐ble? Yes ☐ No
3. Are you participating in external quality control testing before? Yes ☐ N☐
4. Is HIV test kits are stored out of sunlight and have its proper storage area? Yes ☐ No ☐
5. Is there a written procedure for collecting, processing and storing specimens? Yes ☐ No ☐
6. Did you label all sample and kit during HIV test? ☐Yes ☐lo

7. Is there national test algorism posted in Point of care test YES ☐NO ☐

8. Is there completed and standardized national HIV rapid testing register or logbook available and in use at testing site? YES ☐ NO ☐

9. 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? YES ☐ NO ☐

10. Are all the elements in the register or lo[gbook recorded or captured correctly (such as client demographics, kit names, lot numbers, expiration dates, tester name and individual and final HIV results)? YES ☐ NO ☐

11. Is the total summary at the end of each page of the register or logbooks completed accurately?

YES ☐ NO ☐

12. Are invalid test results recorded in the register or logbook? YES ☐ NO ☐

13. Does the testing point receive periodic supervisory visits? YES ☐ NO ☐

14. Are invalid tests repeated and the results properly recorded in the register or logbook?

YES ☐ NO ☐

15. Is there External quality audit through proficiency testing, or supervision by facility laboratory or regional laboratory?

YES ☐ NO ☐

Annex VI: Observational checklist

Observational checklist To assess performance and associated factors of non-medical laboratory professional working on rapid HIV testing in Adama public Hospital and health centers Oromia, Ethiopia from Feb to April 2020

Study Area _____date _____

Standard Element to be observed		Yes	No	Comments
1	Followed all safety precautions as per SOP (*lab coat, gloves, etc….*)			
2	Working area is clean and organized			
3	The samples are verified *Note: Verify that the plasma tubes are properly labeled and they are the correct samples*			
4	Check and record expiry date of test kits on the kit package			
5	Write sample ID on kit and the right kit is used according to test algorithms			
6	Is the buffer used for test is the same batch			
7	Set timer correctly before proceeding with testing.			
8	Transfer sample using the correct sample collection device provided by test kit (loop) *Note: Verify that loopful (right amount of sample pipetted) plasma is collected*			
9	Right amount of Sample is added in to sample hole properly			
10	The *integrity* of test strip is verified before opening pouch *Note: Verify there is no damage of pouch or strip and desiccant pack is present inside pouch.*			
11	Handle test strip properly while preparing for test			
12	Start the time immediately once the puffer is added to the hole			
13	Record test result ONLY at the end of waiting time without delay and report reported according to national standard			
14	Refer to Job Aides while performing Test			
15**	Use correct result interpretation *(Positive, negative, Invalid)* and record according			
16	Properly dispose of waste into benchtop biohazard bag through testing *(Lancet should be disposed of in sharp container if applicable)*			
17	Record results in HIV test Logbook (or QC Testing Logbook) correctly *(All required information is correctly captured)*			
18	Disinfect and clean workspace at the end of testing and dispose of wastes in correct waste bins *(gloves, wrappers, benchtop waste, etc.)*			

1.0 TITLE
Preparation of Dried Tube Specimens for HIV-1 Rapid Test

2.0 PURPOSE
The purpose of this procedure is to provide guidance on how to prepare dried tube specimens (DTS) quality control (QC) panel for HIV-1 rapid test

3.0 SCOPE
This procedure applies to quality assurance activities.

4.0 RESPONSIBILITIES
Regional Laboratory Staff who have been trained on Preparation of Dried Tube

Specimens for HIV-1 Rapid Test

5.0 EQUIPMENT
5.1 Biosafety cabinet (optional)
5.2 Vacuum pump unit for PBS-Tween-20 buffer filtration(optional)
5.3 Pipette aide
5.4 20µL multi-dispensing pipettes (Rainin E4 Electronic Pipette, LTS E4-300XLS+ - catalog # 17014448; Globe Scientific Diamond RV-Pette PRO™ Repeat Volume Pipette - Fisher 22-010-1162, or equivalent)
5.5 Centrifuge for plasma separation
5.6 Water bath for plasma heat inactivation

6.0 SUPPLIES
6.1 2.0mL conical bottom Sarstedt cryo-tubes (catalog # 72.694-007; www.sarstedt.com)
6.2 1L deionized water
6.3 PBS with 0.05% Tween 20, pH 7.4 powder (cat P3563, www.sigmaaldrich.com)
6.4 Green food coloring dye
6.5 Pipette or syringe tips for multi-dispensing pipettes
6.6 Disposable transfer pipettes (Samco transfer pipet, catalog # 282) or 200µLlab pipette with tips for DTS rehydration
6.7 Tube racks to accommodate 1.5mL tubes (Labet)
6.8 Tube racks to accommodate 2.0mL tubes
6.9 Cryo labels for tubes (Diversified Biotech, catalog #LCRY-2380) and freezer boxes (Diversified Biotech, catalog #LCRV-1258)
6.10 50mL conical tubes (Fisher, catalog # 14-432-22)
6.11 Serological pipette, 10mL
6.12 250mLstorage bottles (Cole Palmer Catalog # WU-06106-14)
6.13 Zip Lock bags, large, for storing plasma units in freezer

6.14 1L Disposable 0.2 µM filter flask - optional
6.15 Absorbent surface protectors or bench pad/linen saver
6.16 Paper towel
6.17 Gloves
6.18 Lab coat
6.19 Benchtop biohazard bag and bag holder
6.20 Biohazard autoclave bags
6.21 Decon tradecon bleach-based disinfectant

7.0 SPECIAL SAFETY PRECAUTIONS

7.2 Wear personal protective equipment (PPE) while handling DTS and other biological material.

7.2 Handle DTS as potentially infectious material.

7.3 Ensure that equipment, supplies and, linen contaminated with infectious material is either disinfected or discarded properly as biohazardous waste.

7.4 Follow universal safety precautions for handling biological materials and manufacturer's safety precautions for handling chemical materials.

8.0 PROCEDURE

8.1 Preparation and HIV Sero status Verification of Specimen Bank Units (Prior to Panel Preps)

8.1.1 Obtain rejected whole blood or plasma units from local blood bank of different HIV status including both HIV positive and negative samples. Initially acquire >50 units to build specimen inventory. Continue to acquire more units to build a large specimen inventory.

8.1.2 When using whole blood units, transfer whole blood from bags to clean 50 ml conical tubes. Centrifuge whole blood at 1,000 x g for 10 minutes to separate plasma. Using a serological pipette, carefully transfer plasma from the conical tubes to clean and labeled 250mL storage bottles.

8.1.3 When using plasma unit, transfer plasma from bags directly to a clean and labeled 250mL storage bottle.

8.1.4 Store plasma at 2-8°C up to 7 days until further testing has been conducted. If further testing cannot be conducted within 7 days, transfer the plasma to -20°C. Minimize freeze-thaws.

8.1.5 Regardless of HIV status provided by the blood bank, the specimen reactivity must be verified by the laboratory that is responsible for preparing the panel by using either of the following methods:

8.1.5.1 Rapid Test Algorithm: Test plasma specimens based on the country's HIV rapid test diagnostic algorithm. Make sure the rapid test algorithm is able to differentiate identifying and distinguishing HIV-2 positive samples if appropriate.

8.1.5.2 ELISA and Confirmatory Test Algorithm: Test plasma specimens using ELISA and confirm positive results with either Western Blot or Geenius confirmatory tests.

8.1.5.3 Ensure that you have at least 30 confirmed HIV-1 positive plasma specimens prior to preparation.

8.2 Preparation and Characterization of Plasma Units for Dried Tube Specimens for HIV-1 Rapid Test

8.2.1 Select confirmed HIV positive samples from your verified specimen bank. Use only those samples that have been verified as HIV positive by all testing methods based on the national testing algorithm. Heat inactivate the confirmed HIV positive units:

8.2.1.1 Set up water bath at 56°C

8.2.1.2 Incubate samples in 50mL tubes for 30 minutes

8.2.1.3 Ensure sample is completely immersed in the water bath

8.2.2 Identify and select negative samples that have been verified as negative by national testing algorithm. Do not heat inactivate HIV negative samples

8.2.3 Make sure the samples are clear of any clots or fibrosis.

8.2.4 Characterize these HIV positive and negative samples using country Dried Tube Specimens for HIV-1 Rapid Test (e.g. Asante HIV-1 Rapid Recency Test or Maxim Swift Rapid Infection Assay).

8.2.5 Identify samples that are clearly HIV negative for DTS preparation.

8.3 Preparation of DTS Buffer (PBS-Tween-20) for DTS rehydration

8.3.1 Powder of phosphate buffered saline (PBS) with Tween-20 can be commercially purchased from Sigma (catalog # 5563).

8.3.2 Dissolve one foil pouch of PBS with Tween-20, pH 7.4 in 1L of deionized water. It will yield 0.01 M PBS; NaCl 0.138 M; KCl 0.0027 M; 0.05% Tween 20; pH 7.4.

8.3.3 Optional: if vacuum pump unit is available, filter solution through a 0.2µM filter flask.

8.3.4 Label 5mL aliquots in pre-labeled 50mL conical tubes as master stock for 50L lot.

8.3.5 Prepare 1.0mL aliquots in 2.0mL Sarstedt conical bottom tubes for testers to rehydrate DTS prior to RTRI testing.

8.3.6 Each tube should be labeled with the below information:

8.3.6.1 DTS buffer

8.3.6.2 Expiration date of 1 year from the date of preparation.

8.4 DTS Rehydration (see DTS Rehydration Job Aid)

8.4.1 Rehydrate DTS sample overnight at room temperature.

8.4.2 Tap the tube gently to ensure that the colored pellet falls to the bottom of the tube.

8.4.3 Use either of the following methods to rehydrate:

8.4.3.1 Use a lab pipette to add 200uL of DTS buffer to each tube.

8.4.3.2 Use Samco transfer pipet (catalog # 282) to carefully add 7 drops of DTS buffer to reach the fill line.

8.4.3.3 Use Samco transfer pipet to add drops of DTS buffer, the volume of which is equal to 200uL. The specific number of drops must be validated by the national reference lab.

8.4.4 Once rehydrated, DTS samples must be tested the next day.

8.4.5 Mix the specimen by gently tapping the tube before testing.

8.5 Preparation of DTS Panel

8.5.1 Before preparing the bulk panels, verify the expected result of DTS of each selected plasma unit.

8.5.1.1 Prepare at least three tubes of DTS for each plasma unit, following the same procedure as bulk panel preparation detailed in steps 8.5.2 to 8.5.7.

8.5.1.2 Rehydrate each DTS tube with DTS buffer and verify the expected Dried Tube Specimens for HIV-1 Rapid Test Document the DTS expected result of each plasma unit to guide the large scale panel preparation.

8.5.2 Once reactivity is confirmed, proceed with the large scale panel preparation. Print specimen labels indicating specimen ID, preparation date, and name of laboratory where panels are prepared. Label as many 2.0mL conical bottom micro tubes as needed.

8.5.3 Prepare a 1:1001 dilution of green food coloring dye to specimen. For example, add 8.4µL of dye to 8.4mL of QC specimen. Vortex the specimen to mix well.

8.5.4 Prepare DTS by pipetting 20µL of colored plasma specimen to the bottom of a Sarstedt 2.0mL conical bottom cryo-tube.

8.5.4.1 Aliquot each specimen into properly labeled tubes.

8.5.4.2 Aliquot only one specimen type at a time to avoid -cross-contamination.

8.5.5 Leave tubes uncapped in a Biosafety Cabinet (if available) or in a clean lab space (cover tubes with clean paper towel) overnight at room temperature to facilitate drying. To avoid cross-contamination, keep tubes made from different plasma units separate in the BSC or clean lab space.

8.5.6 The following day, ensure the specimens have dried completely; a visible colored pellet should be present at the bottom of each tube. Once completely dry, cap each tube.

8.5.7 Store capped DTS at 2-8°C for up to 7 days until ready for shipment to the participating laboratories. For long term storage, store the DTS at -20°C or colder.

8.6 Establish DTS Panel Reference Data

8.6.1 Randomly select at least 3 sets of QC panels from stock.

8.6.2 At least three different laboratorians should perform testing independently on the panels.

8.6.2.1 Rehydrate DTS tubes following instructions in step 8.4

8.6.2.2 Test all DTS samples of the panel using the HIV-1 has been designated for use by the program and record results.

8.6.2.3 Record visual results from all operators in Panel Prep Reference Data Form.

8.6.2.4 Enter the final interpretation, which is the best of 3 results.

8.7 Packaging and Transport of DTS panels

8.7.1 Prepare DTS panels for shipment to include one tube of each panel member and sufficient DTS Buffer tubes.

8.7.2 Provide transfer piper specified for DTS rehydration along with clear instructions.

8.7.3 PackDTS panel, DTS buffer,and transfer piperin labeled Ziploc bags (or boxes for training)

8.7.4 The packed DTS panels can be stored at 2-8°C for up to 7 days until dispatch or delivery to testing sites.

8.7.5 The DTS panels can be transported at room temperature (18-25D) to the testing sites.

8.7.6 Once received at the testing sites, the DTS panels stored at room temperature (18-25D) up to 4 weeks.

9.0 REFERENCES

9.1 Dried tube specimens: a simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings.Parekh BS, Anyamwa J, Patel H, Downer M, Kalou M, Gichimu C, Keipkerich BS, Clement N, Omondi M, Mayer O, Ou CY, Nkengasong JN.Journal of Virological Methods, v183, issue 2, Feb 2010, pp 295-300.

10.0 RELATED DOCUMENTS

10.1 Stat-pack ,Abon and SD BIO Line Test kit insert

10.2 Maxim Swift RIA kit insert

11.0 APPENDICES

11.1 Stat-pak ,Abon and SD BIO Line Job Aid

11.2 Maxim Swift Job Aid

11.3 DTS Rehydration Job Aid

11.4 TOT Panel Prep Reference Results Form

Declaration

I, the undersigned agree to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the research publications office.

M.Sc. candidate: **Gemechis Bulti (B.Sc.)**
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This thesis has been submitted with our approval as advisors.

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