2017

HTS Test Register – A Quality Monitoring Tool

VERSION 1.5 | OCTOBER 2017

Guidance Document- Logbook Implementation

I. Background

As PEPFAR-supported countries strive to reach epidemic control, ensuring the quality and accuracy of HIV test results becomes all the more critical in HIV diagnosis and the contiuum of care. A number of tools to monitor and improve test accuracy such as dried tube specimen-based proficiency testing programs, retesting strategies, and supervisory visits have been implemented as part of a national quality assurance (QA) program in resource limited settings. Although these QA tools have encountered varying degrees of sucess, the data and information generated only reflects the performance of a testing site in that particular moment in time. Other tools such as test registers have been implemented at HIV testing sites but are generally used for inventory purposes and do not adequately capture key quality assurance elements such as test kit information and individual test results. Multiple registers may be used at a testing site and the information collected is not always consistent from site to site or even within the same site. This has presented a significant challenge in identifying problems and targeting areas for improvement.

In order to address these challenges, a simple paper based standardized HTS test register was designed to capture specific information, including test kit name, lot number, expiration date, individual test results and final result. Test result options are preprinted, thus allowing test performers to simply circle the correct result. Page totals at the bottom of each page allow supervisors to monitor the testing by determining the agreement between tests 1, test 2 and test 3. The test register can be customized for specific use as long as the critical QA elements such as the test kit information, individual test results and page totals are retained.

II. Goals and Objectives

- To monitor the performance of testing sites using a standardized test register for HIV rapid testing
- To develop and support data management procedures for the standardized HTS test register for HIV rapid testing

- To strengthen capacity for personnel in-country to provide adequate support supervision to HTS sites

III. Method

I. Advocacy and Consensus

Buy-in at the higher level is critical in order to ensure the use of a standardized HTS test register at all sites and to incorporate this monitoring tool as part of the National QA policy. Therefore, a series of sensitization and consensus meetings should be organized by key stakeholders in the Ministry of Health (MOH) in collaboration with other local partners and CDC in-country teams. These meetings are crucial since the customization phase will involve all key HTS stakeholders from Laboratory, HIV/AIDS Programs, Health Management Information Systems, Monitoring and Evaluation team, the MOH department in charge of procurement and lab commodities, as well as the end users. The purpose of these meeting is to seek endorsement and consensus on the final register. Because of challenges to implementing a single test register that captures all program-specific variables, several registers that include key QA indicators may be developed for use at specific sites, as part of the plan for national roll out. Already existing HTS registers should be modified to accommodate the data collection needs of all programs, sites, partners, and the Ministries of Health, before printing.

II. Design of standardized HIV testing logbook

The purpose of a standardized HTS test register is to simplify data aggregation for report generation and improve the ease of review by the site supervisor or manager. The standardized register will allow analysis for ongoing monitoring of the quality of testing. The HIV testing registers will be customized to incorporate key QA elements such as; test kit names, lot numbers, expiration dates, results of each test, name of testing personnel, and other key quality indicators. The inclusion of these testing variables will allow for more rapid and efficient identification of the source of errors and deficiencies. The overall design will be a list of indicators for each category (see

table 1). Examples include 1) Serial number, 2) client unique identifier, 3)age, 4) sex, 5) date of testing, 6-8)individual test results (invalid, non-reactive, reactive), 9) final test results (negative, positive, indeterminate), 10) test provider name, to streamline the entry process and avoid transcription errors. An instructions page and a sample of a filled page will be included to provide guidance on how to document in the HTS test register. The monthly summary forms include the total number of non-reactive/negative, reactive/positive, invalid, and indeterminate/inconclusive results for each month as well as the test kit lots used. The annual summary forms include the total number and percentage of non-reactive, reactive, and invalid results for each test kit used in the national testing algorithm. Both forms should be completed and submitted to MOH or other local partners for analysis. While additional variables (i.e. consumption log, referrals, TB screening, CD4, etc.) may be included, it is important that the key QA elements are retained. The standardized HTS test registers should be rolled out in a phased approach eventually scaling-up to all testing sites and programs.

Table 1: QA Indicators for a Standardized HTS register

Mandatory QA Indicators	Required and Customizable
• Test provider name • Test date • Test kit lot information • Individual test results for each test in the algorithm • Final Results • Page totals	• Client ID • Client Age • Sex • Program specific variables • Comments

III. Training Plan

All facilities offering HTS services should effectively use a standardized HTS test register and the appropriate data reporting tools. Training on the use of the register should be conducted for end users, site supervisors, district/regional/provincial lab/program focal persons and the national reference laboratory staff that oversees this QA activity. Training should also include the Ministry of Health, M&E teams, and the Strategic Information departments. The training and materials should be incorporated into the national HIV rapid test training curriculum as well as the hands-on practical using specimen panels so that the end-users can practice documenting the test results in the standardized HTS test register. Additional copies of the register can be distributed at the training for test providers to bring back to their sites. The following is the type of training needed at each level:

a. National Reference Laboratories

Technology on the HTS test register and data management tools will be transferred to the National Reference Laboratories and or local partners who will then organize a training of trainers (TOT) workshop for district and regional/provincial personnel on the implementation of the logbook, data management, and reporting. NRL and local partners will also assist with subsequent trainings of the testing site personnel.

b. Regional/Provincial Level

Regional lab/program focal persons will be trained on how to use the HTS test register and the data collection tools as well as understanding the aggregated data analyzed at the district level. The regional staff should also be trained on how to use the HTS test register data to evaluate site performance and identify areas for improvement based on the quarterly reports that are generated at the district level so that they may assist in any support supervision.

c. District Level

Entities or institutions that are normally responsible for the operational and logistical aspects of the trainings should collaborate with the National Reference

Laboratories and local partners to train district level staff (i.e. district lab focal persons [DLFPs], district medical laboratory technologist [DMLTs], district quality officers [DQA], etc.) on the electronic and paper-based data collection tools (monthly, quarterly, and annual summary forms), analyzing the aggregate HTS test register data and generate reports on a monthly basis to the head of the HTS sites and on a quarterly basis to the regional/provincial and central levels. The training curriculum for the district staff should include QA measures for HIV testing, review of the monthly summary forms, the type of analysis to be performed, and what type of reports should be generated for the sites, regional/provincial level, and central level (i.e. NRL/NASCOP) . Support supervision should also be provided by the district level staff. Therefore, the district staff should also be trained on performing QA audits using the Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing (SPI-RRT) to assess site performance and identify any issues or challenges within the site infrastructure.

d. Site Level

Whenever applicable, supervisors should be trained on how to accurately record, review and conduct troubleshooting on testing information and test results. They should also be trained on the data collection tools and QA measures for HIV testing to aid the district staff on collecting monthly HTS test register data from the sites as well as provide support supervision.

e. Test Provider (End-Users)

Personnel from all testing sites will be trained on how to record and enter all pertinent information in the standardized HTS test register. The end-users will be provided with a specimen panel as part of refresher training on the HIV rapid testing algorithm and document the test results in the register as a practical.

IV. Printing

Once a consensus is reached on the customized version of the HTS test register, it should be pre-printed to make it user friendly. Printing should be managed at the national level with support from implementing partners and the format should be customized as follows:

- Columns should contain enough writing space to allow the end-user to enter information in the appropriate columns legibly (see table 2).
- The monthly, quarterly, and annual summary forms should be in the form of a perforated or carbon copy to for easier data collection by the district level staff
- The pages can be double sided to allow more pages in the HTS register
- At most 20 data entries should be allowed per page
- The HTS test register can include as many pages as needed depending on the testing volume at the sites

V. Pilot Plan

Implementation of the standardized HTS register should be in a phased approach at a sites in one or two districts to evaluate the logistics of distribution, data management and supportive supervision. The MOH should select and model high volume health facilities for the initial implementation phase for approximately 3-4 months. Once the initial implementation phase is complete and all challenges have been addressed then the standardized HTS register should be scaled up nationally on an incremental basis.

VI. Logistics

a. Distribution

For distribution logistics, multiple options should be explored. If there is already a distribution system in place, then it is important for countries to use this existing system. If there is no distribution system currently available, then there are several options that can be explored:

- The use of a tiered system whereby the standardized HTS test registers are printed at the central level and distributed to the district staff. The staff at the district level will then distribute the logbook to the sites within their district. Printed can also be decentralized to local implementing partners within the district or region.

- Using a drug and/or lab supplies commodity system. Some countries use this type of system to distribute clinical drugs or test kit supplies to HTS sites on a routine basis.
- Local courier services (i.e., interdepartmental courier system).
- Distribution during supervisory or follow-up visits for routine QA audits.

A mechanism should also be put in place for the sites to request additional standardized HTS test registers when needed. A requisition form should be designed so that testing sites can submit their request for additional registers to the district staff either thru postal service or during routine follow-up visits. If there is an existing commodities requisition form, then the request for additional registers should be incorporated into this form.

b. Mechanism for Data Collection and Reporting Strategy

There are two types of collection tools that can be used: paper-based or electronic.

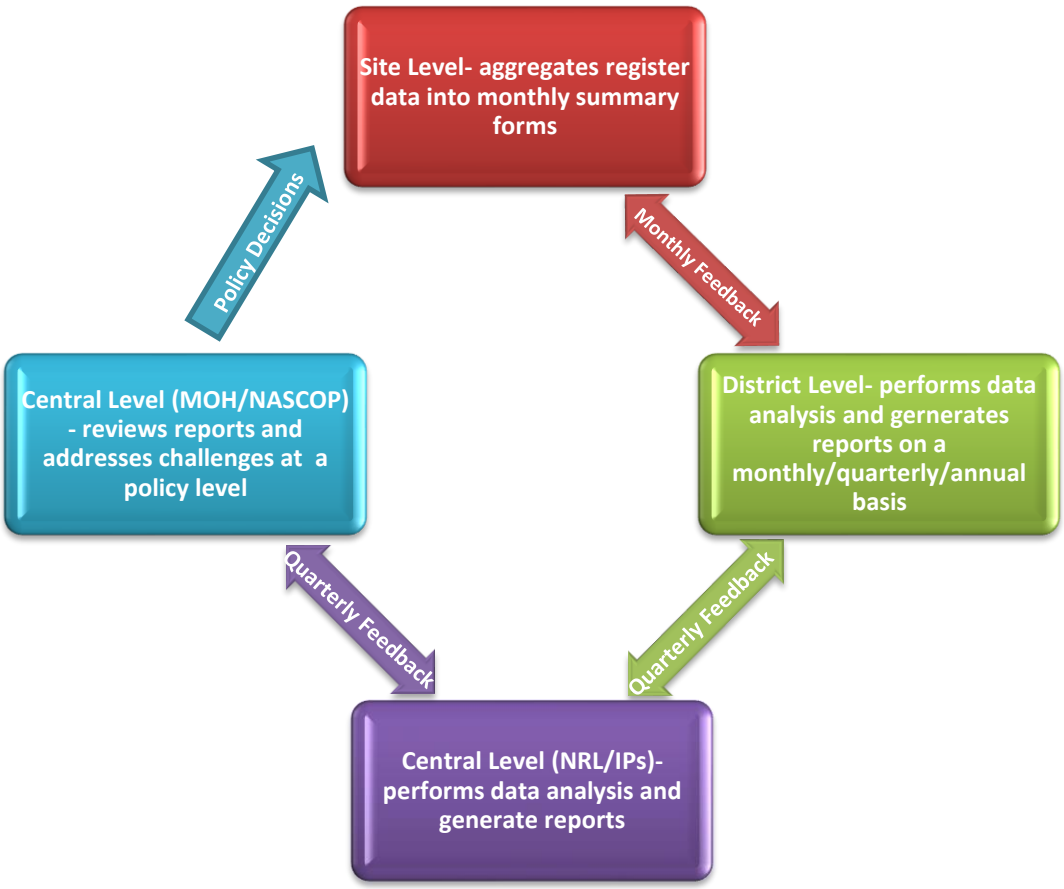
- Paper-based- data will be aggregated on monthly, quarterly, and annual summary forms which will be included at the end of the logbook as perforated or carbon copies. The data will be aggregated by the testing site personnel and the copies will be collected by the district level staff; 1) during routine supportive supervision 2) through courier, 3) or using the Q-corp for data collection. The data can also be collected using SMS text from mobile phones at regular intervals.
- Electronic forms- excel spreadsheet, access database, or web-based platform linked to a tablet for collection. Tele-forms are another option whereby the forms are coded with the specific register parameters and completed by the test providers. Once the form is collected by district level staff that can be scanned and imported into a simple, user friendly database for analysis. The electronic

forms will allow reduction of transcription errors and make it easier for the district level staff to perform data analysis.

c. Frequency of Data Collection and Monitoring

The frequency of data collection and monitoring of the sites should be based on the volume of testing. For high volume HTS sites, data collection and monitoring should occur on a monthly basis. However direct supervisor review of the register data should be performed weekly. For sites that have a low volume of testing, quarterly data collection and monitoring should be sufficient. If there is already a system in place for data collection and analysis, then it is recommended that the country use what already exits instead of having parallel systems.

Figure 1: Flow of Data Management



VII. Data Management

a. Flow of Data Management

The page totals at the bottom of each page allows the monitoring of the test results, mainly the agreement rate between the first and second test or third test in the national testing algorithm as well as between final reported HIV status and results of retesting before ART initiation (1st and second test events), if performed. Therefore, it is critical to obtain the data from all testing sites in a systematic manner at the district level. As previously stated, data collection and monitoring will be based on the volume of testing. For example, in a high-volume site it is recommended that test providers or Q-corp aggregate the register data on a monthly basis to submit to the district level for review and analysis. The district level staff or IPs can compile the data into a central database (Microsoft Excel, SASS, EpiInfo, web-based platform etc.) for analysis and provide feedback reports to the site on a monthly basis. Quarterly reports will be generated by the district level and disseminated at the regional and central levels (see Fig. 1). Alternatively, a local partner may be tasked to collect the data and submit it directly to MOH for analysis.

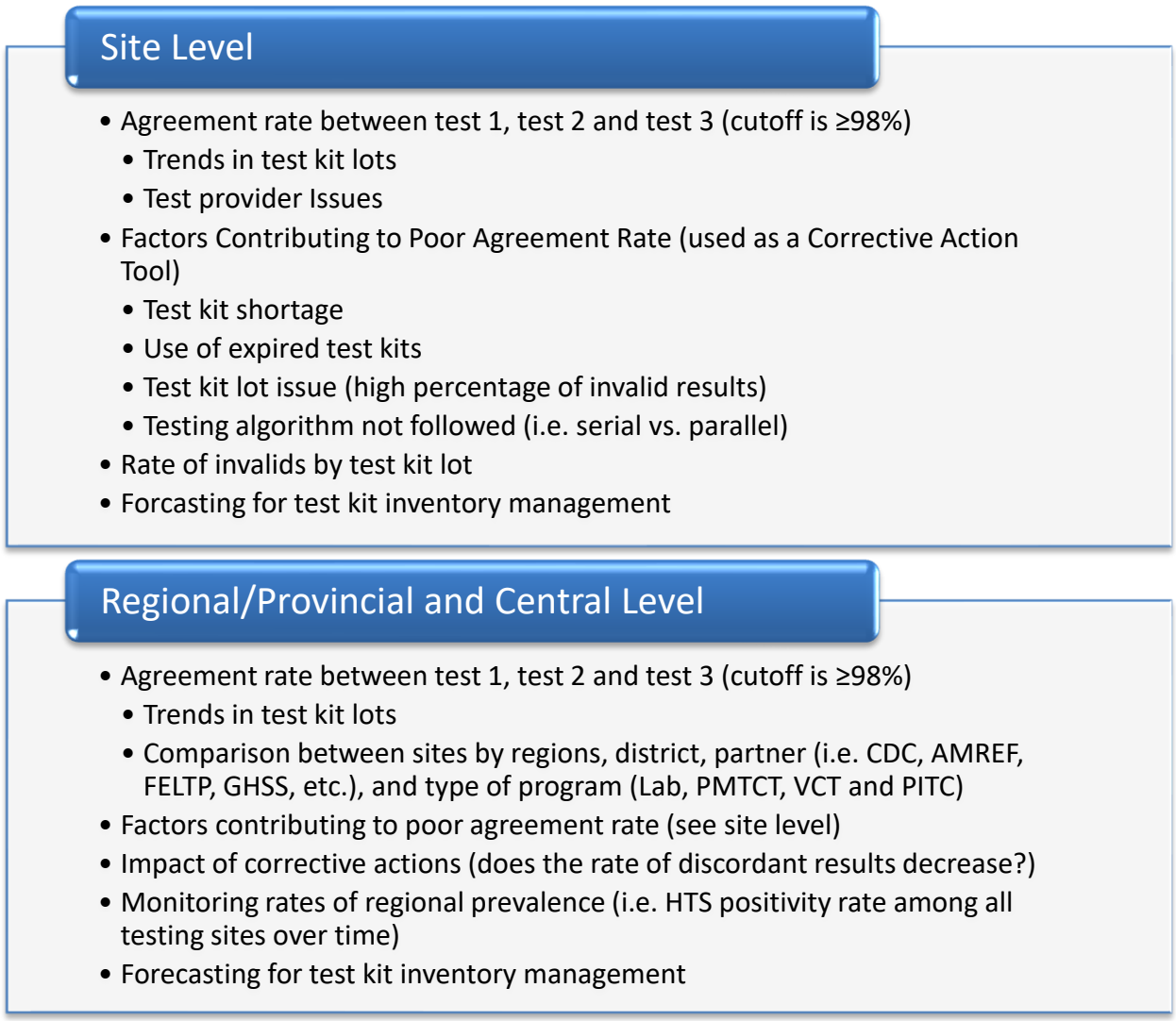
b. Data Analysis

The HTS test register will allow for ongoing monitoring and evaluation of testing sites, providers, and kit performance based on the agreement rate between the different tests observed or reported. Key quality assurance indicators collected from the logbook will be analyzed using a simple user-friendly database such as web-based platform, Microsoft Excel, etc. It is recommended that data entry is performed by trained data clerks and cross-checked by staff at the district level. Data analysis should be conducted by the data manager (i.e. personnel with lab, QA and IT or data management background) to: 1) identify testing problems at a site monitored over time; 2) compare the performance of different operators and identify operators needing more training; 3) compare the performance

of different sites and identify sites requiring more attention and 4) assess validity of the testing algorithm over time. Higher rates of discordance between tests at all sites will indicate problems likely related to the quality of the test kits or an inappropriate testing algorithm. The following is the acceptable agreement rate and types of analysis recommended:

1. Acceptance Criteria
    - The acceptable agreement rate is ≥98%.
    - Discordant rate should be less than 2%.
2. Types of Analysis by Level (see Fig. 2 below)

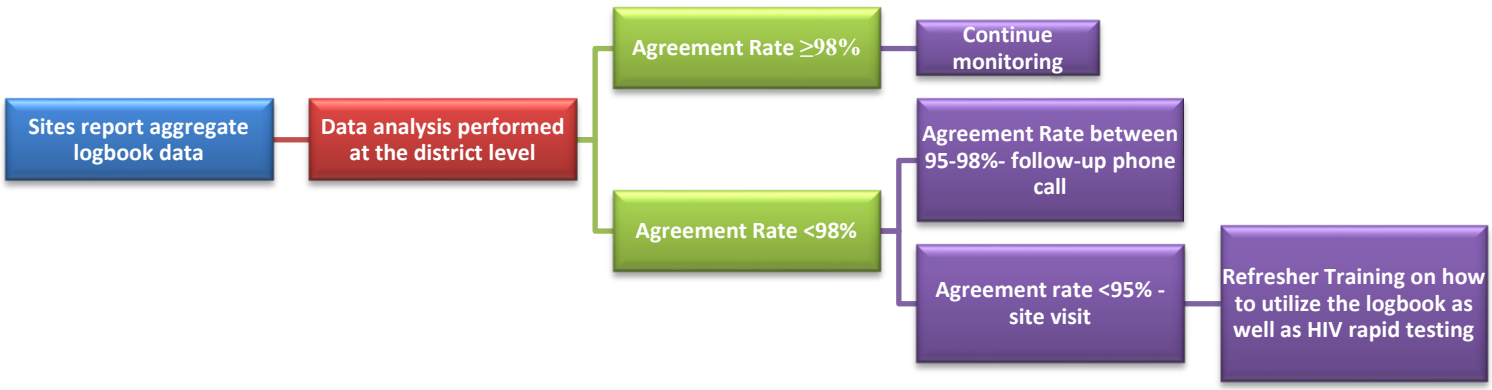
Figure 2: Type of Analysis of HTS test register data



VIII. Support Supervision

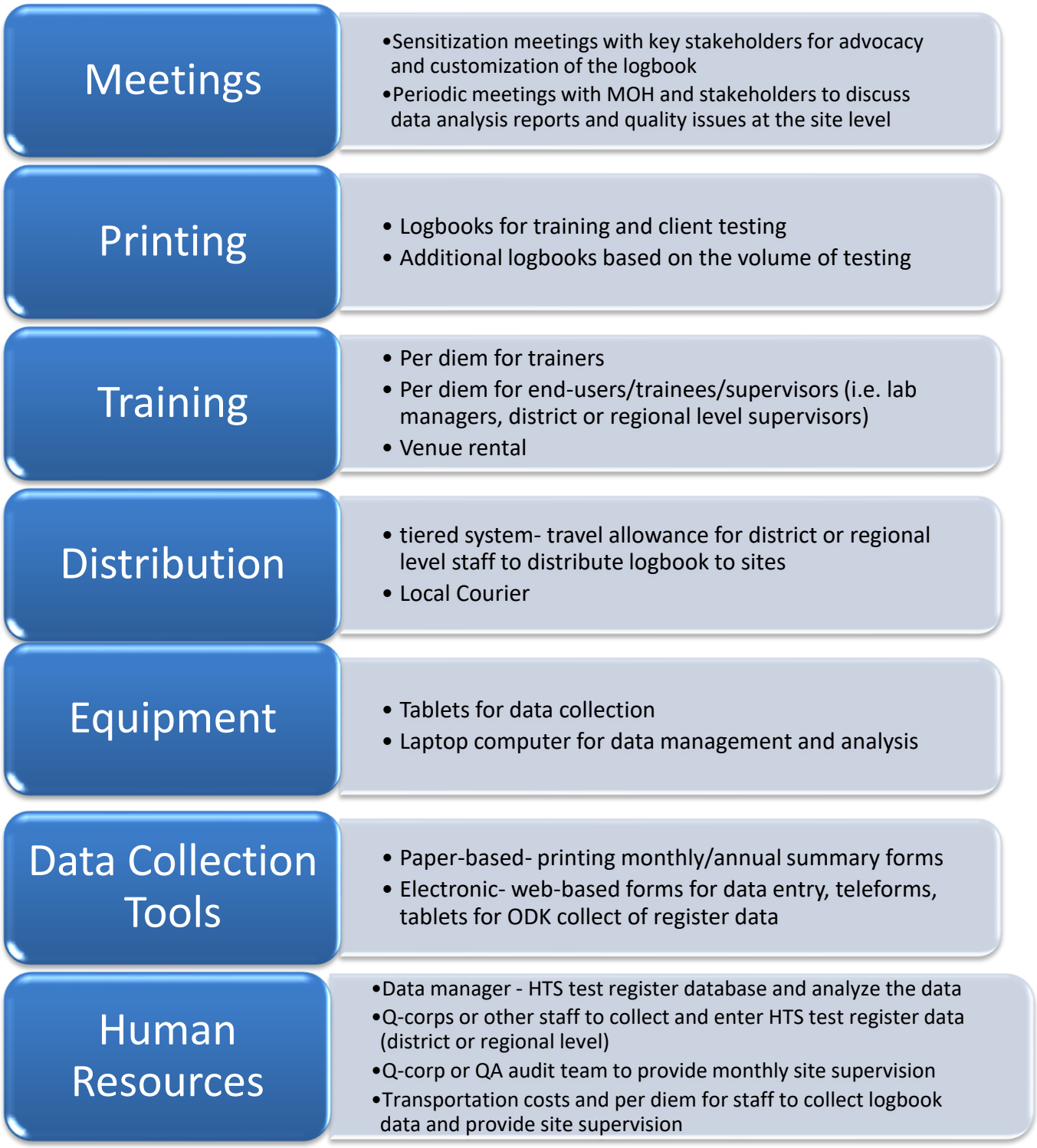
Supervisors overseeing testing sites should assess site performance by using the SPI-RRT checklist. The checklist assesses the HIV testing sites to ensure all QA measures, including HTS test registers, are in place, identify any challenges or gaps in the quality management systems and offer on-site mentorship with the view of helping to institute corrective actions and improving the quality of services provided to the clients. It is recommended that regular follow-up visits be conducted by a team of trained laboratory QA professionals or quality corp officers (Q-corp), representing the MOH, NRLs and other partners (if applicable), using standardized supervisory tools or guides. Testing sites with high discordant rates (<98%) between tests observed from the HTS test register monthly reports, should receive additional support supervision visits. Visits should be scheduled monthly for sites with high discordant rates between tests and corrective measures applied for improvement. The following is a recommended decision tree for support supervision (see figure 3).

Figure 3: Predefined Decision Tree for Support Supervision



IV. Budget Items for Consideration

Figure 4: Budget Items Based on Activities for Logbook Implementation



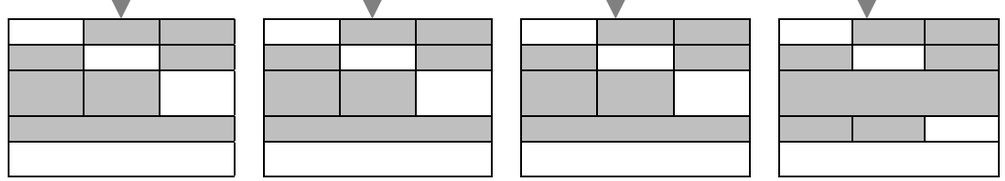
V. Proposed Timeline

Activity		Year											
		1	2	3	4	5	6	7	8	9	10	11	12
1	Sensitization Meetings												
2	Design of Standardized Logbook												
3	Technology Transfer												
4	Training Phase												
5	Pilot Phase												
6	Data Collection												
7	Data Analysis												
8	Report- monthly to sites												
9	Report- quarterly to higher level												
10	Dissemination of pilot phase												
11	Incorporation of lessons learned												
12	National Roll-Out												

Table 2: Logbook

	1	2	3	4	5	6	7	8	9	10	11	12	13
	Serial No.	Patient/Client Code	Age (Years)	Sex	Date Tested (dd/mm/yy)	HIV Test-1* Kit Name _____ Lot No. _____ Expiration Date ____/____/____ (Circle one)	HIV Test-2* Kit Name _____ Lot No. _____ Expiration Date ____/____/____ (Circle one)	HIV Test-3* Kit Name _____ Lot No. _____ Expiration Date ____/____/____ (Circle one)	Final Results** (Circle one)	Tester	Mark if sent for Confirmation or EQA	Confirmation or EQA Results (Circle one)	Comments
1				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
2				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
3				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
4				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
5				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
6				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
7				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
8				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
9				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
10				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
11				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
12				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
13				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
14				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
15				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
16				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
17				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
18				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
19				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	
20				M F	/ /	NR R INV	NR R INV	NR R INV	NEG POS IND		☐	NEG POS IND	

Total non-reactive/negative
Total reactive/positive
*Total invalid
**Total indeterminate
Total tests



Examples of frequent comments:
- *kit expired*
- *IND specimen sent to reference lab*
- *asked patient to return in 1 month*

* Test is considered invalid (INV) if control line does not develop, irrespective of presence or absence of client line. If invalid, please record and repeat using the same test on a new row.

** Final interpretation is considered indeterminate (IND) if Test-1 and Test-2 results are not the same and a 3rd Test (tie-breaker) is not available.

COMPLETING PAGE TOTALS WILL ASSIST WITH ONGOING QUALITY ASSURANCE AND PREPARING MONTHLY REPORTS.

Supervisor Signature_____

Monthly Summary Report for HIV Logbook

Month/Year		Site Type		District		Contact Information (name, number, email)	
Facility Name		Site Address		Province Region		Logbook Number Page Number Range	
Site Name		City		Longitude Latitude		Start Date End Date	

Data Entry for 1st Lot Number of the Month	**Test 1 Name:**				**Test 2 Name:**				**Test 3 Name:**				**Final Results (Enter the total number of NEG, POS and IND)**		
	Lot #:				**Lot #:**				**Lot #:**						
	Exp. Date:				**Exp. Date:**				**Exp. Date:**						
	NR	**R**	**INV**	**W**	**NR**	**R**	**INV**	**W**	**NR**	**R**	**INV**	**W**	**NEG**	**POS**	**INC**
	45	14	1		2	12	0		1	11	0		45	11	3

Data Entry for 2nd Lot Number of the Month	**Test 1 Name:**				**Test 2 Name:**				**Test 3 Name:**				**Final Results (Enter the total number of NEG, POS and IND)**		
	Lot #:				**Lot #:**				**Lot #:**						
	Exp. Date:				**Exp. Date:**				**Exp. Date:**						
	NR	**R**	**INV**	**W**	**NR**	**R**	**INV**	**W**	**NR**	**R**	**INV**	**W**	**NEG**	**POS**	**INC**
	39	21			2	19			4	15			39	15	6

Overall Comments:
NR - Nonreactive; R- Reactive; INV - Invalid; W-Wastage; S- DBS cards sent; NEG - Negative; POS - Positive; INC - Inconclusive

Supervisor Name and Signature: _____ Date: _____