General STI and VCT Laboratory QA/QI Checklist

Name of Implementing Agency:		**Facility Name:**	
Assessment team member:		**Date:**	

Reminder: This general laboratory checklist should be completed as part of a broader facility assessment. Please also utilize the 'General Management, Administration and Operations', 'General Infection Control', 'STI' and 'Pre-post HIV Test and Counseling' checklists, and the 'TB/HIV' list, if appropriate. It is recommended that only personnel with appropriate laboratory expertise complete this checklist. Please file this checklist with the other checklists completed during the facility assessment.

1. Training	**Method**	**Score**				**Observation/rationale for score**
1.1 Laboratory personnel have been adequately trained on tests presently being conducted.	SI	NA	MS	-	2	
1.2 Laboratory personnel received refresher training in the last 6-12 months.	SI	NA	MS	-	2	

2. STI and HIV laboratory	**Method**	**Score**				**Observation/rationale for score**
2.1 Copy of written job description for all staff working in the laboratory is available: a. Laboratory technician b. Laboratory support staff c. Laboratory attendant	R	NA	MS	-	2	
2.2 Copy of written SOP for collection of different types of specimen is available: a. Blood collection b. Vaginal/cervical swab c. Urethral swab	R	NA	MS	-	2	
2.3 Copy of written SOPs for all tests presently performed by the laboratory are available: a. RPR test b. TPHA test c. Gram staining for urethral/cervical swab d. Gram staining for BV e. Wet mount microscopy f. Microscopy for candidiasis g. HIV rapid test	R	NA	MS	-	2	

Scoring Notes:

(NA) Score 0 on an item that is not applicable
(MS) Failure to reach minimum standard
(0) No (1) Yes, partially (2) Yes

Method Notes:

O= Observation
R= Records Review
CI=Clinical Interview
SI= Staff Interview
MI = Management Interview

2. STI and HIV laboratory	Method	Score				Observation/rationale for score
2.4 Copy of SOP for infectious material collection and disposal is available.	R	NA	MS	-	2	
2.5 A written procedure for collection, storage and shipment of QC specimen is available and follows the SOP for such procedure.	R	NA	MS	-	2	
2.6 Copy of written SOPs for expired kits and reagent disposal/destruction are available.	R	NA	MS	-	2	
2.7 Guidelines and protocol for immediate and long- term management and accidental inoculation/laboratory-related injuries are available.	R	NA	MS	-	2	
2.8 The laboratory follows the diagnosis strategy as recommended by national guidelines/study protocol: a. HIV b. Syphilis c. Cervical infection d. Bacterial vaginosis e. T. vaginalis f. Other infection	MI	NA	MS	-	2	
2.9 Laboratory technicians wear lab coats and gloves during specimen collection, processing and testing.	O	NA	MS	-	2	
2.10 Laboratory staff members use disposable needle and syringe for venepuncture.	O	NA	MS	-	2	
2.11 Venepuncture site was cleaned with alcohol swab and the arm was placed on fixed surface for the procedure (table or arm rest of phlebotomy chair).	O	NA	MS	-	2	
2.12 After completion of venepuncture, band aid/tape was used to stop bleeding.	O	NA	MS	-	2	
2.13 Serum separation process is started 15-30 minute after venepuncture and the sample is not haemolysed.	O	NA	MS	-	2	
2.14 The primary sample, subsequent testing device (centrifuge tube, slides, RPR card) and sample aliquots are labeled with the proper ID No.	O	NA	MS	-	2	

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2. STI and HIV laboratory	Method	Score				Observation/rationale for score
2.15 The following equipment is available and in functioning condition with appropriate monitoring chart: a. Refrigerator with temperature monitoring chart b. Centrifuge c. RPR rotator d. Microscope with clean lens e. Micropipette f. Laboratory equipment repair/maintenance logbook	R O O O O	NA	MS	-	2	
2.16 Kits and reagent for all the tests are available and are stored at the temperature recommended by the manufacturer.	O	NA	MS	-	2	
2.17 All kits, reagents and devices used and in store are not expired (expired kits, if present, are stored in separately with clear marking of expired status).	O	NA	MS	-	2	
2.18 Kits, reagents and devices for the next three months are in stock.	O/R	NA	MS	-	2	
2.19 Tests are performed as per the SOP and using appropriate internal controls as recommended in the SOP or as instructed by the manufacturer: a. HIV b. Syphilis c. Other infection	O/R	NA	MS	-	2	
2.20 Kits are taken out of the refrigerator and brought to room temperature before use.	O	NA	MS	-	2	
2.21 RPR rotator is used at 100/rpm for 8 minutes and the card is read.	O	NA	MS	-	2	
2.22 HIV test results are read after recommended period and test failure, if any, is recorded.	O	NA	MS	-	2	
2.23 All biological specimens remaining after the test are disposed as per SOP	O	NA	MS	-	2	
2.24 Lab book containing all primary source data is available and stored appropriately.	SI/R	NA	MS	-	2	
2.25 Register book containing the daily test results with remarks, if necessary, is available.	SI/R	NA	MS	-	2	
2.26 Laboratory staff members complete, verify, and report data as per the national and program protocols.	O/R	NA	MS	-	2	

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2. STI and HIV laboratory	Method	Score				Observation/rationale for score
2.27 Laboratory staff members keep a copy of the submitted report for future reference.	SI/R	NA	MS	-	2	
2.28 Laboratory staff follows QA procedures.	O	NA	MS	-	2	
2.29 Laboratory staff participates in internal/external quality assurance programs.	MI	NA	MS	-	2	
2.30 Laboratory staff members comply with the guidelines and time line of the quality assurance program.	R	NA	MS	-	2	
2.31 Needle destroyer is available.	O	NA	MS	-	2	
2.32 Waste bin for infectious and non-infectious material, and a sharp collection container are available.	O	NA	MS	-	2	
2.33 Contact details of laboratory experts are available for trouble shooting purposes.	O	NA	MS	-	2	

TOTAL SCORE:	/ 70	TOTAL MS MET:	/ 35	NUMBER NAS CIRCLED	/ 35

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