Rapid HIV Diagnostic Algorithm (rHIVda) ASSESSMENT TOOL CHECKLIST

National Reference Laboratory-San Lazaro Hospital/ STD AIDS Cooperative Central Laboratory

I. GENERAL INFORMATION

Name of Laboratory Facility	
Address	
Tel/ Fax No:	
Name of Owner of Governing Body (if corporation)	
Name of Head of Laboratory	
• Contact details (Mobile number and Email)	
Name of RMT	
• Contact details (Mobile number and Email)	
Classification of Laboratory	( ) Government ( ) Private
Type of Laboratory	( ) Free- standing ( ) Institution based
	( ) Treatment Hub ( ) Social Hygiene Clinic ( ) Others

II. Management Requirements

Management Responsibility		Yes	No	Comments
License to operate (LTO)	Does your laboratory have LTO?			
	Is this updated?			
	Please indicate LTO # and its validity date			

Manpower	Is the organizational chart updated and placed in a conspicuous area visible to client?			
	Are the personnel requirements being complied? Head of the rHIVda site: Pathologist_____ SHC Physician _____ Treatment Hub physician/ manager _____ Technical staff: Medical Technologist ____ Quality Officer _____ Encoder _____			
	If NOT, How do you plan to comply? Do you have the support needed for hiring personnel?			
	Are duties and responsibilities of personnel documented in the quality manual?			
	Does your laboratory have schedule and record of pathologist and CMT visits?			
Quality Policy and Objectives	How often do you update your Quality Operating Procedures Manual			

Standard Operating Procedures	Have you developed rHIVda SOP's on pre testing, testing and post testing			
Policy on Quality Assurance Program and Continuous Quality Improvement	Does your laboratory regularly participate in Annual Serology EQAS (HIV) conducted by the NRL- SLH/ SACCL? For the last three (3) years?			
	Are all EQAS results kept and recorded?			
	Do you consistently get EXCELLENT ratings in your Serology EQAS participations (HIV)? For the last three (3) years?			
	Are there repeats of same errors in EQAS after implementation of its corrective actions?			
	Does your institution/ laboratory have certification or accreditation on Quality Management Systems standards (ISO,CAP, etc)			
Policy on Management Review	How often does your HOL conducts meeting for review of problems, including incident report, updates in rHIVda and in the laboratory?			
Procedures for handling complaints, client feedback, incidents and adverse events in	Does your laboratory provide suggestion box for customer feedback?			

laboratory	How often do you review this?			
	Do you provide record or logbook for incident or adverse events reported?			
	Do you have a protocol on this and is this strictly observed?			
	If protocol is not observed, what measures have been taken to ensure safety of the staff?			
Policy on record keeping and specimen keeping	Do you have a documented procedure on record/document and specimen retention?			
	Do you have a documented procedure on retrieval of documents and specimen			
Budget and Procurement	Is there a regular budget for the rHIVda implementation from the LGU or hospitals?			
	Do you have a documented procedure on stock level inventory?			
	How do you set critical supply level?			
	How often do you do inventory?			

III. Technical Requirements

Personnel	Is the number of RMT staff adequate to workload? (50 test/ RMT/ 8 hours)			
	How often does the Chief Medical Technologist (CMT) do supervision on the staff?			
	Do you have professional and staff competency development programs?			
	How do you assess competency of your staff?			
	Have your staff undergone rHIVda training? Pathologist_____ Medical Technologists_____			
	Are all RMTs doing HIV testing an HIV proficient? Updated Proficiency certificate?			
Physical plant/ Facility/ Work environment/ Equipment and Instruments	What is the floor area of your laboratory? (minimum working area is 10sq. meters)			
	Does your laboratory have designated receiving and releasing area?			
	Does it able to accommodate at least			

	one (1) patient a time?			
	Is the area clean and well- organized?			
	Is there a provided office for the HOL?			
	Is the extraction area clean, well- lit and private?			
	Is there an available storage area for kits, reagents and specimen keeping?			
	Is the storage area away from direct sunlight with sufficient space?			
	How do you keep/ store records?			
	Is the area provided for this well- lit, well organized and has enough space for storage?			
	Is the required ventilation (high ceiling, exhaust fan/ fume, air condition) for the working area met?			
	Does your laboratory have policy and procedure on waste disposal management?			
	Do you keep records of waste collection? Please provide MOA with the collector and indicate its effectivity date _____			

	Is the water supply adequate and continuous?			
	Is there a provided hand washing facility for personnel?			
	Do you have a documented program for the proper maintenance of equipment/ instruments? Is this being followed?			
	If Not, What measures have been taken ensure quality test?			
	Do you keep records of the certificates and reports of machine and equipment maintenance?			
	How often do you do preventive maintenance?			
	Do you have available contingency plan (backup plan) in case of equipment breakdown?			
	Are the following equipment available in your laboratory? a. computer and printer_____ b. -20C Biological freezer _____			

	c. reagent refrigerator 4-8C __ d. tabletop centrifuge _____ e. pipettor _____ f. consumables (cryovials, syringes, EDTA blood collecting tubes, yellow and blue tips) g. supplies (coupon bond paper and ink printer)			
	Does your laboratory have a complete set of PPEs and are these accessible and adequate to the staff? PPE (gloves, mask, laboratory gown) First- aid kit (bandage/ band- aid, alcohol, betadine, cotton)			
	How often does staff uses PPEs?			
Policy on referral	Do you have a documented procedure on test referral to NRL-SLH/ SACCL			
	Do you keep records of these referrals and get access to the result at NRL- SLH/ SACCL?			
Pre- testing phase	How do you ensure proper identification of patient? • Govt issued IDs (passport, driver's license, PRC, etc) • Company ID			

	Do you have a documented procedure on receipt of specimen including handling, labeling and encoding?			
	Does your laboratory have established a criteria for specimen acceptance and rejection?			
	Do you require pre- test counseling of patients?			
	How do you ensure that there is pre-testing counseling done to the patient?			
	Do you have a registration/ receiving logbook for the general entry of tests?			
	Are the following identifiers completely and correctly filled in? a. UNIQUE PATIENT ID b. CLIENT DEMOGRAPHICS			
	Does your laboratory provide requisition form adapted from the NRL- SLH/SACCL recommendation?			
Testing phase	Do you have a documented procedure on specimen testing or analysis?			

	Are these documents placed near the RMT's work area?			
	How do you validate test results? • All results should validated by 3 rHIVda trained personnel (RMT, Senior RMT/ CMT, pathologist)			
	How do you ensure tests are done correctly?			
	Do you use worksheet with the following identifiers as recommended by the NRL- SLH/ SACCL a. KIT NAME b. LOT NUMBERS c. EXPIRATION DATES d. UNIQUE PATIENT ID e. TESTER NAME f. QC RESULTS g. TEST VALIDITY h. TEST RESULTS i. DATE OF TESTING			
	Does RMT use timer in testing?			
	Does RMT use specimen collection device accurately and with ease?			
	How often do you run QC?			

Post- testing phase	Do you have a documented procedure on test reporting and releasing?			
	Do you have a result logbook for encoding of test results?			
	Do you have separate logbook for encoding of invalid results?			
	Do you have a documented procedure or protocol on invalid test results?			
	How do you report test result? Computerized_____ • All test reports should be computer generated using official rHIVda result form			
	Do you have a documented procedure on confidentiality of data?			
	If None, How do you ensure no unauthorized access of data?			
	How is releasing of test report done in your laboratory?			
	Do you have a releasing logbook?			
	How do your ensure that results are			

	released to authorized person? • Use of claim stub, official IDs, Authorization letters			

Remarks/ Recommendation: _____

_____

Note: Collect LTO copy, result forms

Name of Assessor: _____ Name of Assesse: _____
(Signature over printed Name) (Signature over printed Name)

Date and Time of Monitoring: _____