MONITORING TOOL for CONTINUING COMPLIANCE of Certified rHIVda Confirmatory Laboratory (CrCL) ACCREDITATION

I. GENERAL INFORMATION

Name of Certified rHIVda Confirmatory Laboratory (CrCL) :	
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 and rHIVda certification	Please indicate LTO # and validity date			
Manpower	Are the following rHIVda personnel requirement continuously being complied with?			
	Head of CrCL ○ Pathologist Technical staff: ○ Medical Technologist ○ Senior Medical Technologist/Quality Officer ○ Encoder			
	If NOT why? and, what have been done to address this non compliance?			
Standard Operating Procedures	Have you updated the rHIVda SOP's on pre-testing, testing and post testing for continuous quality improvement? If YES, Please send to NRL-SLH/SACCL revised version for appreciation.			

Policy on Quality Assurance Program and Continuous Quality Improvement	Have you been participating regularly to **rHIVda EQAS**?			
	Do you consistently get EXCELLENT ratings in **HIV EQAS**? Are the results being recorded for reference and analyzed? Please comment.			
	Do you submit all samples required for validation to NRL- SLH/ SACCL? If NO, why? How often is this being done?			
	Do you submit monthly census report on samples tested as to? ○ Total tests performed monthly: ○ T1 reactive? T1 not reactive? ○ T2 reactive? T2 not reactive? ○ T3 reactive? T3 not reactive?			
	How many inconclusive samples were referred to NRL-SLH/SACCL?			
Policy on Management Review	Did the head of the laboratory discuss the rHIVda updates and disseminate to all concerned staff including senior management ?			
	Are all issues and concerns addressed since the start of operation? Not addressed? Please comment.			
Procedures for handling complaints, client feedback, incidents and adverse events in laboratory	Have your site receive complaints about any of the ff: ○ Delayed TAT? ○ Release of erroneous results? ○ Lost results? ○ Data confidentiality? ○ Others (Please specify) _____ How was this handled? Did you do root cause analysis?			
Policy on record keeping and specimen storage	Do you consistently follow the recommended proctocol of the NRL-SLH/ SACCL on record keeping and specimen storage? Please comment.			
Budget and Procurement	Is the rHIVda operation in your site			

	dependent on the support from the DOH-HIV Program? Can you sustain operations even without support from the DOH?			
	Have you alloted budget for the procurement of rHIVda reagents ? Have you allotted budget for outside referrals? If No, What are the impediments?			

III. TECHNICAL REQUIREMENTS

Technical Responsibility		Yes	No	Comments
Personnel	Does the site have adequate number of staff with the corresponding workload? (50 test/ RMT/ 8 hours)?			
	Are all staff conducting test rHIVda trained? HIV proficients? Are the certificates updated? If not? How do you address such non-compliances? Do you need additional training for rHIVDA? How many participants?			
	Do the staff in charge &/or Med Tech on duty strictly follow all SOP's of rHiVda operation/ testing?			
Physical plant/ Facility/ Work environment/ Equipment and Instruments	How often have you done preventive maintenance and calibration of equipment and other instruments since the start of rHIVda operation? ○ Biological freezer ○ Reagent refrigerator 4-8C ○ Centrifuge ○ Pipettors			
	Has there been an occurrence of equipment (as applicable e.g freezer, reader) breakdown since the start of operation? What was done to address the problem?			
Policy on referral	Do the staff in charge &/or Med Tech on duty strictly follow SOP on test			

	referral?			
	Do you accept specimen referrals from other labs outside your site or treatment hub? If yes, Please provide census of referrals._____			
	How do you release results to the referring laboratories? Do you have same TAT for the in house samples and outside referrals?			
Technical Responsibility		Yes	No	Comments
Pre- testing phase	Are the consumables and supllies available and adequate? ○ cryovials, syringes, EDTA blood collecting tubes, yellow and blue tips) ○ supplies (coupon bond paper and ink printer)			
	Have you had reagent stock out or laboratory consumables since the start of your operation? What was done to address the problem? Any recommendation?			
	Do you inform DOH -HIV Program or regional coordinators on reagents status (stock level and expiry date)?			
	Do you think network sharing will help to maximize use of expiring kits?			
	Do you regularly update inventory of reagent kits? How often?			
	Are reagents stored at proper temperature? Where?			
Testing phase	Have you encountered an invalid test run? What did you do? Please provide census.			
	Have you conducted tests with discordant results? What was done to addresss this? What was your recommendation?			

	Provide census for each discordant result. ○ (T0) and (T1) ○ T1 and T2 ○ T2 and T3			
	How do you validate test results? **Note: All results should be validated by 3 rHIVda trained personnel (RMT, Senior RMT/ CMT, pathologist).**			
	How often do you run QC if applicable? Have you experienced problem with availability of test control since the start of your operation? What was done to address this?			
	Do you use the recommended rHIVda standard worksheet of the NRL-SLH/ SACCL?			
Post- testing phase	Do the staff incharge&/or MT on duty strictly follow the SOP on releasing of results?			
	Have you encountered problem with eHARP encoding?			
	How do you ensure that results are released properly? (Ex: use of claim stub, official IDs)			
	How do you maintain data confidentiality?			

Remarks/ Recommendation:

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Name of Assessor: _____

(Signature over printed Name)

Name of Assessee: _____

(Signature over printed Name)

Date and Time of Monitoring: _____