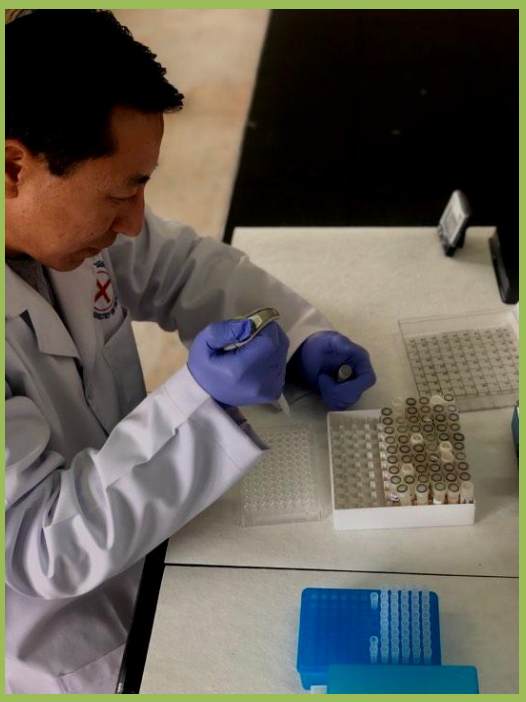
GUIDELINE FOR NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME FOR STI/TTI(S) SEROLOGY



2nd EDITION 2018

ROYAL CENTER FOR DISEASE CONTROL
MINISTRY OF HEALTH
ROYAL GOVERNMENT OF BHUTAN
THIMPHU BHUTAN

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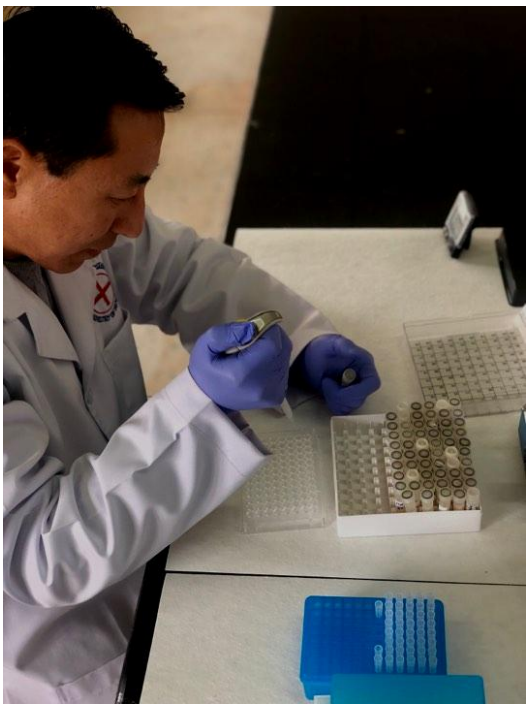

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4. Ms. Sonam Pelden, DCLO, RCDC, Serbithang
5. Mr. Diwash Rai, Lab. Officer, JDWNRH
6. Mr. Tenzin Dorji, Sr. Lab. Tech, RCDC, Serbithang
7. Mr. Rinchen Wangdi, Sr .Lab. Tech, RCDC, Serbithang
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10. Mr. Dorji Wangchuk, Lab. Officer, RCDC, Serbithang

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ACRONYMS

AIDS	Acquired Immuno Deficiency Syndrome
EQA	External Quality Assurance
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immuno Deficiency Virus
NEQAS	National External Quality Assessment Scheme
IDSL	Infectious Disease Serology Laboratory
RCDC	Royal Center for Disease Control
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
RPR	Rapid Plasma Reagin
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TTI	Transfusion Transmissible Infection
TP	*Treponema pallidum*

1. Introduction

Royal Centre for Disease Control (RCDC) is mandated to assess and monitor the performance of Serological tests by the laboratories across the country in line with the National Health Policy of Bhutan. In order to ensure correct diagnosis of Sexually Transmitted Infections (STIs) through accurate and reliable laboratory results by the testing laboratories, RCDC (former PHL) established National External Quality Assessment Scheme (NEQAS) for STIs in 2006. STIs and Transfusion Transmissible Infections (TTIs), if left unmanaged have far reaching health, psycho-social and economic consequences and is an additional burden of disease to the national health system. Thus accurate testing for STIs and TTIs for clinical diagnosis and transfusion safety is indispensable. EQAS is a fundamental tool for quality evaluation and improvement of clinical laboratories. It involves evaluation of laboratory performance by an outside agency on the materials supplied. This is achieved by using an appropriate QC material in NEQAS according to the objectives of the scheme. RCDC is responsible for selection of appropriate QC materials in compliance with international standards and scientific recommendation and ensure that the NEQAS samples mimic patient specimens, homogeneous, stable and non-infective in nature. Ever since the NEQAS for STI was established, it has been helpful not only for the assessment of participants' performance, but also the performance of instruments, methods test devices used. NEQAS guideline has been designed based on the quality specification and scoring system suitable to the laboratory set up in Bhutan, in consultation with experts from relevant agencies.

Therefore, using this guideline, it is imperative that a continuous mechanism of monitoring and improvement is conducted which is an important step towards achieving high-quality laboratory performance nationwide.

2. Objectives

1. Assess the performance of nationwide testing centers
2. Compare the inter-laboratory performances
3. Identify common errors and provide corrective measures
4. Institute and upgrade uniform quality system in each laboratory in the country

3. Structure of NEQAS

3.1 Organizing laboratory

RCDC as mandated by the Ministry of Health, RGoB shall be the organizing laboratory for the NEQAS in STIs and TTIs namely HIV, Hepatitis B, Hepatitis C and syphilis serology.

3.2 Participating centre

All the testing centers are mandated to participate in the NEQAS program. These centers include national, regional, districts laboratories/ BHUs, blood centres, voluntary counseling and testing centers (VCTs) and the private laboratories.

3.3 Frequency of Assessment

NEQAS will be conducted bi-annually

3.4 Roles and responsibilities

3.4.1 The Organizing laboratory

The Royal Center for Disease Control will be the organizing laboratory for the NEQAS program

3.4.1.1 Should have the necessary resources and expertise

3.4.1.2 Should be aware of available screening and diagnostic assays used in the country

3.4.1.3 Provide training to participating centers (Pre/Post NEQAS)

3.4.1.4 Prepare, package and dispense the NEQAS panel samples

3.4.1.5 Receive results, analyze data and share reports

3.4.1.6 Provide feedback to all testing centers

3.4.1.7 Conduct monitoring and on-site supervision

3.4.1.8 Periodic review and update of the NEQAS guidelines

3.4.2 Participating Centers

The entire testing centre must participate in the NEQAS program

3.4.2.1 The testing centers should ensure that their staff receive appropriate training

3.4.2.2 The staff should adhere to all the documents, including the NEQAS guidelines, instructions accompanying the panel samples and feedback reports

3.4.2.3 Test the panel samples in the same manner as any routine samples

3.4.2.4 Return the completed test result form to organizing laboratory within the given deadline

3.4.2.5 Study the feedback report and recommendations provided by organizing laboratory and implement corrective actions and preventive measures

4. NEQAS Design

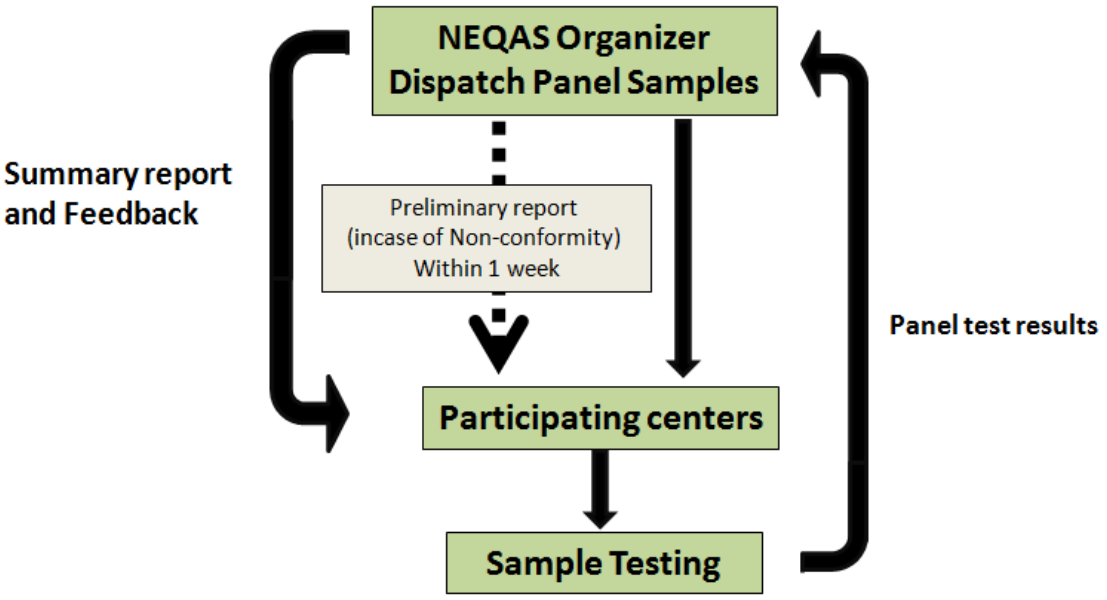


Figure 1: NEQAS flow process

4.1 Panel samples

The panel sample comprises of serum with

- Antibodies to HIV1&2
- Hepatitis B surface antigen
- Antibody to Hepatitis C
- Antibody to *Treponema pallidum*
- Confirmed negatives to all the above antigens or antibodies

Each Panel Member will be identified by the following numbering system

(SR.00.00.00: SEROLOGY. YEAR. CYCLE NO. UNIQUE PANEL NUMBER)

Refer **Annexure 1, 2 and 3** for the preparation, dilution and characterization of panel samples

4.2 Stability during transportation

Before introducing a quality assessment scheme, the organizers should establish the stability of specimens during transportation to participating laboratories. The organizer should demonstrate that the stability of the specimens remains unaltered in any of the test systems in local use. A small number of participating laboratories (1-3), preferably those to whom delivery is expected to take longest, should receive two panels and will be requested to return one panel unopened to the organizing laboratory. RCDC will retain 2 sets of panels and each will be stored at room temperature and at 2-8°C. The panel stored at RT will be tested once in two weeks while the one at 2- 8°C will be tested at the end of the cycle upon receiving the panel that has been sent out. This is to ensure that the specimens have remained stable during the stringent conditions of twice the normal period of transport. Refer **Annexure 4** for the panel stability log.

4.3 Panel packaging and transport

The vial should be packed in plastic zip-lock pouch and put in double-bubbled plastic bag with adsorbent paper at ambient temperature in compliance with local postal regulations for transportation of infectious substances. The packing label shall include name of the scheme, contact details of the consignee and that of the RCDC. The package insert will bear the instructions for handling the panel samples (**Annexure 5).** The transportation of the panel would be contracted to registered national courier service.

4.4 Result submission

Each participating center must fill in the standard result form which should be returned to RCDC either through Fax, Email or by post. Once the report has been submitted to RCDC, no resubmission of rectified reports after the issuance of any preliminary reports will be accepted. Only the first reports submitted within the time frame will be evaluated. The participating lab can however retain the rectified report in the lab for record and reference. Refer ***Annexure 6 and 7*** for report forms using RDTs and EIAs respectively**.**

4.5 Data Analysis

4.5.1 Part A; Test conformity

Every sample performed accurately will be awarded '1' point and '0' points will be awarded for those not showing conformity with the reference lab results as depicted in the following table;

	RCDC results	Participating Lab. results	Score on conformity
1	**Positive**	**Reactive**	**1**
		Non-reactive	**0**
2	**Negative**	**Reactive**	**0**
		Non-reactive	**1**

Accuracy is calculated using the following formula: -

$$\textbf{Accuracy in (\%)} = \frac{\textbf{Total number of correct results}}{\textbf{Total no of panel samples}} \times 100$$

4.5.2 Part B; Test kit information

This part would require submission of the detailed information about the test kits used for testing the NEQAS panel members including the test kit manufacturer and the individual carrying out the testing of the samples. There will be a loss of score for every missing information or any incorrect entries made in this section of the assessment.

4.5.3 Over-all score

The participants will be provided an overall score for their performance. This would be computed by adding 80% of the total scores obtained in the PART A and 20% of the total scores obtained in PART B.

The following scoring scheme would be used to award scores to the participants

		Part B					
	Inadequate Info* ➡	0	-1	-2	-3	-4	-5
	Scores (%)	20	16	12	8	4	0
Non-conformity ⬇ Part A							
0	80	100	96	92	88	84	80
-1	56	76	72	68	64	60	56
-2	48	68	64	60	56	52	48
-3	40	60	56	52	48	44	40
-4	32	52	48	44	40	36	32
-5	24	44	40	36	32	28	24
-6	16	36	32	28	24	20	16
-7	8	28	24	20	16	12	8
-8	0	20	16	12	8	4	0

Note; *The '-' in the PART A indicates the number of panel members with inaccurate result*

The '-' in the PART B indicates the errors committed in submitting the kit data and the performer's information

Score Interpretation

- 100 Excellent
- 95-99 Very good
- 90-94 Good
- 80-89 Satisfactory
- ≤79 Need improvement

5. Time frame

All participating centers should fill the test results and other required information in the report form**.** The participants should also retain and document a copy of the report form. A maximum of one month (from the day the panel samples are dispatched), is allowed for the testing center to report the results to the organizer lab. Delay in reporting will not be entertained and the particular testing centre should be marked "late-responder" and "non-responder" for those who fail to participate in the program. Consequently, the responsible staff of the centers shall be liable for explanation to the concerned authority.

6. Test kits

Brand name of test kits with the methods/principle; etc, used by participating laboratories should be recorded. This will give an overview of different type of test kits used and its performance, which may be helpful in future for evaluation of the test kits.

7. Feedback Report

The feedback report will be sent to the participating centers in two formats; preliminary report and summary report. In the event of non-conformity, preliminary reports (**Annexure 8**) will be sent immediately on receiving the individual panel report**.** However, **s**ummary reports (**Annexure 9)** would be sent to the entire participants once analysis is complete for the entire cycle. Each summary report will contain a description of the overall performance of each participating laboratories Misclassification score and accuracy percentage as shown above in 4.5.3. An inter-laboratory comparison chart will be included in the summary report so that the participating laboratories understand their performance in comparison to other participating centers.

8. Interventions

Onsite evaluation and validation of the procedures will be conducted by the NEQAS organizing lab in the event of repeatedly poor or unsatisfactory performances of the participating lab. Onsite supervisory visit shall be carried out to evaluate, trouble shoot and provide recommendations for continuous improvement (QI) of the labs against the standard checklist **(Annexure 10).**

9. Confidentiality

Unique codes would be assigned to all the participating centers to maintain confidentiality

Annexure: 1

Panel sample preparation procedures

1. Preparation of negative stock solution

Collect large volume of blood sample from blood bank for serum and plasma extraction by re-calcification. The negative stock must be tested for all STI serology before proceeding for panel preparation.

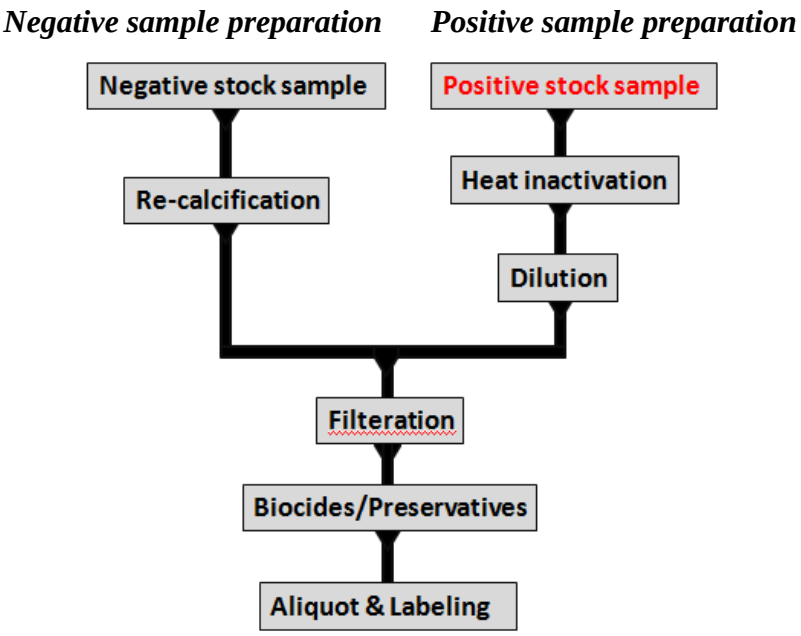


Figure 3: Flow chart for panel specimen preparation

2. Re-calcification procedures

2.1 Make a 2 moL/L solution of $CaCl_2.2H_2O$ by adding 3g of $CaCl_2.2H_2O$ to10 mL of distilled water in the plastic bottle.

2.2 Add 0.5ml of the freshly prepared $CaCl_2$ solution to100 mL of volume of plasma.

The final concentration

Should be 0 .01 M $CaCl_2$.

2.3 Mix the solution and plasma properly and incubate in a water bath at 37ºC for 1hour. Large volume may require several hours to clot plasma. If plasma has not clotted, add more $CaCl_2$ (but not exceeding total of 1% of the 2 moL/l solution) and incubate the mixture further.

2.4 When the plasma has clotted, remove mixture from the water bath and transfer plasma to the bottle and place in a freezer at –20ºC over night.

2.5 Remove the bottle from the freezer; allow thawing at room temperature.

3. Preparation of positive stock samples

Use strong known positive samples (HIV, HBV, HCV and syphilis) for the preparation of positive stock. Use the negative stock to dilute positive stock.

4. Dilution of positive stock samples

4.1 Carry out serial 2-fold (for rapid test kit) and 10-fold dilution (for ELISA) as shown in Figure 2.

4.2 Add 1ml of known positive serum in the first tube and 1ml of negative serum OR 100ul of known positive serum in the first tube and 900ul of negative serum in all the rest of the tubes.

4.3 Pipette out 1ml/100ul of serum from tube 1 and transfer to tube 2.

4.4 Mix well, transfer 1ml/100ul serum to tube 3.

4.5 Repeat the step and continue till the last tube.

4.6 Discard1ml/100ul of mixed serum from the last tube.

4.7 Test mix serum from each test tube by the ELISA and rapid test kit to determine the appropriate concentration (OD value).

4.8 Test mix serum from each tube by the rapid test kit to determine detection titer level.

4.9 Record results in worksheet **(Annexure 2)**

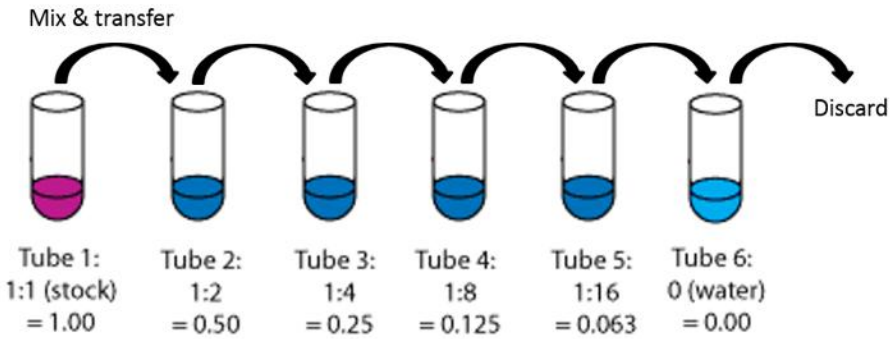


Figure 2: Dilution of positive stock

5. **Selection of known positive stock samples for panel**

The composition of positive panels should consist of strong reactive, weak reactive and negative samples for every test concerned. However, weak positive should be the priority by large to assess the proficiency.

6. **Heat inactivation**

Set the water bath at a temperature of 56ºC and monitor the temperature with a thermometer. Once the temperature has reached 56ºC, place the selected positive samples in the water bath and heat for 60 minutes. ***Note: Do not heat samples beyond 56ºC and do not heat-inactivate negative panel because heating may cause false positive reactions.***

7. **Filtration**

Centrifuge the heat inactivated positive and negative samples at10,000 RPM at 4˚C for 10 minutes and filter the samples through a membrane filter of 0.45µM pore size. Filter small volume at a time to avoid clogging.

8. **Preservation**

To inhibit the growth of bacteria contaminants in the sample, use chemical disinfectant as preservative/biocides. The commonly used preservatives are 0.05% of Proclin300, and 0.05% Bronidox L (5bromo-5-nitro-1, 3-dioxane in propylene glycol. Add 0.05 mL (50µL) of preservatives to every 100 mL of serum and mix well.

9. **Characterization of panel samples**

Characterize the panel to be tested for range of diagnostic test kits available with participating prior to distribution. The ranges of test used should be adequate to establish the sera as positive, negative, or indeterminate. Selection of specimens should be made to compose a particular panel for the distribution. Record the results (**Annexure 10)** for traceability and to use as an expected result for preliminary report to participants.

10. **Aliquot and Labeling**

Dispense 500 uL the panel samples into a leak-proof, screw-capped plastic microvials with O-ring. Properly label the samples with a consecutive number for each specimen. The labeling should not be washed off or removed from vial.

Annexure 2

POSITIVE STOCK PREPARATION (for organizing lab)
Panel no:-……

Test	Result	*Stock Dilution*											
		1:2	**1:4**	**1:8**	**1:16**	**1:32**	**1:64**	**1:128**	**1:256**	**1:512**	**1:1024**	**1:2048**	**1:4096**
HIV													
HBsAg													
HCV													
TP													
RPR													

(Note:-P-Positive, N-Negative)

Panel Prepared by;
Date;

Annexure: 3

PANEL SPECIMEN CHARACTERIZATION FORM (for organizing lab)

Panel no: - ……..

Sample ID	***Anti-HIV***		***Anti-HCV***		***HBsAg***		***RPR***	***TP***	
	Test Type								
	Rapid	*EIA*	*Rapid*	*EIA*	*Rapid*	*EIA*	*Rapid*	*Rapid*	*GPA*
SR.00.00.01									
SR.00.00.02									
SR.00.00.03									
SR.00.00.04									
SR.00.00.05									
SR.00.00.06									
SR.00.00.07									
SR.00.00.08									

Panel Specimen Characterized by;

Date;

Annexure: 4

SAMPLE STABILITY LOG
NEQAS Cycle……..

Sample ID	Retention Panel					Outgoing Panel ^ (Upon receipt)					
	(RT)*			(2-8°C)#		Site……		Site……		Site……	
	2nd week …./…./…	4th week .../.../…	Initial	4th week .../.../…	Initial	.../.../…	Initial	.../.../…	Initial	.../.../…	Initial
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

***Samples will be tested every 2 weeks**

 # and ^ Samples will be tested at the end of the cycle

Annexure: 5

Instructions for the participating labs on handling NEQAS panel samples

(Please read the instructions carefully before performing tests)

- Record the date, time and condition of the panel samples upon reception
- Keep NEQAS panel in the refrigerator at 2-8˚C until ready to perform test
- The NEQAS panel comprises 8-10 coded samples, each containing 0.5ml of test serum/ plasma
- Samples may contain 0.05% Proclin 300 as preservative which does not interfere with the test methodologies
- The positive samples have been inactivated by heating at 56˚C for 1hour; however, it should be handled as potently infectious specimen
- Vortex samples for few seconds before testing
- The samples have to be processed in the same way as routine specimens to reflect day-to-day functions of your laboratory
- Record results in the form provided
- Complete the form for each type of test performed
- Fax result format **02332464** or attach as an e-mail message idslphl@gmail.com to RCDC before deadline

Annexure: 6

SAMPLE REPORTING FORM (RDT)

NEQAS Cycle……

Name of Hospital:-……...District:-…… Lab CODE:-……..					
Name of Contact Person:-…….……Mobile:-……..……. Phone:-……Fax:-…… E-mail:-……...……...…….					
Test Result					
Sample ID	**Anti-HIV (P/N)**	**Anti-HCV (P/N)**	**HBsAg (P/N)**	**RPR (R/N)**	**TP (P/N)**
SR.00.00.01					
SR.00.00.02					
SR.00.00.03					
SR.00.00.04					
SR.00.00.05					
SR.00.00.06					
SR.00.00.07					
SR.00.00.08					
Kit Used:-					
Manufacturer:-					
Expiry date:-					
Performed By:-					

(Note:-P-Positive, N-Negative, IND-indeterminate/Intermediate-Reactive, NR-Non-reactive)

******Comment on your results and give details of any further testing you may do or send away to confirm any of the results******

Comments: -

……
……
……
……
……
…….

Received (panel) date:- Test Date:-

Dated signature of the technician;-

Annexure: 7

SAMPLE REPORTING FORM (EIA)
NEQAS Cycle……..

Name of Hospital:-……....District:-…… Lab CODE:-……..					
Name of Contact Person:-…….……Mobile:-……..……. Phone:-……Fax:-…… E-mail:-……...……...……..					
Test Result					
Sample ID	**Kit used; Manufacturer; Expiry date;**	**OD Sample**	**OD Cutoff**	**Results (R/NR)**	**Interpretation (POS/NEG/IND)**
SR.00.00.01					
SR.00.00.02					
SR.00.00.03					
SR.00.00.04					
SR.00.00.05					
SR.00.0006					
SR.00.00.07					
SR.00.00.08					

(Note:-P-Positive, N-Negative, IND-indeterminate/Intermediate-Reactive, NR-Non-reactive)

******Comments on your results and give details of any further testing ou may do or send away to confirm any of the results******

Comments: -

……
……
……
……
……

Panel Receipt date:- Test Date:-

Dated signature of the technician;-

Annexure 8

PRELIMINARY REPORT
NEQAS Cycle……..

LAB NO: -……

Sl. No	RCDC Result	Test Parameters				
		HIV	HBsAg	HCV	RPR	TP
		Participating Lab Result				
SR.00.00.01						
SR.00.00.02						
SR.00.00.03						
SR.00.00.04						
SR.00.00.05						
SR.00.00.06						
SR.00.00.07						
SR.00.00.08						

(SR.00.00.00: SEROLOGY. YEAR. CYCLE NO. SAMPLE NUMBER)

Recommendations:

……
……
……
……
……

******In compliance to the requirements of the EQAS programme the identity of participating laboratories is kept confidential******

(Head)

RCDC

Annexure: 9

SUMMARY REPORT

NEQAS Cycle……

Lab No:-……

PART A (Test Conformity)

Sl. No	RCDC Result	Your Result	Score	Maximum score
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
SR.00.00.00				1
Total Score				8
Total Score (%)				100%
80% of score obtained				

Part B (Kit data and performer information)

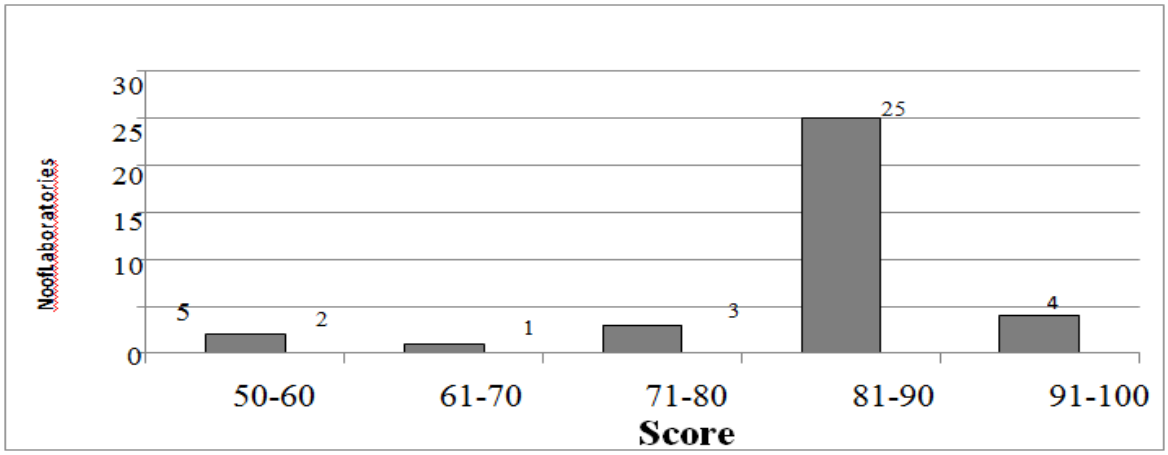
Sl.no	Kit data	Data adequacy (Y/N)	Participant's Score	Maximum Score
1	Kit name ;			1
2	Manufacturer;			1
3	Batch/ lot. Number;			1
4	Expiry;			1
5	Test Performer;			1
Total Score				5
Total Score (%)			…..%	100%
20% of score obtained			……	

Overall Score

Overall **Score = (80% of Scores From Part A + 20% of the Scores from Part B)**

= …….. (%)

Inter-Laboratory Comparison



Annexure: 10

NEQAS
Assessment checklist for on-site evaluation

1. **Name of the Hospital: -**
2. **DMO/CMO/Superintendent:-**
3. **Name of Laboratory Technician: -**
4. **Head of Laboratory/ Contact person:-**
5. **Name and designation of supervisor:-**

Tick the most appropriate one and provide comments where necessary.
Y: Yes N: No P: Partial NA: Not Applicable

Section	ITEM	Y	P	N	Comment
A. Personnel and Organization					
A.1	Does the laboratory have sufficient staff?				
A.2	Are the laboratory technicians aware of NEQAS activities that RCDC conducts half-yearly?				
A.3	Have deputies/alternates for all key functions been identified, if the authorized personnel are not available?				
B. Training					
B.1	Has the new staff received proper training in NEQAS?				
B.2	Has there been any change in the staff since last NEQAS cycle?				
B.3	Has every laboratory personnel participated in refresher training/workshops within past two years?				
B.4	Does the laboratory have CV & training records of the laboratory personnel?				
C. Waste Management					
C.1	Do you have a copy of National Infection Control and waste management guildelines? If yes, do you follow it?				
C.2	Is the waste segregated at source in appropriate containers including needles & sharps?				
C.3	Is the waste decontaminated & autoclaved before disposal?				
C.4	Are the equipments used for the disposal of waste (e.g. Autoclave) validated for their performance?				
D. Specimen Shipment					
D.1	Does the laboratory ship specimens to a reference laboratory for confirmation?				
D.2	Does specimen transport follow proper protocol for packaging and shipment to ensure integrity, timely and safe transfer of samples?				
D.3	Are the specimens accompanied with complete details (name, specimen ID, test, other details)				
D.4	Does your lab have a minimum cold chain facility for sample shipment?				
E. Standard Operating procedures/Manuals/Guidelines					
E.1	Does the lab have SOP for specimen collection and handling?				
E.2	Does the lab have SOP for equipment maintenance, calibration, operation and cleaning?				
E.3	Does the lab have SOP and work instructions for STI/TTI test procedures?				

E.4	Does the laboratory have NEQAS guideline?				
E.5	Is the SOP reviewed & updated regularly?				
F. Documentation					
F.1	Does the lab have organization charts and job descriptions in your laboratory				
F.2	Are the records and reports of calibration, maintenance of equipments (daily logs) and validation reports archived?				
F.3	Are the Internal and external quality control, and inspection records archived?				
F.4	Does your lab have records of technical reports during equipments break down ?				
G. Quality assurance					
G.1	Does the laboratory check the quality of new batch of rapid test kits?				
G.2	Are the records of Internal quality control retained?				
G.3	Does the laboratory visually cross-check test results by another staff in the same laboratory?				
G.4	Has the laboratory participated in External Quality Assessment by Proficiency Panel Testing by RCDC this year / last year?				
H. Safety measures					
H.1	Do the Laboratory personnel use PPE every time serology work is performed?				
H.2	Is there Autoclave in the Laboratory?				
H.3	Does the laboratory monitor the function of autoclave?[If yes, how-mention in comment.]				
H.4	Does laboratory worker used is disinfectant? Mention kind of disinfectant used?				
H.5	Is there a wash basin or a sink where worker can wash hands at every interruption of work?				
H.6	Are workers wearing lab coats & removed prior to leaving the laboratory?				
H.7	Is bio hazard waste bin with lid available?				
H.8	How often do the laboratory workers take medical examination including for HIV& HBsAg?				
I. Stock Register					
I.1	Is there stock register in place to monitor stock balance?				
I.2	Is the test kit used in First-Expiry-First-Out basis?				
I.3	Has the laboratory technician maintained the stock register properly?				
I.4	Does the Laboratory have logbook for equipment maintenance?				
J. Logbook					
J.1	Do the Laboratory have log book for equipments like refrigerator?				
J.2	Do the Laboratory have log book for equipment maintenance?				
J.3	Are all user’s Logbook for equipments properly entered and up dated?				

Glossary

1. ***Quality Control (QC):***-comprises of all those measures that must be taken during each test run to verify that the test is working properly. It includes ensuring correct temperature conditions, kit controls, etc. it indicates that the test run was valid and has produced acceptable results. It does not guarantee the accuracy of results and reports provided to the physician.

2. ***Quality Assurance (QA):***-it is the total process that guarantees the accuracy of the results and reports provided. It involves inspecting specimens, reviewing transcriptional details, reliability of assays used and verifying the final reports and results

3. ***External Quality Assessment (EQA):***-It is an external evaluation of a laboratory's performance using known but undisclosed panel samples. Quality assessment is undertaken at periodic intervals to evaluate the effectiveness of the QA program of a participating laboratory. EQA allows participating laboratories to assess their performance levels in comparison to others in the networks that corrective action and preventive action (CAPA) can be implemented for improvement.

4. ***Sexually Transmitted Infections (STIs)*** or Venereal Diseases (VD) that are passed on from one person to another through sexual contact, and sometimes by genital contact - the **infection** can be passed on via vaginal intercourse, oral sex, and anal sex.

5. ***Transfusion Transmitted Infections* (*TTIs)*** are diseases caused by a virus, parasite or other potential pathogen that can be transmitted in donated blood through a transfusion to a recipient.

6. ***Acquired Immuno deficiency Syndrome (AIDS)*** is a spectrum of conditions following infection with the human immunodeficiency virus. AIDS is a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. Without treatment, average survival time after infection with HIV is estimated to be 9 to 11 years, depending on the HIV subtype.

7. ***Hepatitis B Surface Antigen (HBsAg)*** is a surface antigen of hepatitis B virus (HBV) which affects the liver. It can cause both acute and chronic infections.

8. ***Hepatitis C Virus (HCV)*** is a small (55–65 nm in size), enveloped, positive-sense single-stranded RNA virus of the family *Flavi viridae*. Hepatitis C virus is the cause of hepatitis C and some cancers such as liver cancer (Hepato cellular carcinoma, abbreviated HCC) and lymphomas in humans.

9. ***Human Immuno Deficiency Virus (HIV)*** is a lenti virus, a subgroup of retrovirus that

causes HIV infection and over time acquired immunodeficiency syndrome (AIDS). Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells.

10. ***Standard Operating Procedure (SOP)*** is a standard operating procedure, is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

References and suggested reading;-

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4) Guidelines for organization national External Quality assessment schemes for HIV serology testing, UNAIDS/96.5.

5) Regional External Quality Assessment Scheme, National Institute of Health, Bangkok Thailand.

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