Report

National External Quality Assurance Scheme: 15th Round (Feb-April 2018)
NEQAS Organiser: Royal Center for Disease Control, DoPH, MoH

Background
National External Quality Assessment Scheme (NEQAS) for HIV/STI was introduced in 2006. This program started off in 2006 with 26 participants which later expanded to include most of the laboratories with serological testing facilities across the country. In this round 15, 2018 we have 47 participants. The External Quality Assessment Scheme (EQAS) is one of the most effective tools to access the laboratory performance.

Objectives:

1. To assess and monitor the performance of individual testing centers.
2. To provide reliable results to the users (physician and patients)
3. To compare the inter-laboratory performances
4. To identify common errors and provide corrective measures.
5. To encourage and good laboratory practice, using standardized procedures, appropriate definitions, methods of documentation.
6. To institute and upgrade uniform quality system in each laboratory in the country.

NEQAS Round 15

Each participant laboratory was sent a panel of samples; panel number SR20180301, which is composed of 8 samples (SR-18-15-01, SR-18-15-02, SR-18-15-03, SR-18-15-04, SR-18-15-05, SR-18-15-06, SR-18-15-07 and SR-18-15-08).

For reporting your test reports to RCDC, participants were given options to use any social media, emails and facsimile.

As per the instructions that accompanied the panel samples, the participants were expected to perform Anti-HIV, HBsAg, Anti-HCV and *Treponema pallidum* rapid tests on each of the samples.

For scoring your laboratory performances the results were assessed in two parts.

For every concordant result a score of '1' was awarded and '0' for every non-concordant result in part A whereas for each wrong entry of test kit particulars will result in the loss of each point in Part B

Part A
The test results were evaluated for agreement with that of NEQAS organizer (RCDC).
(80% of your score in this part will be used for computing your final score)

Part B
Completeness and correctness of the test kit details used for testing each parameter (viz. Anti Hiv, HBsAg, Anti-HCV, TP)
(20% of your score in this part will be use for computing final score)

Overall score
Overall scoring will be out of 100%; i.e 80 % from part A + 20 % from part B. the following table will be used to compute. (See figure 1)

			Part B					
		Inadequate Info* ➡	0	-1	-2	-3	-4	-5
	Non-conformity	Scores (%)	20	16	12	8	4	0
	↓ 0	80	100	96	92	88	84	80
	-1	56	76	72	68	64	60	56
Part A	-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

Score Interpretation

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

Figure 1: Scoring criterion. The part B in the figure shows assessment and scoring for only 5 parameters (test kit details) which may vary in each round.

Overall laboratory performance in the 15th round

Overview

- Total Number of panel sent out; 47
- No. Of laboratories responded within 1 month; 42
- Late responders; 02
- No. of laboratories not participated; 03
- Laboratory that used expired test kits for;
  - ✓ Anti-HIV 0
  - ✓ HBsAg 0
  - ✓ Anti-HCV 0
  - ✓ TP 21
- Panel broken during shipment; 1
- No. of undelivered panel; 0

RCDC has shipped out 47 NEQAS panels to the corresponding 47 sites of which 42 sites have tested at least one of the four test parameters (anti-HIV, HBsAg, anti-HCV, Syphillis). The chart below shows the number of sites that have tested the panels, their results and those sites who passed report submission the deadline.(See figure 2)

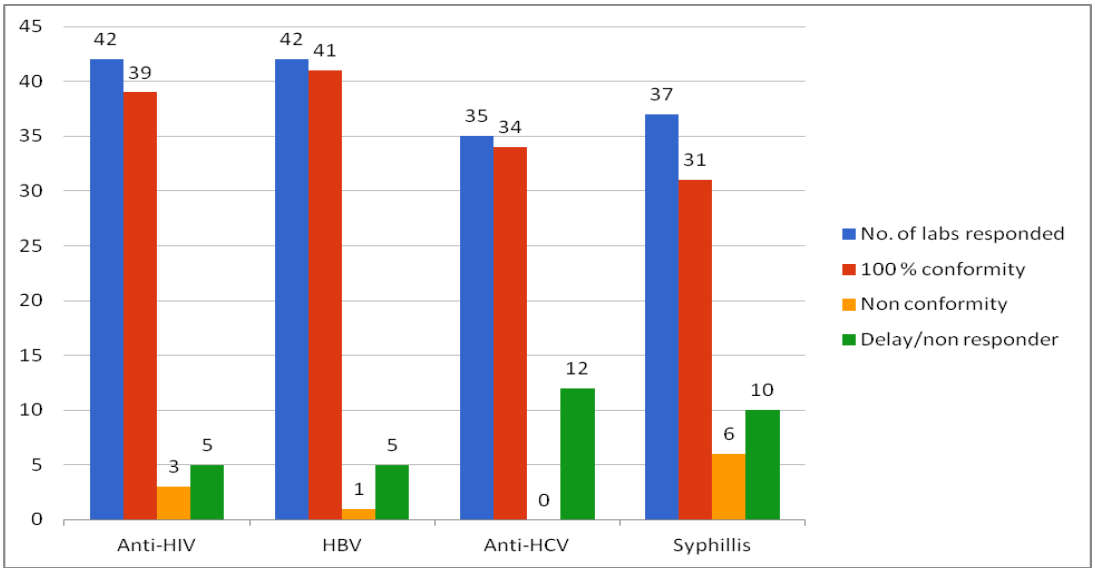


Figure 2; Overall participation and performance (47 NEQAS sites)

Only 28/42 (66.67%) of the participating laboratories have demonstrated 100% conformity and completeness where as 15/42 (33.3%) sites that have participated by testing at least one of the parameters, have shown non-conformity or non participation in selective parameters. Lab ID 28 has received only half of the test panels fit for testing with the others of the set broken during transportation. Most laboratories have not reported for anti-HCV panel resulting in the loss of score in part A of the program.

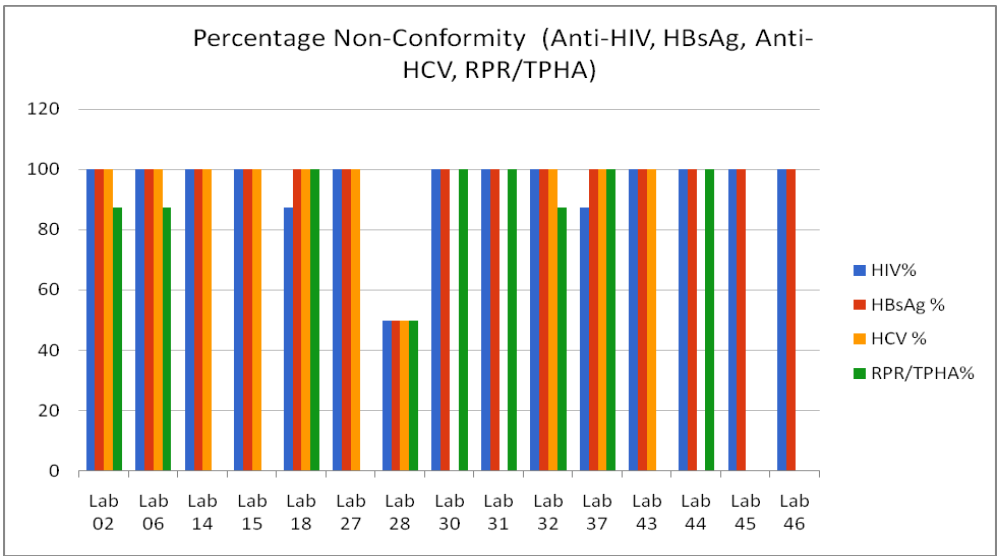


Figure 3; A breakdown of the testing errors (%)

Test kits used by different labs;

The most common test kits used for Anti-HIV serology were the First response, Premier (n=27) and Determine™ HIV 1/2, Alere (n=15). Only one laboratory used SD Bioline HIV, Alere. Two of the 27 laboratories using First response, Premier have reported discordance.

SD bioline HBsAg (Alere) was used by most laboratories (n=24) followed by Determine ™ (Alere). Certain labs (n=1) reportedly used Orchid (n=1), Hepacard (Jai Mitra and Co. Pvt. Ltd) (n=2).Three of the 41 labs did not identify the test kits used. No discordance was found in the HBsAg panel. The figure below shows the diverse test kits used for screening HBsAg within the country.

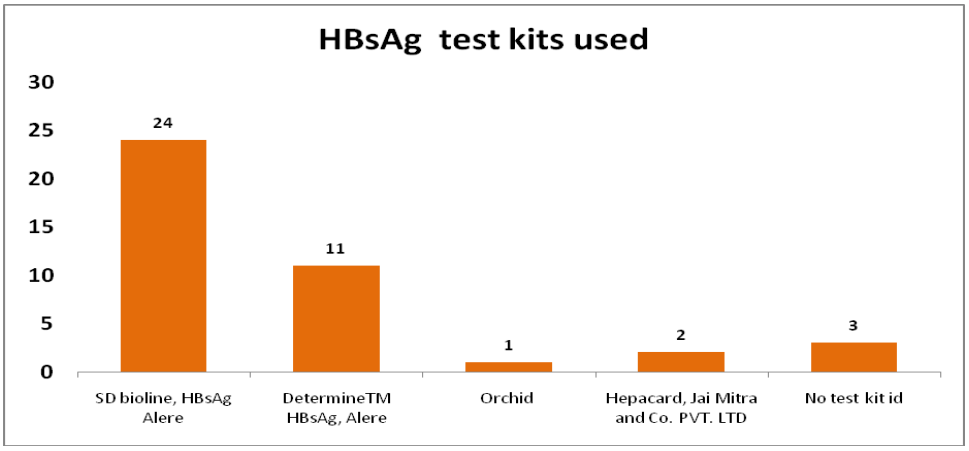


Figure 4; Diverse test kit for testing HBsAg

For testing anti-HCV panel, the single most test kit used by all the participating labs (n=35) was SD bioline from standard diagnostics. No discordance was seen in any of the results.
Of the 36 laboratories that have tested the syphilis panel, 23 laboratories have used both rapid plasma reagin (Carbogen) and Determine™ SyphilisTP. (see table 1)

Table 1; Sporadic use of dual test kits for screening syphilis

Test kits used	No. of labs
Both RPR (Carbogen) and Determine™ syphillis TP	23
Only Determine™ syphillis TP	6
Only RPR (Carbogen)	5
No test kit details	1

Unlike other panels, Syphilis panel has seen much higher non-confirmity between the two test kits used by the participants. Of the 23 labs that have performed testing using, 15 laboratories (65%) showed discrepant results using the two types of test kits. However 8 laboratories (35%) reported agreement between the Rapid and the RPR screening tests.

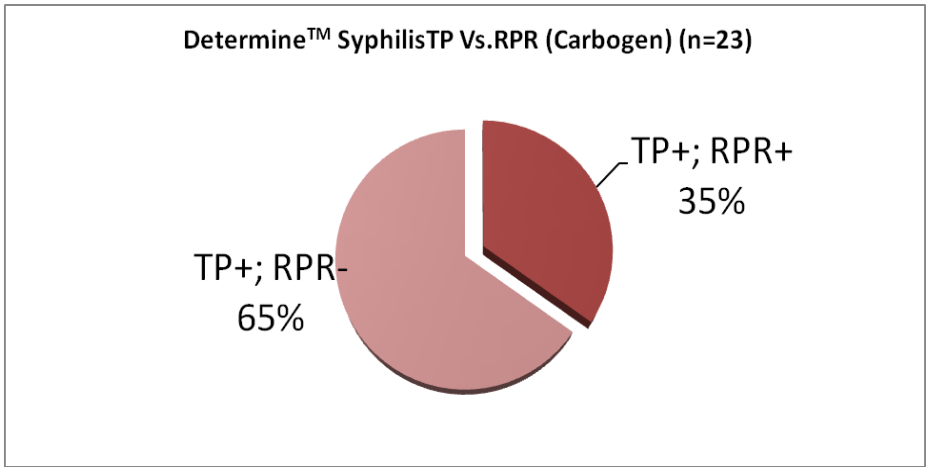


Figure 5; Result discrepancy between Determine™Syphilis and rapid plasma regain (Carbogen)

Summary; NEQAS- TTI Serology Round 15

Of the 47 laboratories across the country enlisted as NEQAS participating centers, 42 laboratories participated in the 15th round. Majority of the laboratories performed within the "excellent" (29%) and the "very good" (43%) category however it is observed that the new participants in this round particularly the health information and service centers (HISCs) are among those falling within the "need improvement" category (21%) either due to the lack of the sensitization on the process of NEQAS-Serology as well as the lack of certain test parameters in the center. Two (5%) of the 42 laboratories performed 'Good' and only one laboratory has a "satisfactory" score. Almost 30% of the participants have scores below 'Very good' which calls for urgent attention.

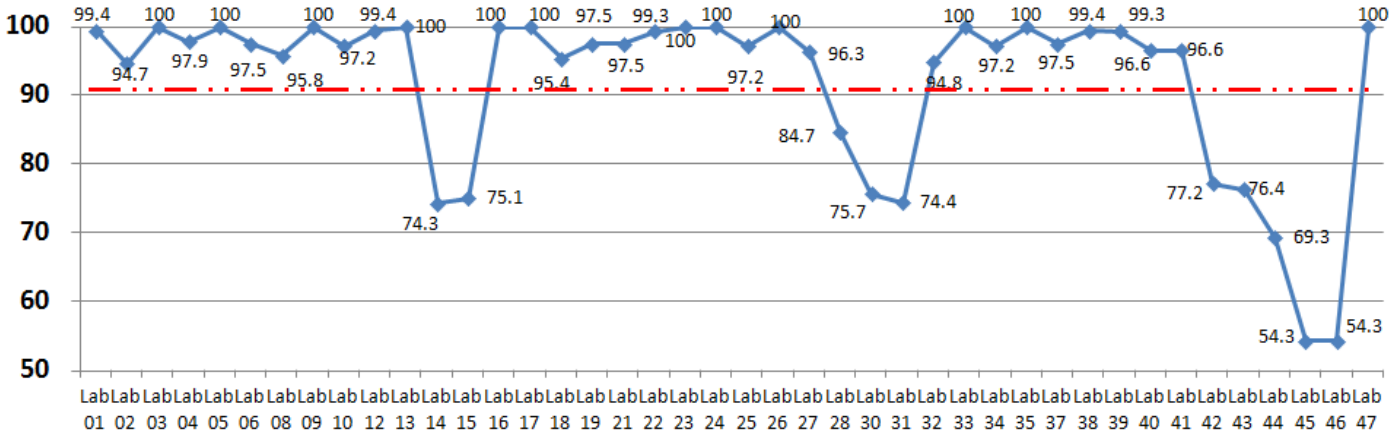
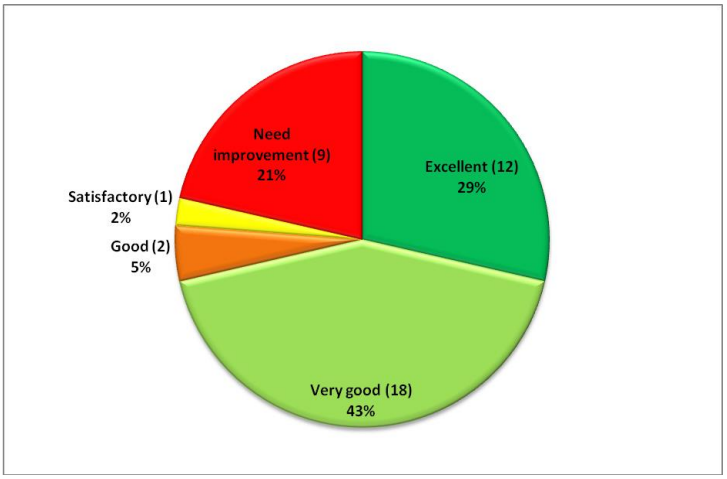


Figure 6 ; Overall performance (scores from part A+Part B)



100	Excellent
95-99	Very good
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Figure 7; Overall performance grading

Among the 5 laboratories 2 (Lab ID 20 and 29) have submitted the results after the closure of the submission dateline whereas Lab ID-07, 11 and 36 have not participated in the program.

Highlights of round of TTI Serology NEQAS Round 15

1. **Shipment;**
    - late delivery to the sites
    - broken tubes
2. **Lab personnels' ;**
    - incomplete test kit identification skill
    - numbering and reporting error
    - delay in testing after receiving the samples (more than 10 days upto 18 days for some labs;Lab ID:14,23,28,38)
    - non participation on repeated reminder from some labs

How to improve laboratory performance

The one third of the laboratories performing within the 'need improvement' category is alarming with several laboratories scoring just above 50%. Any QA program encourages testing the panel members along with the routine samples in order to subject the panel to the normal laboratory testing conditions. Therefore the quality of test results undoubtedly reflects the testing conditions of the laboratory and as well as the competency and integrity of the laboratory personnel performing the tests.

Only 12 laboratories of the 42 have excellent performance, which is quite low for straight forward serology assays like the RDTs. In fact this calls for an immediate attention on-site to the laboratories performing below satisfactory. It would be a challenge to otherwise shift all the laboratory into this category in the subsequent rounds of Serology NEQAS.

All the HISCs are participating in this program for the first time and they lack sensitization on the procedures. Moreover the NEQAS guideline has newly been drafted and the entire participating labs need orientation on the new procedures and the scoring systems.

A batch-wise sensitization of the laboratory technicians on the new NEQAS guideline need to be conducted at the earliest to ensure quality of the results in all the laboratories and to help establish a quality culture in the new participating lab personnel.