National Laboratory for HIV Reference Services
National HIV and Retrovirology Laboratories
National Microbiology Laboratory
Public Health Agency of Canada

HIV Serology Quality Assessment Program

Revised Summary for Panel HIVSER 2017Oct27

2017Oct27 HIV Serology Panel			
Panel Sample	**True Status**	**Labs Reporting Incorrect Status**	
A	HIV-2 Ab Positive		
B	HIV-1/2 Ag/Ab Negative		
C	HIV-1 Ab Positive		
D	HIV-1/2 Ag/Ab Negative		
E	HIV-1 Ag Positive	**Incorrect Status**	• HV15 • HV74

Incorrect interpretations based on their assay result(s):

HV15, HV74
Did not detect the HIV-1 Ag (Sample E) and did not refer the sample to a provincial laboratory/reference laboratory for further testing.

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HIV Serology Quality Assessment Program

Revised Final Report for Panel HIVSER 2017Oct27

Originally Issued 12-Dec-2017 and Revised 22-Jan-2018

Introduction

The NLHRS distributed the 2017Oct27 panel and the 2018Apr19 panel on Oct 11th 2017. This is final report is specific to the 2017Oct27 panel only and is publicly available; however the identity of participants is not disclosed. This report was amended due to transcriptional errors found in the summary page, Table 3, Table 4 and Appendix 2 in the report. The corrections being made are highlighted in grey.

Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition*
  - 2017Oct27 HIV Serology Panel: Five samples; two HIV negative (B, D), one HIV-2 Ab positive (A), one HIV-1 Ab positive (C) and one HIV-1 Ag positive (E). Samples A, C, and E were diluted with defibrinated human plasma (Basematrix 53, Seracare Life Sciences). Testing and characterization by the NLHRS prior to shipment are presented in Appendix 2. Panels were sent to 43 participants including the NLHRS on Oct 11th, 2017. The deadline for data entry for the 2017Oct27 panel was October 27th, 2017.
    - Sample A was diluted 1/2 with defibrinated human plasma.
    - Sample C was diluted 1/4 with defibrinated human plasma.
    - Sample E was diluted 1/10 with defibrinated human plasma.

- *HIV Test Kits* –Nine different assays were used by the 43 participants excluding the NLHRS who returned results (Table 1, Figure 1 and Figure 2). The majority of participants, 83% (36/43) used a 4th generation EIA while 1 participant continued to use a 3rd generation assay and 4 participants ran only the rapid test for screening which raise potential issues with the ability of labs to detect acute infections. The Bio-Rad Geenius HIV1/2 Supplemental Assay is now being used as a confirmatory assay by all participants.

- *Data entry* - The NLHRS Quality Assessment Program used the web based Survey Monkey system to capture results.

Table 1: Summary of the assays used in the 2016Oct28, 2017Apr19 and 2017Oct27 HIV Panels (excludes the NLHRS).				
Type	**Assay**	**# of Users**		
		2016Oct28	**2017Apr19**	**2017Oct27**
Screen – 4th Generation	Abbott ARCHITECT HIV Ag/Ab Combo CMIA	31	30	32
	Abbott AxSYM HIV Ag/Ab Combo MEIA	1	--	--
	Roche Elecsys HIV Combi ECLIA	2	2	2
	Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) ChLIA Assay	2	2	2
	Bio-Rad Genscreen ULTRA HIV Ag/Ab	0	0	1
Screen – 3rd Generation	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA	2	2	1
	Abbott AxSYM HIV HIV 1/2 gO MEIA	--	--	--
Screen – 3rd Generation- HIV2	Bio-Rad Genetic System HIV-2 EIA	1	1	0
Screen – Rapid test	bioLytical INSTI HIV-1/HIV-2 Antibody Test Kit	4	4	4
Confirmatory – p24	bioMerieux VIDAS HIV p24 II ELFA	2	2	2
	Bio-Rad Genscreen HIV-1 Ag EIA	1	1	1
Confirmatory-Ab	Bio-Rad Multispot HIV-1/2 Rapid Test	--	--	--
	Bio-Rad Genetic System HIV-1 Western Blot	5	3	0
	Fujirebio INNO-LIA HIV-I/II Score	0	0	0
	Bio-Rad Geenius HIV-1/2 Supplemental Assay	4	6	11

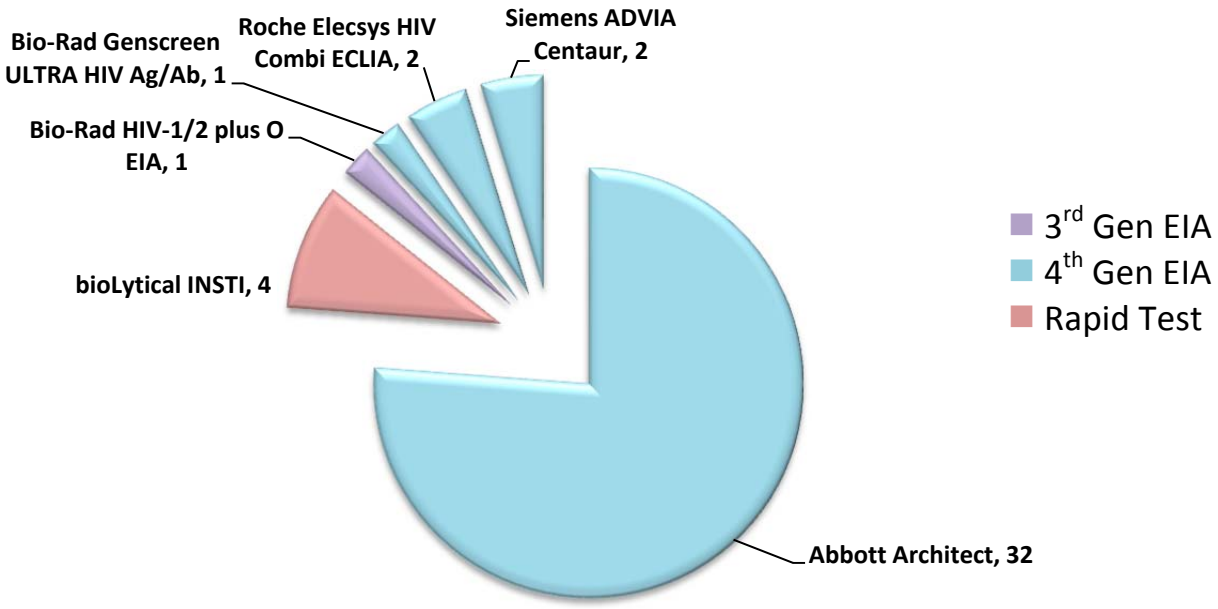

Figure 1: Breakdown of the screening assays used by the 43 participants in the 2017Oct27 HIV serology panel (excludes the NLHRS)

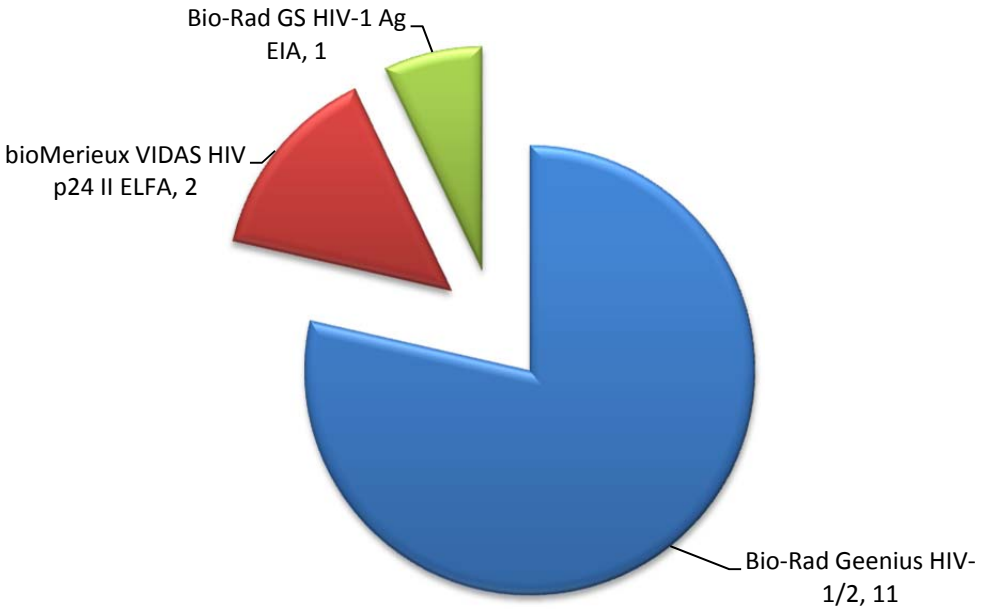

Figure 2: Breakdown of the confirmatory assays use by the participants in the 2017Oct27 HIV serology panel (excludes the NLHRS)

Table 2: Level of the different flags and causes for the flag	
Level of flag	**Causes for flagging**
Major	Incorrect result/status provided
Intermediate	Deviation from kit insert, unresolved status without recommendation
Minor	Minor errors that do not resulted in misinterpretation of the true status of the sample, unresolved status but made a recommendation

Homogeneity and stability

- The homogeneity and stability of the 2017Oct27 HIV serology panel was assessed by comparing the participant's results with the panel characterization results obtained by the NLHRS prior to the panel send-out.
- There was no indication of heterogeneity or instability of the panel samples as the data submitted by the participants is consistent with the expected results from the NLHRS characterization of each panel members (Table 3, 4 and Appendix 3).

External QC and QA activities

1. *External quality control (QC) material* - Used in addition to controls provided in kits allows users to detect technical problems and assay sensitivity from lot to lot.
   - 23 participants (53.5%, 23/43) reported using external QC material.

2. *Quality Assurance (QA) programs* – Allows participants to evaluate their overall use of the assay and reporting of the results
   - 37 of 43 participants reported participation in other quality assurance program (Figure 2).

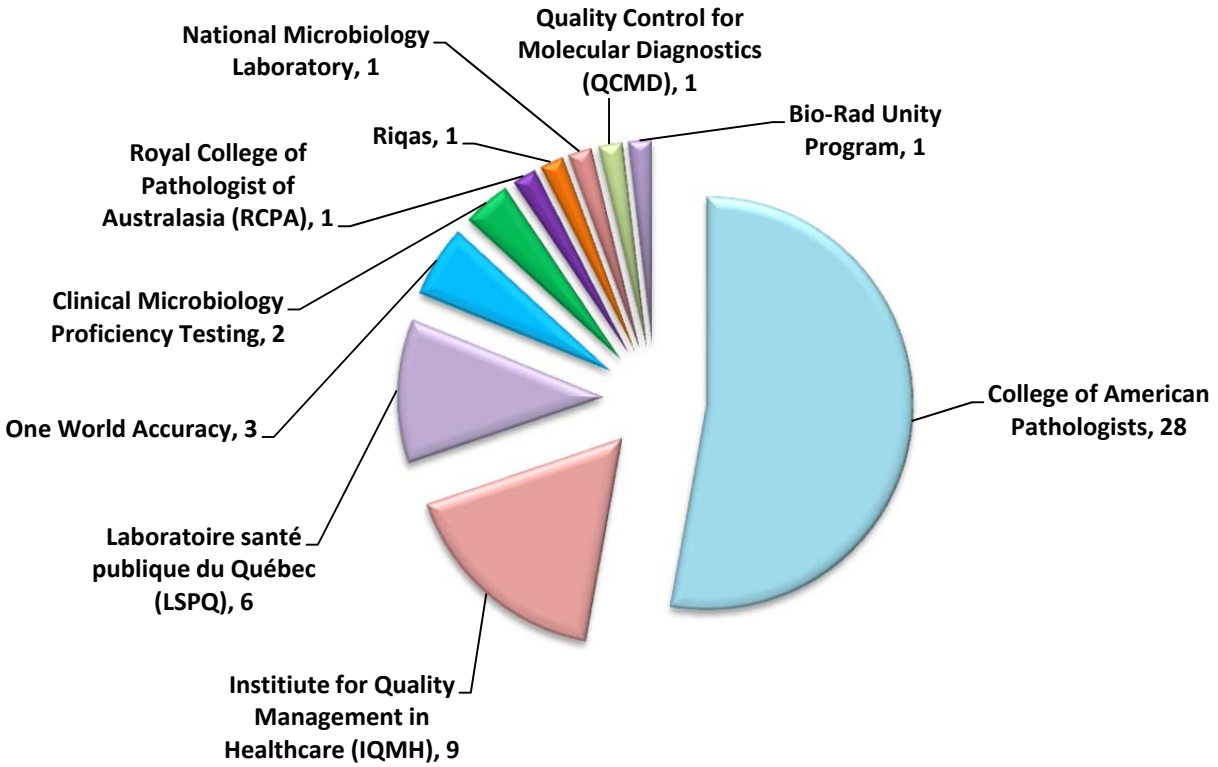

Figure 2: Distribution of external quality assurance programs which participants are enrolled in other than the NLHRS QAP

Participant's feedback

- The participants were asked to give their feedback and suggestions on how the NLHRS as a proficiency testing provider for HIV serology could improve.
- 43 of 43 participants provided feedback. 42 participants found the NLHRS HIV serology quality assurance program to be satisfactory. One participant did not find the NLHRS HIV serology quality assurance program to be satisfactory to their need (Figure 3).
- 9 participants provided no comment when asked to provide suggestions for improvement and 11 participants are happy with the current format.
- An overwhelming response of allowing the user to print their results before result submission was identified (Figure 4).

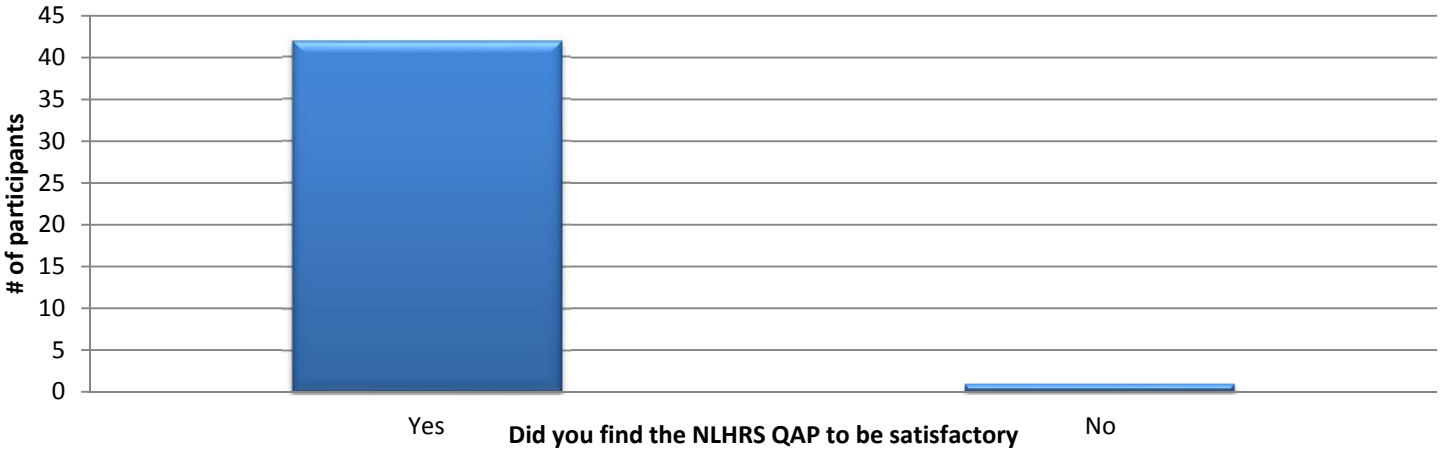

Figure 3: Participant's feedback for the NLHRS as a PT provider

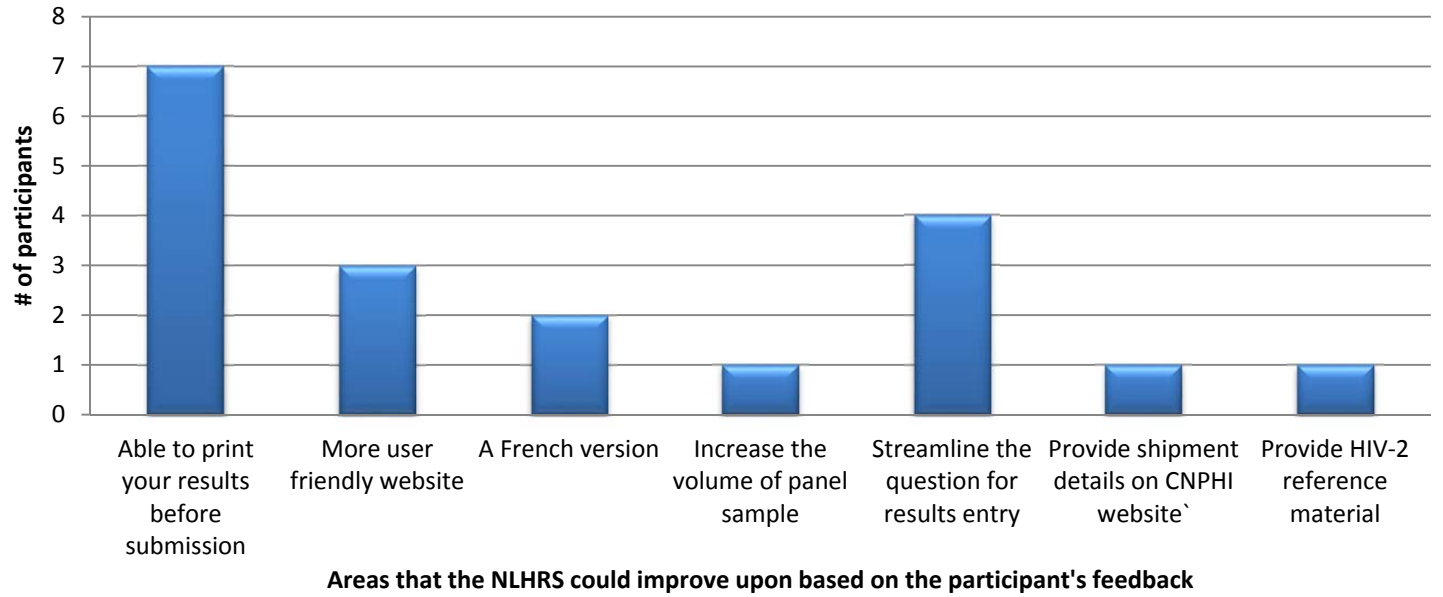

Figure 4: Participant's suggestions for improvements in the NLHRS HIV serology QAP

Legend: **Major** **Intermediate** **Minor**

Table 3: 2017Oct27 HIV Serology Panel final status reported from participants using screening assay only.

LAB	SAMPLE A HIV-2 Ab Positive	SAMPLE B Negative	SAMPLE C HIV-1 Ab Positive	SAMPLE D Negative	SAMPLE E HIV-1 Ag Positive
HV04	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV05	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV07	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV12	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]
HV14	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV17	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV23	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV24	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV26	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV27	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV28	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]
HV30	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]
HV31	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]
HV43	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV44	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV45	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV48	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]
HV49	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV50	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV53	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV54	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV55	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]	HIV-1/2 Ag/Ab Negative	Would not report based on result[1]
HV56	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV57	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV59	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV63	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV64	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV68	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV74	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative	HIV-1/2 Ab Negative
HV76	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]
HV79	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]
HV80	HIV-1/2 Ag/Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1/2 Ag/Ab Positive[1]

[1] Further action recommended by participant; "Refer to reference/provincial laboratory for further testing" or "Request a follow-up sample".

Legend: **Major** **Intermediate** **Minor**

Table 4: 2017Oct27 HIV Serology Panel final status reported from participants (includes the NLHRS) using screening and confirmatory assays.

LAB	SAMPLE A HIV-2 Ab Positive	SAMPLE B Negative	SAMPLE C HIV-1 Ab Positive	SAMPLE D Negative	SAMPLE E HIV-1 Ag Positive
HV01	HIV-2 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab Negative[1,2]
HV02	HIV-2 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab Negative[1,2]
HV03	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab Negative[1,2]
HV13	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative	HIV-1/2 Ab negative HIV-1 Ag Positive[1]
HV15	HIV-2 Ab Positive[2]	HIV-1/2 Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ab Negative[2]	HIV-1/2 Ab Negative[2]
HV16	HIV-2 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab negative HIV-1 Ag Positive[1]
HV18	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ag/Ab IND[1,2]
HV19	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab Negative[1,2] HIV-1 Ag Positive
HV20	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ag/Ab Positive[1,2]
HV21	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ab Negative[1,2]
HV22	HIV-2 Ab Positive[1]	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative[2]	Would not report based on result[1,2]
HV75	HIV-2 Ab Positive, HIV-1 Ag Negative	HIV-1/2 Ag/Ab Negative[2]	HIV-1 Ab Positive HIV-1 Ag Negative	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ag/Ab Negative HIV-1 Ag Positive

1 Further action recommended by participants; "Refer to provincial/reference laboratory for further testing" or Request a follow-up sample"
2 Did not performed the stand alone HIV-1 p24 testing to confirm the presence of HIV-1 p24 antigen

Results

- *Return rate* - Results were returned from 100% of participants excluding the NLHRS (43/43).
    - ***HV64*** *submitted results after the submission deadline.*
- *Group Analysis (Excluding the NLHRS)*

  2017Oct27 Panel (Table 3 and Table 4)
  - *Sample A (HIV-2 Ab Positive)* – 43/43 participants provided either a correct serology status and/or recommendation
    - ***HV19***: Participant performed HIV Ab confirmatory testing but did not provide the result of the confirmatory test to support the serology status reported
    - ***HV24***: Participant performed a 4th gen EIA for screen testing but did not provide the result to support the serology status reported
    - ***HV80***: Participant did not provide a recommendation for further testing or requesting a follow-up sample due to unresolved serology status
    - ***HV74***: Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported

Results *(continued)*

- *Sample B (HIV-1/2 Ag/Ab Negative)* – 43/43 participants provided either a correct serology status and/or recommendation
  - **HV24**: Participant performed 4th gen EIA for screen testing bud did not provide the results to support the serology status reported
  - **HV74:** Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported

- *Sample C (HIV-1 Ab Positive)* – 43/43 participants provided either a correct serology status and/or recommendation.
  - **HV19:** Participant performed HIV Ab confirmatory testing but did not provide the result of the confirmatory test to support the serology status reported
  - **HV24**:Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported
  - **HV80:** Participant did not provide a recommendation for further testing or requesting a follow-up sample due to unresolved serology status
  - **HV74**:Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported

- *Sample D (HIV-1/2 Ag/Ab Negative)* – 43/43 participants provided either a correct serology status and/or recommendation
  - **HV24**: Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported
  - **HV74**: Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported

- *Sample E (HIV-1 Ag Positive)* – 41/43 participants provided either a correct serology status and or recommendation
  - **HV15:** Missed the HIV-1 Ag because it only utilize HIV Ab confirmatory testing
  - **HV24:** Participant performed 4th gen EIA for screen testing but did not provide the result to support the serology status reported
  - **HV74:** Missed the HIV-1 Ag (ran 3rd gen) and did not provide recommendation/refer to reference/provincial laboratory for further testing and did not provide results to support the serology status reported

Results *(continued)*

- *Failed to enter required result of the assay*: ***HV19, HV24, HV74***

  HV19 reported the final HIV-1 serology status of HIV Ab on Sample A and C but failed to provide the results to support the final serology status reported.

  HV24 and HV74 reported the final HIV serology status of on Sample A, B, C, D and E but failed to provide the results to support the final serology status reported.

- *Inability to detect a potential pre-seroconversion sample:* ***HV15, HV74***

  HV74 continued to use a 3rd Generation EIA without supplementing their testing with a stand-alone HIV-1 p24 Ag test was unable to detect the HIV-1 Ag in Sample E which led to misinterpretation and was reported as false negative. HV15 did not supplement their testing procedure with the stand alone HIV-1 p24 Ag test as well and was unable to detect the HIV-1 Ag in Sample E.

- *No recommendation for samples with unresolved serology status :* ***HV80***

  HV80 did not provide a recommendation for panel member A and C with an unresolved status. It was screened reactive on 4th gen but did not recommend for a follow up testing or refer to a provincial or reference lab to resolve the status of the sample.

Discussion

In this panel, the NLHRS noticed that the Bio-Rad Geenius HIV-1/2 Supplemental Assay is the only assay used for HIV confirmatory testing. The NLHRS noted that the remaining participants previously using the Bio-Rad HIV-1 Western Blot have switched over to the Bio-Rad Geenius HIV-1/2 Supplemental Assay. This addressed the issue raised in previous reports on the ability of identifying HIV-2 infection and the poor performance of the HIV-1 Western Blot.

The inability to diagnose acute infection (HIV-1 Ag positive, HIV-1 Ab negative) for laboratories that continue to use 3rd generation EIA assays as their primary screening method was noted in the 2016Apr21 HIV Serology report. This issue is highlighted again in this panel as well as the previous panels. Two participants were flagged for the inability to detect HIV-1 Ag in sample E. One participant was flagged for the inability to detect HIV-1 Ag because they use a 3rd generation EIA as their only screening method. The other participant was flagged because they did not supplement their testing with a stand-alone HIV-1 p24 kit to detect the presence of HIV-1 p24 antigen.

Discussion *(continued)*

Two participants have failed to detect the HIV-1 Ag in more than one panel. The inability to detect a pre-seroconversion (acute) infection which would result in a high viral load and increased transmission capacity could potentiate secondary transmission resulting in negative public health implications. These 2 participants should consider switching to a 4th generation EIA as their primary screening method or supplementing their testing with a stand-alone HIV-1 p24 kit like the Bio-Rad Genscreen p24 kit or the bioMerieux VIDAS HIV p24 kit to detect the presence of HIV-1 p24 antigen.

In addition, the post-analytical transcription errors that were identified in the previous panel did not occur again in this panel; however, the NLHRS noticed that almost half of the participants do not use external quality control materials when performing their assay. The NLHRS recommends that laboratories use external quality control material in their testing.

In this panel, the NLHRS asked the participants to provide feedbacks and suggestions for improvement in the HIV serology Quality Assurance Program. The NLHRS was pleased to hear from our participants of their opinion on the NLHRS HIV serology QAP. However, several areas were identified for improvements, such as allowing the participants to print their results before submission. The NLHRS will take the feedback and suggestions into consideration to improve the overall HIV serology quality assurance program.

Conclusion

External quality control material allows users to detect technical problems and lot to lot variations in assay sensitivity. The NLHRS would like to suggest to the participants that are currently not using external quality control material in their assay to consider implementing external quality control material into their workflow.

Proficiency testing programs are designed not only to test the examination stage but the overall process in patient sample testing. As outlined in Appendix 3, errors in laboratory and medical testing can also occur during the pre-examination stage which includes all elements related to specimen collection.

The quality of HIV serology testing overall in Canada remains very high.

We value each laboratory's participation in these QA panels and your suggestions for improvement. The NLHRS is committed to improve all aspect of the HIV serology proficiency testing program in order provide quality proficiency testing service to our participants

If you would like to make an appeal, please submit your concerns to: nlhrs-lnsrv@phac-aspc.gc.ca

Thank you for your participation in the NLHRS HIV Serology QA Program

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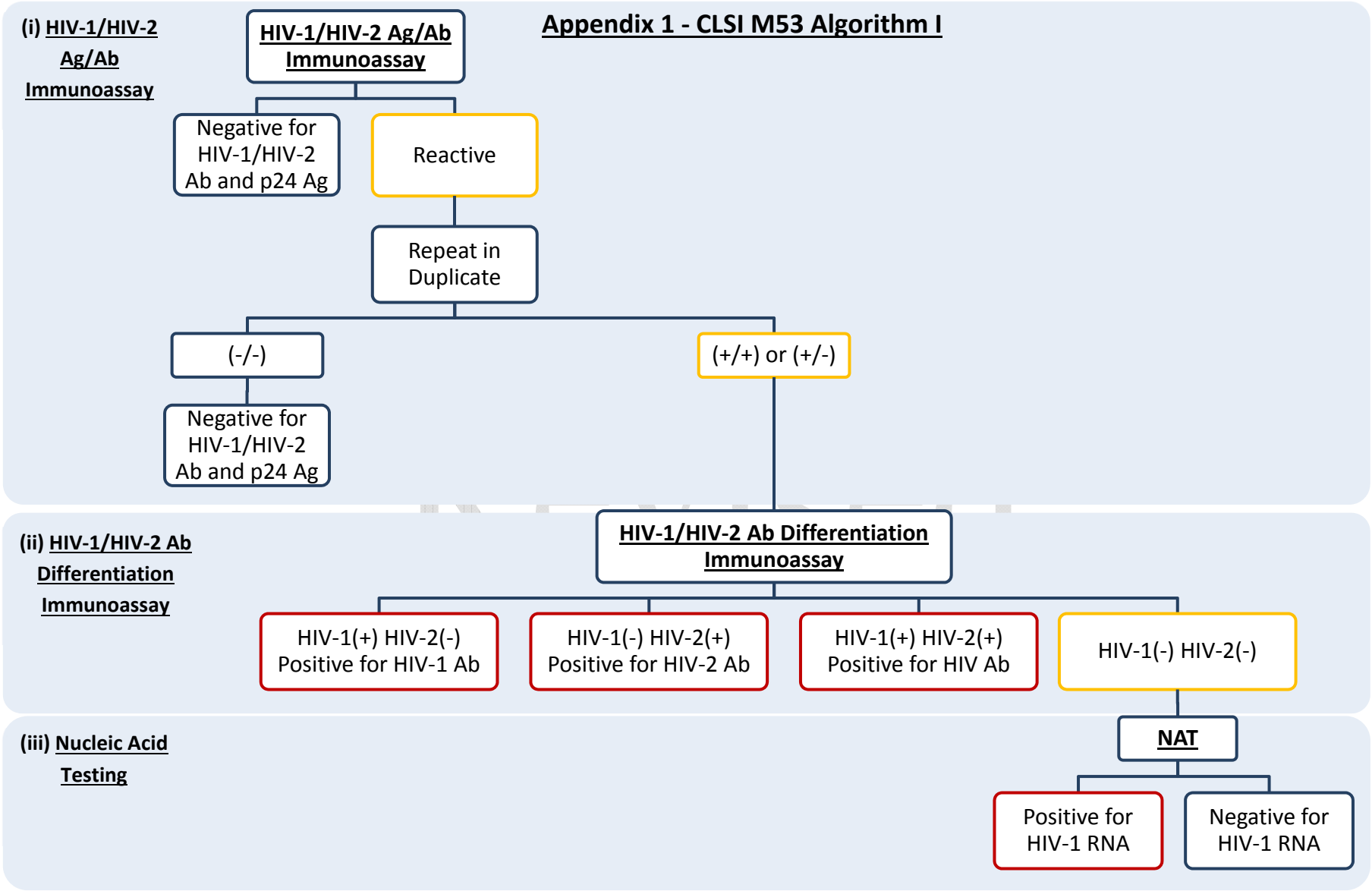

Appendix 1: Adaptation of the Clinical and Laboratory Standards Institute (CLSI) M53-*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline* Algorithm I.

Appendix 2: Characterization

Summary of NLHRS Characterization of the 2017Oct27 HIV Panel Samples

Sample		B/D (Duplicate)	A	C	E
		Negative	**HIV-2 Ab positive**	**HIV-1 Ab positive**	**HIV-1 Ag positive**
Final Status		HIV-1/2 Ag/Ab Negatve	HIV-2 Ab positive	HIV-1 Ab positive	HIV-1 Ag positive
bioLytical INSTI HIV-1/2 Rapid Test	**Result**	NR	R	R	NR
Bio-Rad GS HIV Ag/Ab Combo	**Result**	Non Reactive	Reactive	Reactive	Reactive
Bio-Rad GS HIV p24	**Result**	Non Reactive	Non Reactive	Non Reactive	Reactive
Bio-Rad GS HIV p24 Confirmatory	**Result**	Not Tested	Not Tested	Not Tested	100% neutralization
Bio-Rad GS HIV-1 Western Blot	**Result**	Neg	HIV IND	HIV-1	Neg
	gp160	-	-	++	-
	gp120	-	-	+	-
	p65	-	++	+/-	-
	p55	-	-	+	-
	p51	-	+	+/-	-
	gp41	-	-	++	-
	p40	-	+/-	++	-
	p31	-	++	++	-
	p24	-	+/-	++	-
	p18	-	-	+	-
Fujirebio INNO-LIA HIV-I/II Score	**Result**	Neg	HIV-2	HIV-1	Neg
	sgp120	-	-	++	-
	gp41	-	-	+++	-
	p31	-	+++	++	-
	p24	-	++	++	-
	p17	-	-	-	-
	sgp105	-	++	-	-
	gp36	-	+++	-	-
Bio-Rad Geenius HIV-1/HIV-2 Supplemental Assay	**Result**	Neg	HIV-2	HIV-1	Neg
	gp36	-	+	-	-
	gp140	-	+	-	-
	p31	-	+	-	-
	gp160	-	-	+	-
	p24	-	-	+	-
	gp41	-	-	+	-
	CTRL	+	+	+	+

Appendix 3: Troubleshooting

Troubleshooting; common causes of outlying and/or aberrant results in Serology and Molecular Laboratories.

Type of Error	Possible Cause(s)	Pre-Analytical	Analytical	Post-Analytical
Sample mix-up	Can occur during specimen reception or testing. May result in outlying/aberrant results for one or all samples mixed-up.	✓	✓	
Transcription	• Incorrect test ordering by physician	✓		
	• Incorrect shipment address	✓		
	• Selecting the wrong assay for data entry	✓		
	• Interchanging results for two or more specimens			✓
	• Entering incorrect results			✓
	• Entering values in the incorrect field (e.g., OD as S/Co)			✓
	• Entering values in the incorrect unit (e.g., IU/mL instead of log_{10} copies/mL)			✓
	• Using a comma instead of a dot to denote a decimal point			✓
	• Selecting the incorrect assay interpretation or analyte			✓
	• Failure to recommend follow-up testing where necessary			✓
	It is recommended all results that are manually transcribed or entered electronically be checked by a second individual to avoid transcription errors.			
Outlying and/or Aberrant Results (random error)	Sporadic test results identified as outlying and/or aberrant can be classified as random events. Possible causes of random error include:			
	• Incorrect sample storage/shipping conditions	✓	✓	
	• Incorrect test method	✓	✓	
	• Insufficient mixing of sample, especially following freezing		✓	
	• Poor pipetting		✓	
	• Ineffective or inconsistent washing		✓	
	• Transcription errors	✓		✓
	• Cross-contamination or carryover	✓	✓	
	• Presence of inhibitors to PCR		✓	
Outlying and/or Aberrant Results (systematic error)	A series of test results identified as outlying and/or aberrant may be due to a systematic problem. Systematic problems may be due to:			
	• Reagents contaminated, expired or subject to batch variation		✓	
	• Instrument error or malfunction		✓	
	• Insufficient washing		✓	
	• Incorrect wavelength used to read the assay result		✓	
	• Cycling times too long/short or temperature too high/low		✓	
	• Incubation time too long/short or temperature too high/low		✓	
	• Insufficient mixing/centrifuging before testing		✓	
	• Incorrect storage of test kits and/or reagents	✓		
	• Contamination of master-mix, extraction areas or equipment		✓	
	• Ineffective extraction process		✓	
	• Degradation of master-mix components		✓	
	• Suboptimal primer design (in-house assays)		✓	

This table was modified from a report produced by the National Reference Laboratory (NRL), Melbourne, Australia.