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

HIV Serology Quality Assessment Program

Summary for Panel HIVSER 2018Apr19

2018Apr19 HIV Serology Panel			
Panel Sample	**True Status**	**Labs Reporting Incorrect Status**	
A	HIV-1 Ag Positive		
B	HIV-2 Ab Positive	**Incorrect Status**	• HV80
C	HIV-1/2 Ag/Ab Negative	**Incorrect Status**	• HV01
D	HIV-1 Ab Positive	**Incorrect Status**	• HV80 • HV18
E	HIV-1/2 Ag/Ab Negative	**Incorrect Status**	• HV01

Incorrect interpretations based on their assay result(s):

HV01
Incorrectly reported a negative sample (Sample C and E) as HIV-1/2 Ag/Ab negative and HIV Ab positive

HV80
Incorrectly reported the wrong sample status (Sample B and D) based on the assay used in the testing.

HV18
Incorrectly reported the wrong sample status (Sample D) and did not provide a recommendation

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HIV Serology Quality Assessment Program

Final Report for Panel HIVSER 2018apr19

Issued August-15-2018

Introduction

The NLHRS distributed the 2018Apr19 panel on Oct 11th 2017. This final report is specific to the 2018Apr19 panel only and is publicly available; however the identity of participants is not disclosed.

Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition*
  - 2018Apr19 HIV Serology Panel: Five samples; two HIV negative (C, E), one HIV-2 Ab positive (B), one HIV-1 Ab positive (D), and one HIV-1 Ag positive (A). Samples A, B, and D 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 2018Apr19 panel was April 19th, 2018.

- *HIV Test Kits* – Nine different assays were used by the 42 participants excluding the NLHRS who returned results (Table 1, Figure 1, and Figure 2). The majority of participants, 83% (36/42) used a 4th generation HIV immunoassay. The Bio-Rad Geenius HIV-1/2 Confirmatory Assay is now being used by participants that do HIV confirmatory testing.

- *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 2017Apr19, 2017Oct27, and 2018Apr19 HIV Panels (excludes the NLHRS).				
Type	**Assay**	**# of Users**		
		2017Arp19	**2017Oct27**	**2018Apr19**
Screen – 4th Generation	Abbott ARCHITECT HIV Ag/Ab Combo CMIA	30	32	32
	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	1	1
Screen – 3rd Generation	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA	2	1	0
Screen – 3rd Generation – HIV2	Bio-Rad Genetic System HIV-2 EIA	1	0	0
Screen – Rapid test	bioLytical INSTI HIV-1/HIV-2 Antibody Test Kit	4	4	4
	Alere Determine HIV-1/2	0	0	1
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 Geenius HIV-1/2 Confirmatory Assay	6	11	11
	Bio-Rad Genetic System HIV-1 Western Blot	3	0	0

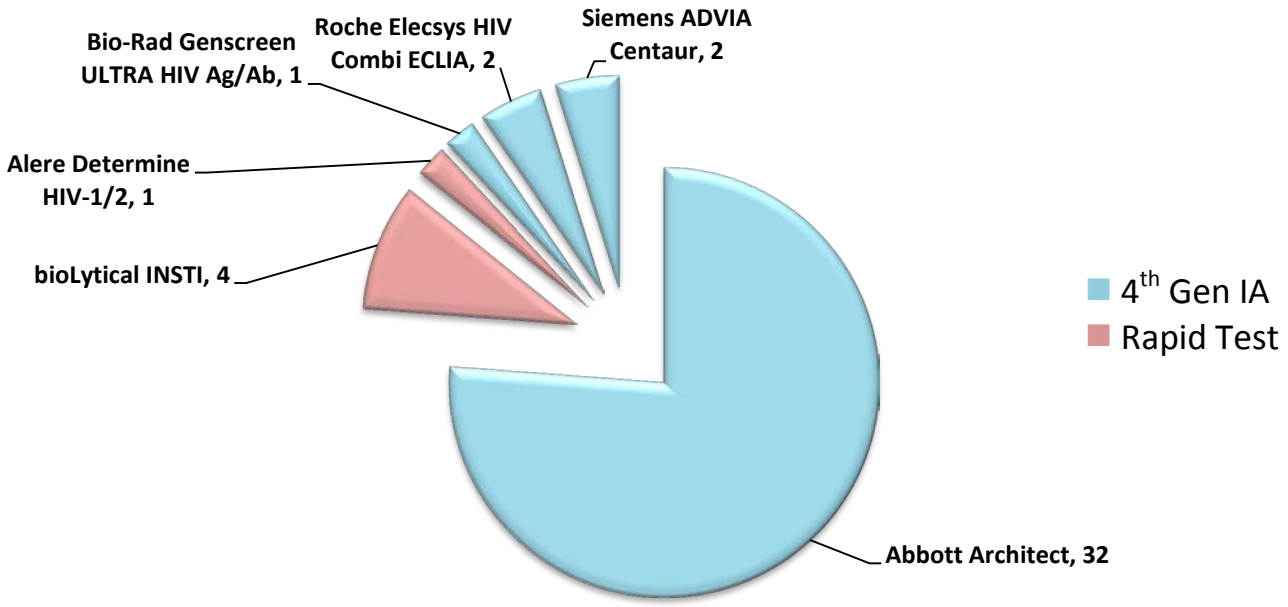

Figure 1: Breakdown of the screening assays used by the 42 participants in the 2018Apr19 HIV serology panel (excludes the NLHRS).

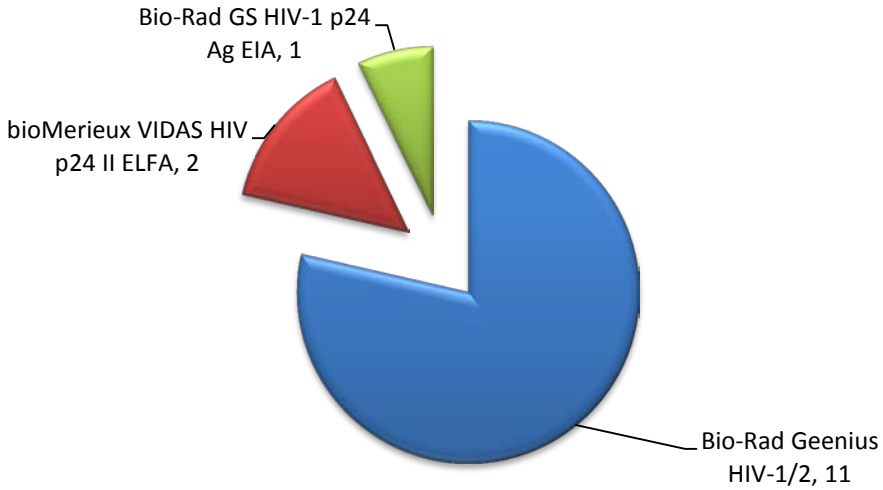

Figure 2: Breakdown of the confirmatory assays used by the participants in the 2018Apr19 HIV serology panel (excludes the NLHRS).

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 result in misinterpretation of the true status of the sample, unresolved status but made a recommendation

Homogeneity and stability

- Panel members of the 2018Apr19 HIV serology panel were randomly selected for testing by the NLHRS during the 2018Apr19 test event. The homogeneity and stability of the panel samples were assessed by comparing the results submitted by the participants for the 2018Apr19 and 2017Oct27 panels.
- There is no indication of heterogeneity or instability of the panel samples as the results are concordant with the participants and are consistent with the expected results from the NLHRS characterization of each panel member (Tables 3, 4, and Appendix 2).

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.
   - 21 participants (50%, 21/42) reported using external QC material. Figure 3 illustrates the source of the external control used.

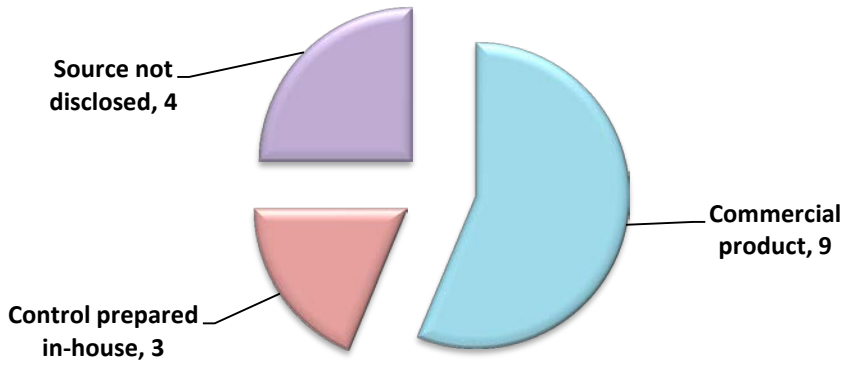

Figure 3: Source of external quality control used in the 2018Apr19 HIV serology panel.

2. *Quality Assurance (QA) programs* – Allows participants to evaluate their overall use of the assay and reporting of the results
   - 39 of 42 participants reported participation in other quality assurance programs (Figure 4).

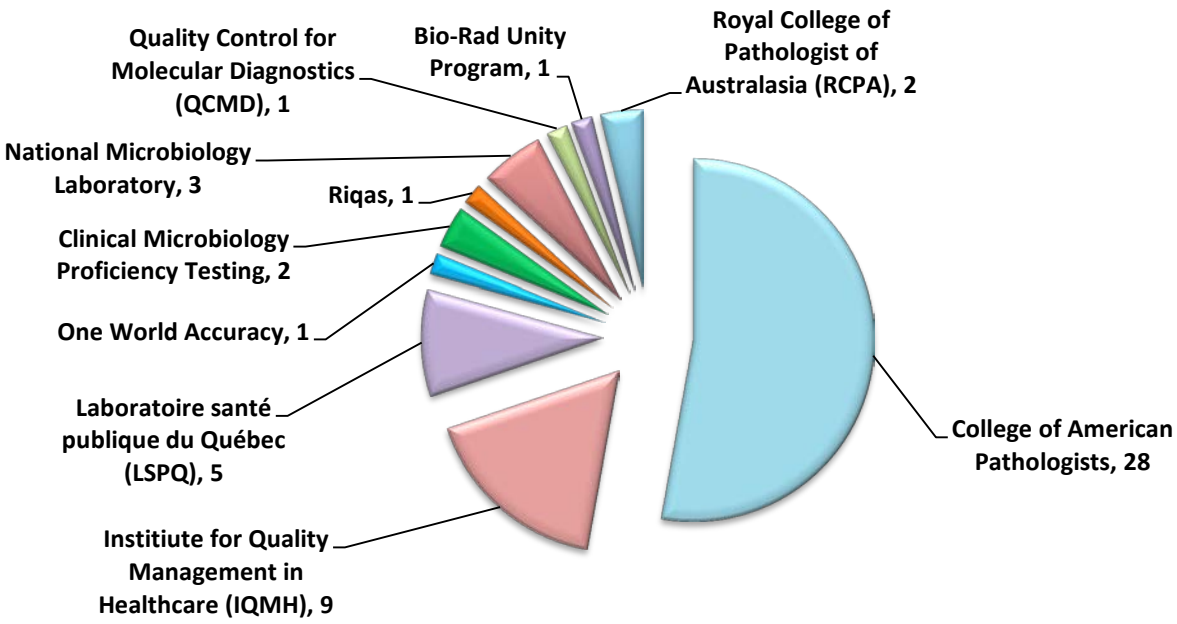

Figure 4: Distribution of external quality assurance programs which participants are enrolled in other than the NLHRS QAP.

Participants' feedback

- Overall, 41 of 42 participants provided feedback regarding the 2018Apr19 HIV serology survey. Thirty-seven participants preferred the changes made to the survey but 4 participants did not (Figure 5).
- Several areas of improvement for the next survey were identified by the participants (Figure 6).

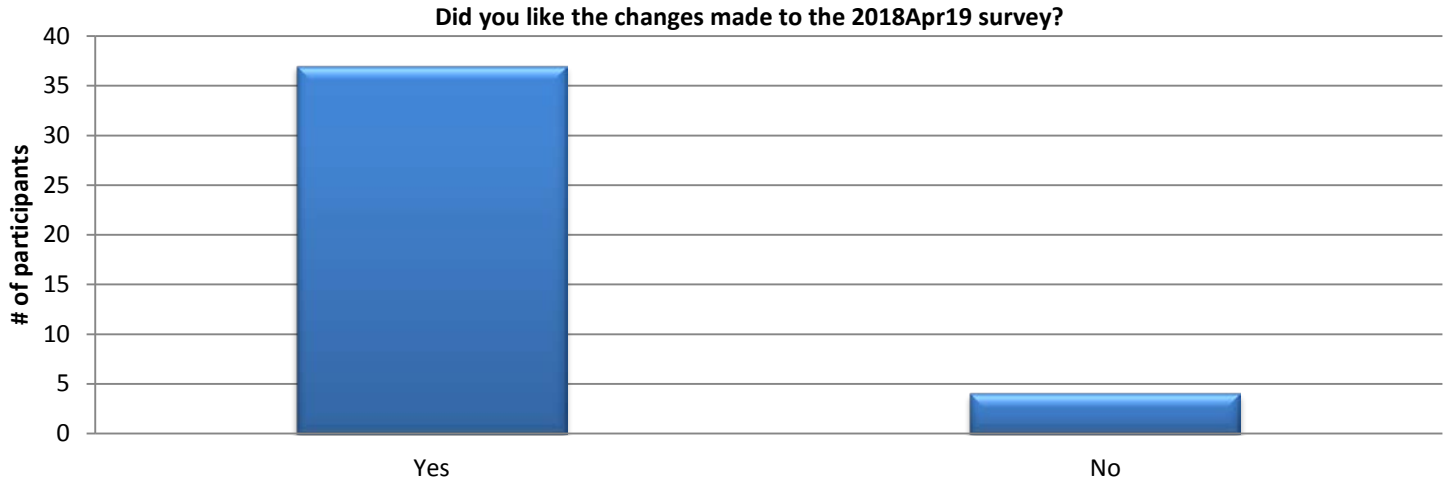

Figure 5: Participants' responses when asked if they liked the changes made to the 2018Apr19 survey

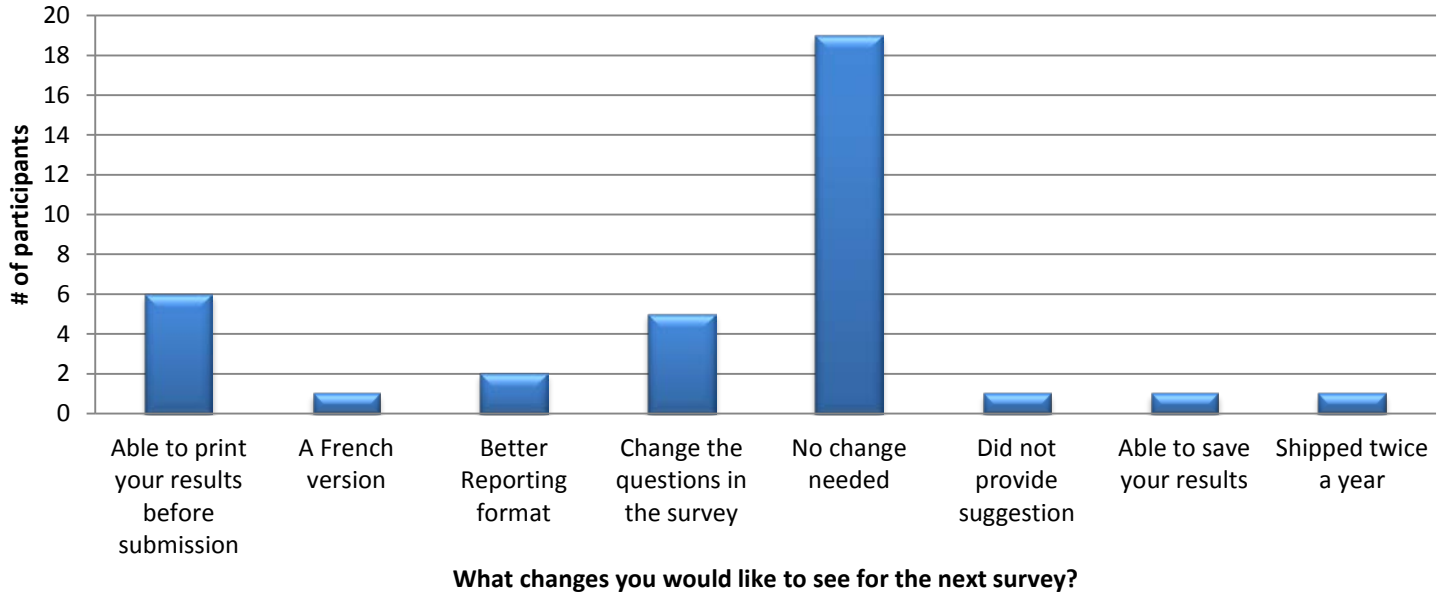

Figure 6: Participants' responses when asked which area requires improvement in the NLHRS HIV serology survey.

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

Table 3: 2018Apr19 HIV Serology Panel final status reported from participants using screening assay only.

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

[1] Further action recommended by participant; “Refer to reference/provincial laboratory for further testing” or “Request a follow-up sample”.
[2] Would not report based on result.

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

Table 4: 2018Apr19 HIV Serology Panel final status reported from participants (includes the NLHRS) using screening and confirmatory assays.

LAB	SAMPLE A HIV-1 Ag Positive	SAMPLE B HIV-2 Ab Positive	SAMPLE C Negative	SAMPLE D HIV-1 Ab Positive	SAMPLE E Negative
HV01	HIV-1/2 Ag/Ab Positive HIV-1/2 Ab Negative[1,2]	HIV-1/2 Ag/Ab Positive	HIV-1/2 Ag/Ab Negative HIV-2 Ab Positive	HIV-1/2 Ag/Ab Positive	HIV-1/2 Ag/Ab Negative HIV-1 Ab Positive
HV02	HIV-1/2 Ab Negative[1,2]	HIV-2 Ab Positive[2]	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive[2]	HIV-1/2 Ag/Ab Negative
HV03	HIV-1/2 Ag/Ab Positive[1,2]	HIV-2 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive[1,2]	HIV-1/2 Ag/Ab Negative
HV13	HIV-1/2 Ab Negative[1] HIV-1 p24 Ag Positive	HIV-2 Ab Positive[1,2]	HIV-1/2 Ab Negative HIV-1 p24 Ag Negative	HIV-1 Ab Positive[1,2]	HIV-1/2 Ab Negative HIV-1 p24 Ag Negative
HV15*	HIV-1/2 Ag/Ab Negative*	HIV-2 Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative
HV16	HIV-1 p24 Ag Positive	HIV-2 Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative
HV18	HIV-1/2 Ag/Ab Indeterminate[1,2]	HIV-2 Ab Positive HIV-1 Ab Indeterminate[1,2]	HIV-1/2 Ag/Ab Negative[2]	HIV-1/2 Ag/Ab Positive	HIV-1/2 Ag/Ab Negative[2]
HV19	HIV-1/2 Ab Negative HIV-1 p24 Ag positive[1]	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]
HV20	HIV-1/2 Ab Negative[1,2]	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]
HV21	HIV-1/2 Ab Negative[1,2]	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]
HV22	Would not report based on result[1]	HIV-2 Ab Positive	HIV-1/2 Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ab Negative
HV75	HIV-1/2 Ab Negative HIV-1 p24 Ag Positive	HIV-2 Ab Positive HIV-1 p24 Ag Negative	HIV-1/2 Ab Negative HIV-1 p24 Ag Negative	HIV-1 Ab Positive HIV-1 p24 Ag Negative	HIV-1/2 Ab Negative HIV-1 p24 Ag Negative
HV80[3]	HIV-1/2 Ab Negative, HIV-1 p24 Ag Positive	HIV-1 Ab Positive, HIV-1 p24 Ag Positive	HIV-1/2 Ab Negative, HIV-1 p24 Ag Negative	HIV-1 Ab Positive, HIV-1 p24 Ag Positive	HIV-1/2 Ab Negative, HIV-1 p24 Ag Negative

[1] Further action recommended by participants; "Refer to provincial/reference laboratory for further testing" or "Request a follow-up sample".
[2] Did not perform standalone HIV-1 p24 testing to confirm the presence of HIV-1 p24 antigen.
[3] Participant performed both an HIV-1/2 Ab rapid test and a 4th gen HIV immunoassay.
* This participant used a modified confirmatory algorithm which does not account for p24 detection.

Table 5: 2018Apr19 HIV panel sample final HIV serology status based on assay performed.

Assay	Sample A	Sample B	Sample C	Sample D	Sample E
Rapid Test	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive	HIV-1/2 Ab Negative
4th Gen HIV Screening Assay	HIV-1/2 Ag/Ab Positive	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 Ab confirmatory Assay	HIV Ab Negative	HIV-2 Ab Positive	HIV Ab Negative	HIV-1 Ab Positive	HIV Ab Negative
HIV-1 p24 Ag test	HIV-1 p24 Ag Positive	HIV-1 p24 Ag Negative	HIV-1 p24 Ag Negative	HIV-1 p24 Ag Negative	HIV-1 p24 Ag Negative

Results

- *Return rate* – Results were returned from 97.7% of participants excluding the NLHRS (42/43).
  - **HV74:** Suspended their participation in the NLHRS QAP for HIV serology until their new HIV testing algorithm is implemented.
- *Group Analysis (Excluding the NLHRS)*

  2018Apr19 Panel (Tables 3 and 4)
  - *Sample A (HIV-1 Ag Positive)* – 41/41 participants provided either a correct serology status and/or recommendation.
    - **HV15:** Excluded from the assessment of this sample because the participant only use an HIV Ab confirmatory test for assessment in the NLHRS HIV serology panel.
  - *Sample B (HIV-2 Ab Positive)* – 40/42 participants provided either a correct serology status and/or recommendation.
    - **HV01**: Submitted an incorrect serology status without a follow-up or recommendation, even though it was correctly identified as HIV-2 Ab positive in their testing.
    - **HV80:** Did not perform HIV Ab confirmatory testing but submitted as HIV-1 Ab positive.
  - *Sample C (HIV-1/2 Ag/Ab Negative)* – 40/42 participants provided either a correct serology status and/or recommendation.
    - **HV01:** Submitted an incorrect serology status. It was submitted both as HIV-1/2 Ag/Ab negative and HIV-2 Ab positive.
    - **HV15:** Submitted the serology status as HIV-1/2 Ag/Ab negative despite using an assay that does not detect HIV-1 p24 Ag.
  - *Sample D (HIV-1 Ab Positive)* – 39/42 participants provided either a correct serology status and/or recommendation.
    - **HV01**: Submitted an incorrect serology status without a follow-up or recommendation, even though they correctly identified the sample as HIV-1 Ab positive in their testing.
    - **HV18**: Submitted an incorrect serology status without a follow-up or recommendation, even though they correctly identified the sample as HIV-1 Ab positive in their testing.
    - **HV80**: Did not perform HIV Ab confirmatory testing but submitted as HIV-1 Ab positive.
  - *Sample E (HIV-1/2 Ag/Ab Negative)* – 40/42 participants provided either a correct serology status and/or recommendation.
    - **HV01:** Submitted an incorrect serology status. It was submitted both as HIV-1/2 Ag/Ab negative and HIV-1 Ab positive.
    - **HV15:** Participant used an HIV Ab confirmatory assay but reported the sample as HIV-1/2 Ag/Ab negative.

Results *(continued)*

- *Incorrect final HIV serology status*: ***HV15, HV80***
  HV80 tested the 2018Apr19 HIV serology panel samples with a 4th Gen screening assay and a rapid test. They did not perform an HIV Ab confirmatory test to confirm sample B as HIV-2 Ab positive and sample D as HIV-1 Ab positive. HV15 reported samples C and E as HIV-1/2 Ag/Ab negative but the assay used only detects HIV-1/2 antibody and not HIV-1 p24 Ag.

- *Transcriptional Error :* ***HV01, HV18***
  HV01 was able to correctly identify the serology status for samples B, D, C, and E but made a transcriptional error when submitting the final result. HV18 made the same transcriptional error for sample D.

Conclusion

Several participants (HV01, HV15, and HV18) made transcriptional errors during the final results submission stage where an incorrect HIV serology status was submitted, or they did not provide a recommendation for a sample with an unresolved HIV status. In all cases, the participants submitted an incorrect result despite correctly identifying the HIV serology status for each sample based on the assay used. To address participant feedback regarding the need for a better reporting format, the NLHRS Quality Assurance Program is currently in the process of developing a new data submission platform that is both more robust and user friendly. This will minimize transcriptional errors that are possibly the result of limitations with our current system for data submission. We anticipate that the new platform will be ready in the near future.

The other error identified in this panel resulted from participant HV80 not realizing the limitation of the assays used in their HIV testing algorithm. In this case, reactive results on both the Alere Determine HIV-1/2 and the Bio-Rad Ultra Combo were used to assign a serology status of HIV-1 Ab positive. Since both tests cannot be used to distinguish between a status of HIV-1 or 2 Ab positive. The correct serology status to report is HIV-1/2 Ab positive.

Participant HV15 was not able to correctly detect the HIV-1 p24 Ag positive sample for 2 consecutive panels, since the Bio-Rad Geenius HIV-1/2 Confirmatory Assay was the only test used for both test events. However, this participant has disclosed that they utilize another assay in their algorithm that would have been able to detect the HIV-1 p24 Ag in sample A. Owing to operational constraints; they were only able to use the Bio-Rad Geenius HIV-1/2 Confirmatory Assay for the NLHRS HIV serology panel. Consequently, the NLHRS will no longer flag participant HV15 in this panel and onward, for reporting a negative result for a sample that is positive for HIV-1 p24 Ag only, as it would not be a fair assessment of their overall testing procedure.

Conclusion (continued)

Proficiency testing programs are designed to test not only the examination stage, but also 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 overall quality of HIV serology testing 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 improving all aspects of the HIV serology proficiency testing program in order to provide quality proficiency testing to our participants.

If you would like to make an appeal, please submit your concerns to:

phac.nlhrs-lnsrv.aspc@canada.ca

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

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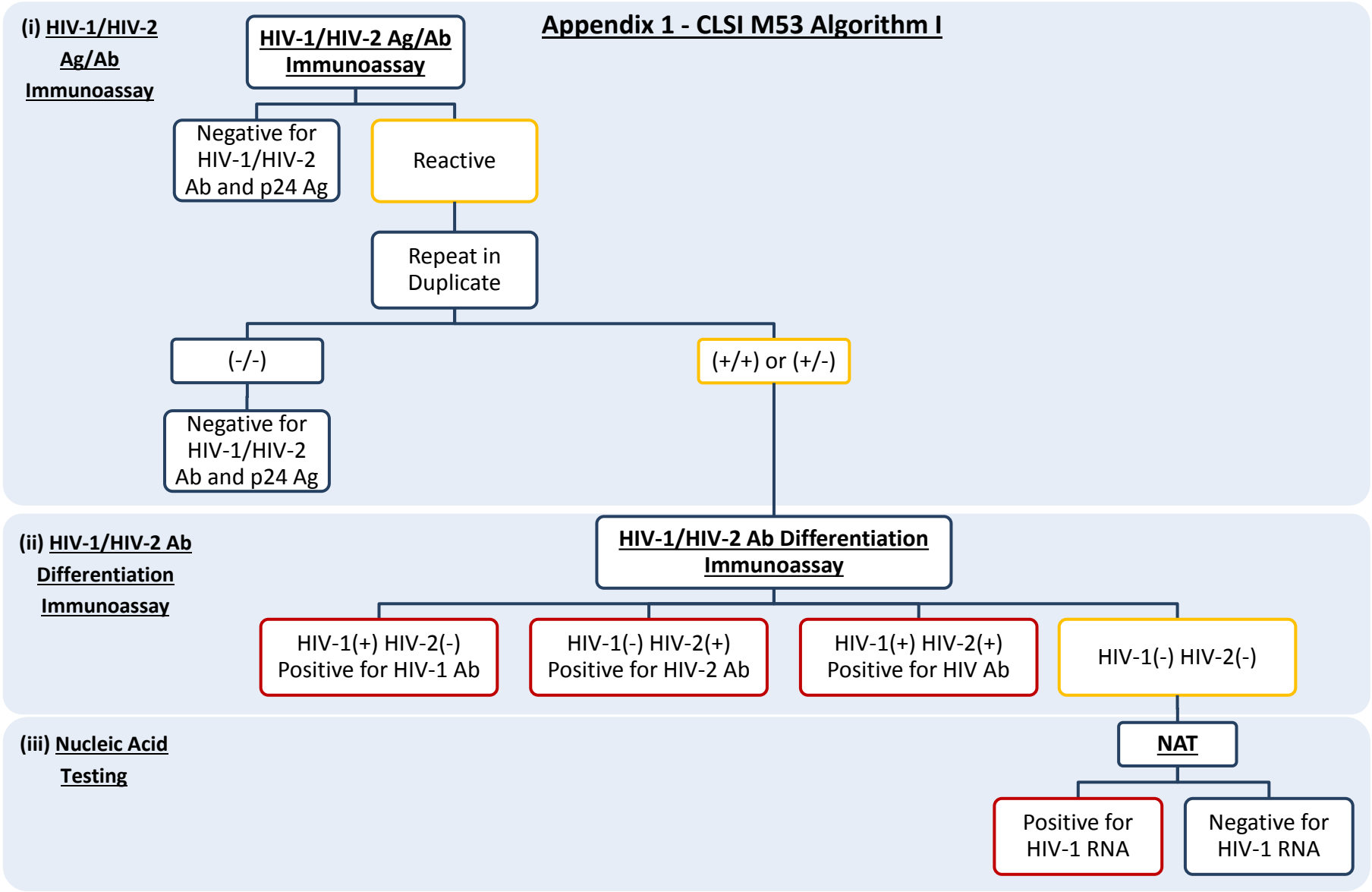

Appendix 1: Adaptation of the Clinical and Laboratory Standards Institute (CLSI) M53-*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline* Algorithm I.

Appendix 2: Characterization

Summary of NLHRS Characterization of the 2018Apr19 HIV Panel Samples.

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