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 2019Oct31

2019Oct31 HIV Serology Panel		
Panel Sample	**True Status**	**Labs Reporting Incorrect Status**
A	HIV-1 Ag Positive	
B	HIV-2 Ab Positive	
C	HIV-1/2 Ag/Ab Negative	
D	HIV-1 Ab Positive	
E	HIV-1/2 Ag/Ab Negative	

There were no incorrect results observed for the 2019Oct31 panel.

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Final Report for Panel HIVSER 2019Oct31

Issued 2019-December-23

Introduction

The NLHRS distributed the 2019Oct31 panel and the 2020Apr17 panel on Oct 16th 2019. This final report is specific to the 2019Oct31 panel only and is publicly available; however the identity of participants is not disclosed. The deadline for results submission is October 31st,2019. The preliminary report was issued on November 15, 2019.

Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition:*
  - 2019Oct31 panel consists of five samples; two HIV negative (C, E), one HIV-1 Ab positive (D), one HIV-1 Ag positive (A) and one HIV-2 Ab positive (B). Sample B and D was diluted 1 in 2 with defibrinated human plasma (Basematrix 53, Seracare Life Sciences). Testing and characterization of the panel by the NLHRS prior to shipment are presented in Appendix 2. Panels were sent to 42 participants and to the NLHRS on Oct 16th, 2019.

- *HIV Test Kits* –Nine different assays were used by the 42 participants (excluding the NLHRS) who returned results (Appendix 3).

- *Data entry* –Results entry for this panel utilized an in-house developed website.

Homogeneity and stability

- The homogeneity and stability of the 2019Oct31 HIV serology panel was assessed by comparing the participants' 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 member (Figure 1, 2 and Appendix 2).

Results

- *Evaluation Criteria:*
  - Negative samples: HIV non-reactive/negative in the final HIV serology interpretation with assay results supporting the final serology interpretation.
  - Positive samples: HIV reactive/positive in the final HIV serology interpretation with assay results supporting the final serology interpretation. Expect the participants to provide a recommendation for further action on samples that they could not determine the true serology status based on the assay used in their testing.

- *Qualitative Group Analysis (Figure 1 and 2)*
  - *Sample A (HIV-1 Ag Positive)* – 42/42 participants provided either a correct serology status and/or recommendation.
  - *Sample B (HIV-2 Ab Positive)* – 42/42 participants provided either a correct serology status and/or recommendation.
  - *Sample C (HIV-1/2 Ag/Ab Negative)* – 42/42 participants provided either a correct serology status and/or recommendation.
  - *Sample D (HIV-1 Ab Positive)* – 42/42 participants provided either a correct serology status and/or recommendation
  - *Sample E (HIV-1/2 Ag/Ab Positive)* – 42/42 participants provided either a correct serology status and or recommendation

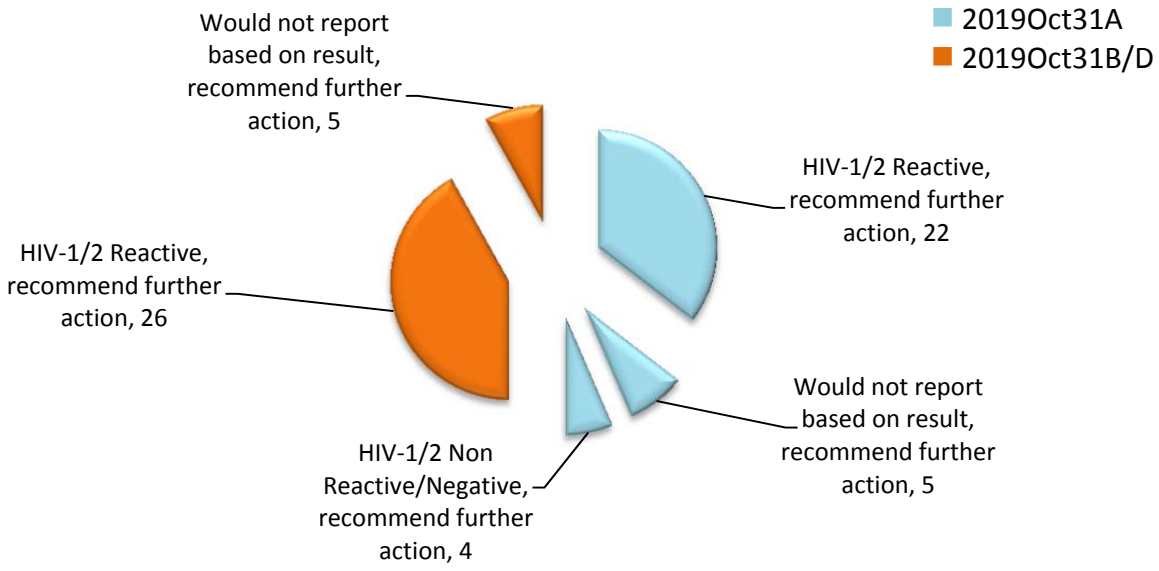
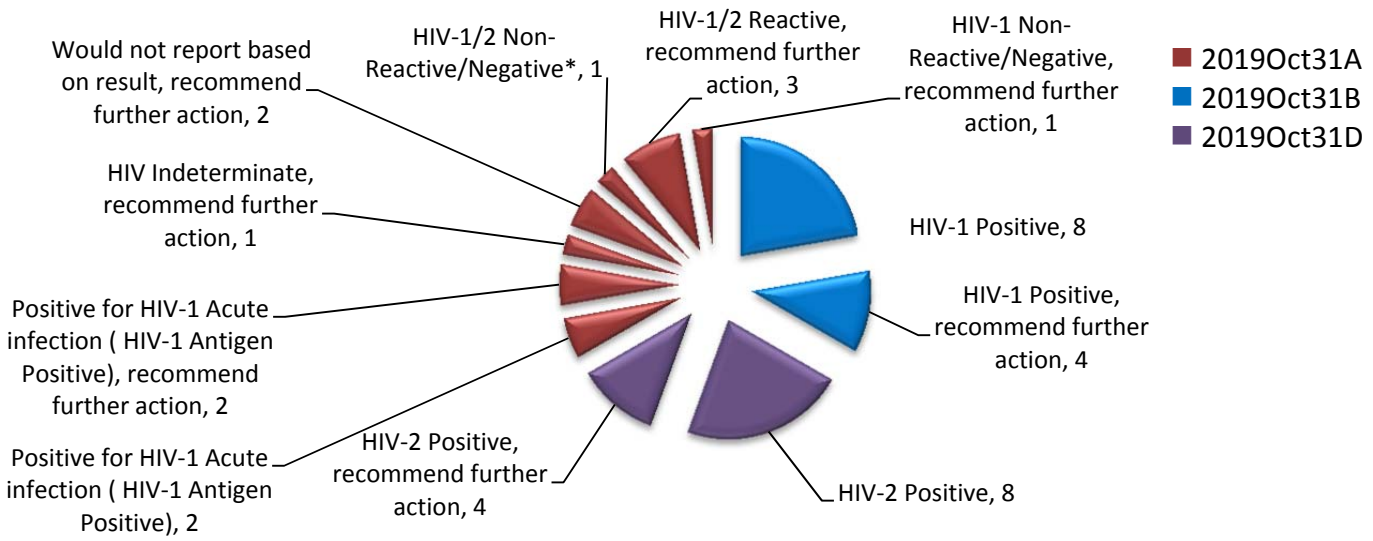


Figure 1: The final HIV serology status of the positive samples in the 2019Oct31 HIV serology panel submitted by participants using only HIV screening assay.



*Waived flag as the participant was only assessed in their confirmatory assay portion of their testing algorithm that used both molecular and serology assay.

Figure 2: The final HIV serology status of the positive samples in the 2019Oct31 HIV serology panel submitted by participants (include NLHRS) using HIV screening and confirmatory assay.

Findings

There are no aberrant results found in this test event. One participant has switched to the Abbott Alinity platform from the Abbott Architect platform; we expect more participants will switch to the newer automated platform in the near future.

If you have any comments, suggestion or concerns, please contact us at:

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

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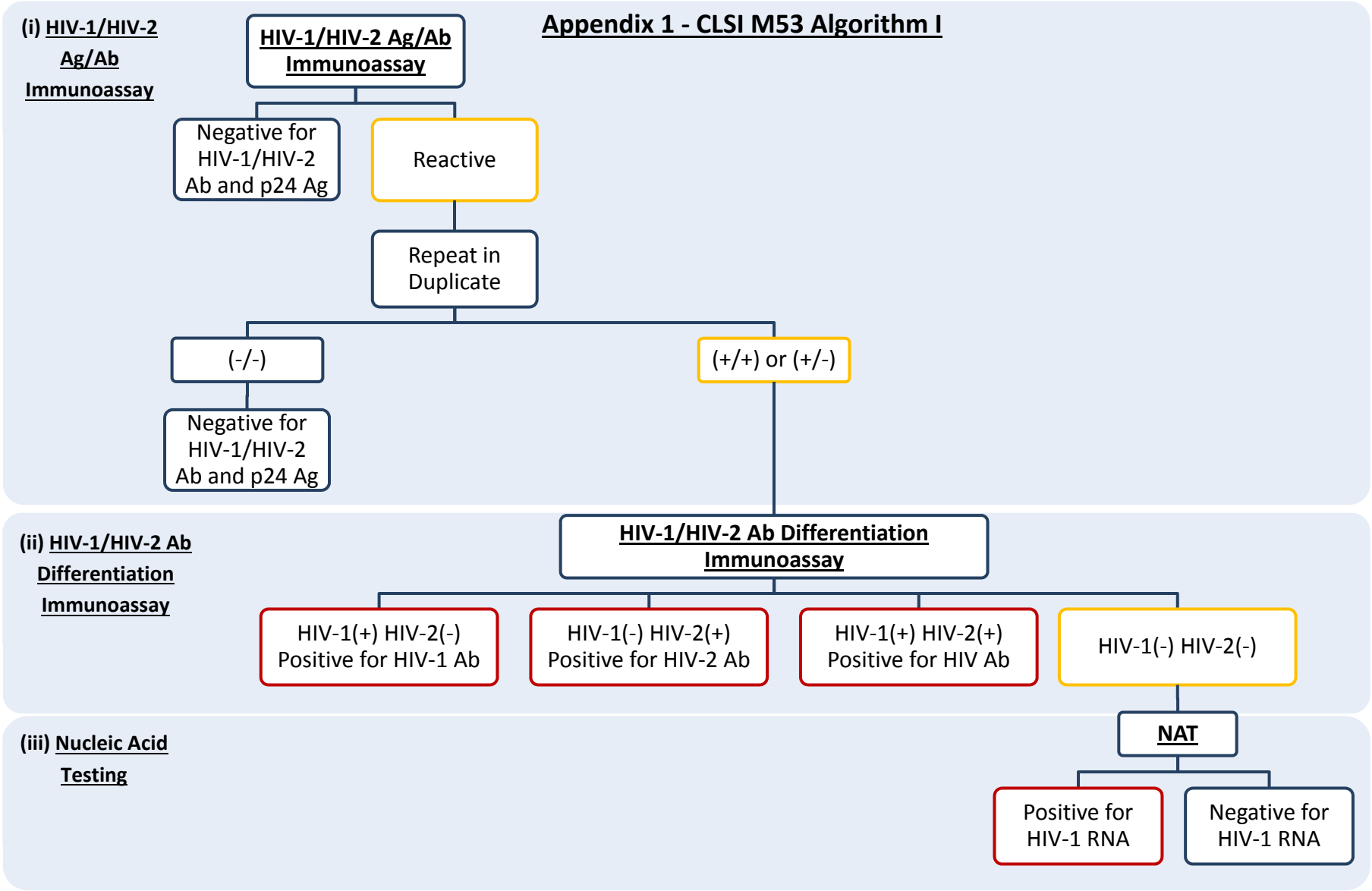
Appendix 1 - CLSI M53 Algorithm I



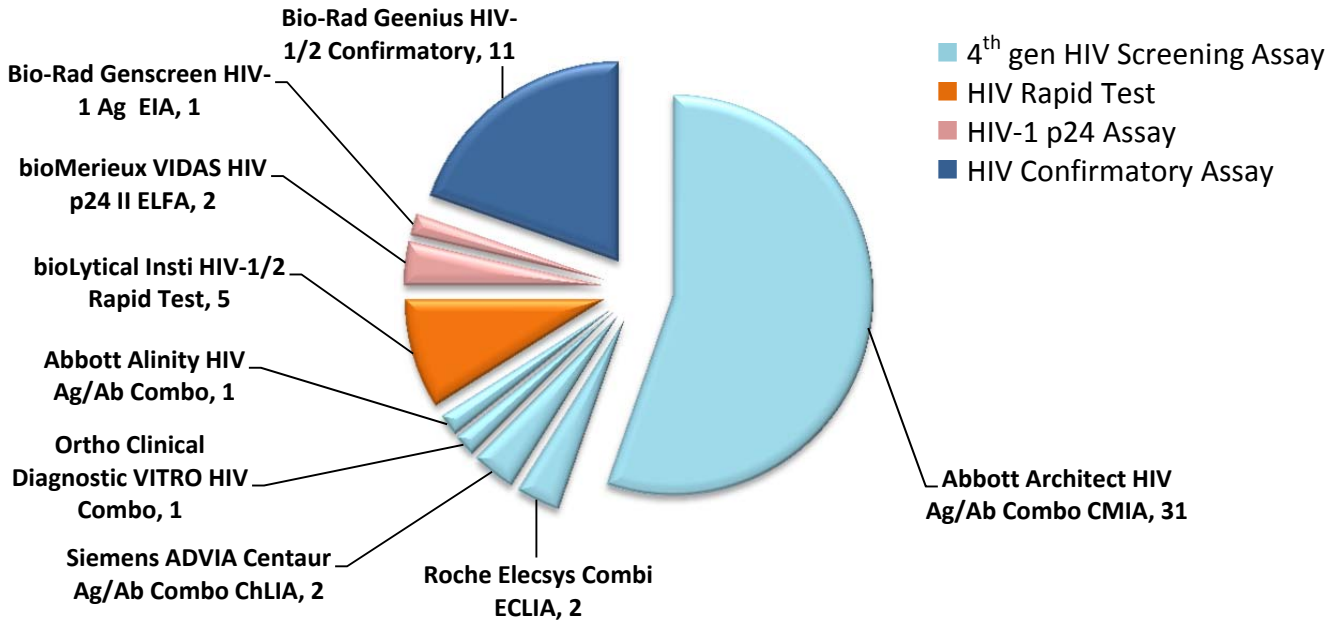
Appendix 1: Adaptation of the Clinical and Laboratory Standards Institute (CLSI) M53-*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline* Algorithm I.

Appendix 2: Characterization

Summary of NLHRS Characterization of the 2019Oct31 HIV Panel Samples

Sample		C/E (Duplicate)	A	B	D
		Negative	**HIV-1 Ag Positive**	**HIV-2 Ab Positive**	**HIV-1 Ab Positive**
Final HIV 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	97% Neutralization	Not Tested	Not Tested
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: Summary of assays used by the participants in the 2019Oct31 HIV serology panel



Appendix 4: Summary of bands detected in Sample A, B and D by the Bio-Rad Geenius HIV-1/2 confirmatory assay in the 2019Oct31 event.

Bio-Rad Geenius	Frequency of Bands Detected						
Sample	gp36	gp140	p31	gp160	p24	gp41	CTRL
2019Oct31A	-	-	-	-	-	-	12
2019Oct31B	12	12	12	-	-	-	12
2019Oct31D	-	6	11	12	12	12	12

Appendix 5: 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.