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 2016Oct28

2016Oct28 HIV Serology Panel			
Panel Sample	**True Status**	**Labs Reporting Incorrect Status**	
A	HIV-1/2 Ag/Ab Negative		
B	HIV-1 Ab Positive	**Incorrect Final Status**	• HV15
C	HIV-1 Ag Positive	**Incorrect Final Status**	• HV13 • HV15 • HV74
D	HIV-1/2 Ag/Ab Negative		
E	HIV-1 Ab Positive	**Incorrect Final Status**	• HV15

Incorrect interpretations based on their assay result(s):

- **HV13**

Did not detect the HIV-1 Ag (Sample C) and did not refer the sample to provincial laboratory/reference laboratory for further testing

- **HV15**

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

Incorrect final status: HIV-1 Ab (Sample B, E) status were confirmed using an HIV-1 Ab only western blot but provided a final status of HIV-1/2 Ab Positive

- **HV74**

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

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Final Report for Panel HIVSER 2016Oct28

Issued 18-Jan-2017

Introduction

The NLHRS distributed the 2016Oct28 panel and the 2017Apr19 panel on Oct 12th 2016. This final report is publicly available; however the identity of participants is not disclosed. Notably, this is the first HIV serology panel send out since the Bio-Rad Geenius HIV-1/2 Supplemental Assay was approved by Health Canada for diagnostic use.

Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition*
  - 2016Oct28 HIV Serology Panel: Five samples; two HIV negative (A, D), two HIV-1 Ab positive (B, D) and one HIV-1 Ag positive(C). Testing and characterization by the NLHRS prior to shipment are presented in Appendix 2. Panels were sent to 43 participants including the NLHRS Oct 12th, 2016. The deadline for data entry was Oct 28th, 2016.

- *HIV Test Kits* – Eleven 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% (35/42) used 4th generation EIA while 3 participants continue to use 3rd generation assays and 4 labs ran only the rapid test for screening which raise potential issues with the ability of labs to detect acute infections. 5 labs are using the Bio-Rad HIV-1 Western Blot confirmatory assay and 4 labs use the recently Health Canada approved Bio-Rad Geenius HIV-1/2 Supplemental Assay.

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

- Flagging incorrect result/data submitted- This year we will implement a color-coded system to identify and quantify incorrect results (Table 2).

Table 1: Summary of the assays used in the NLHRS 2015Oct22, 2016Apr21 and 2016Oct28 HIV Panels (excludes the NLHRS).				
Type	**Assay**	**# of Users**		
		2015Oct22	**2016Apr21**	**2016Oct28**
Screen – 4th Generation	Abbott ARCHITECT HIV Ag/Ab Combo CMIA	29	31	31
	Abbott AxSYM HIV Ag/Ab Combo MEIA	2	--	1
	Roche Elecsys HIV Combi ECLIA	2	2	2
	Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) ChLIA Assay	2	2	2
Screen – 3rd Generation	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA	2	2	2
	Abbott AxSYM HIV HIV 1/2 gO MEIA	1	--	--
Screen – 3rd Generation- HIV2	Bio-Rad Genetic System HIV-2 EIA	1	1	1
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	1	1	--
	Bio-Rad Genetic System HIV-1 Western Blot	6	8	5
	Fujirebio INNO-LIA HIV-I/II Score	1	0	0
	Bio-Rad Geenius HIV-1/2 Supplemental Assay	0	0	4

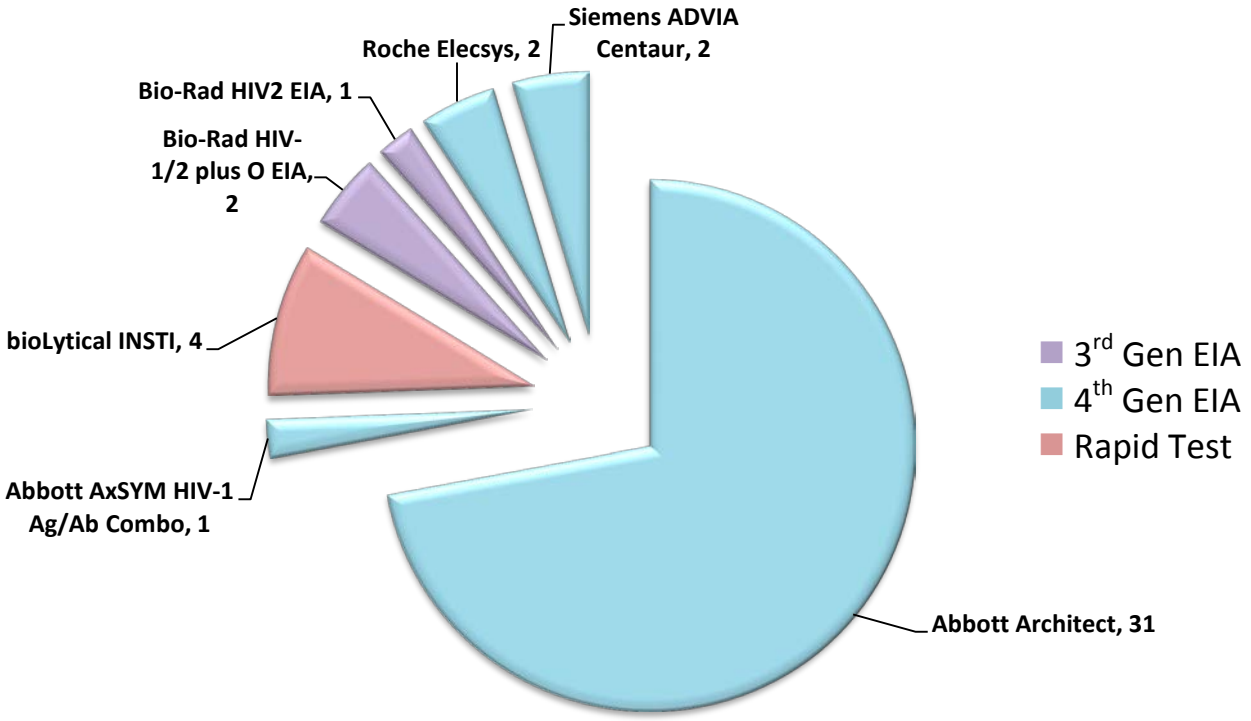

Figure 1: Breakdown of the screening assays used by the 42 participants in the NLHRS 2016Oct28 HIV serology panel (excludes the NLHRS)

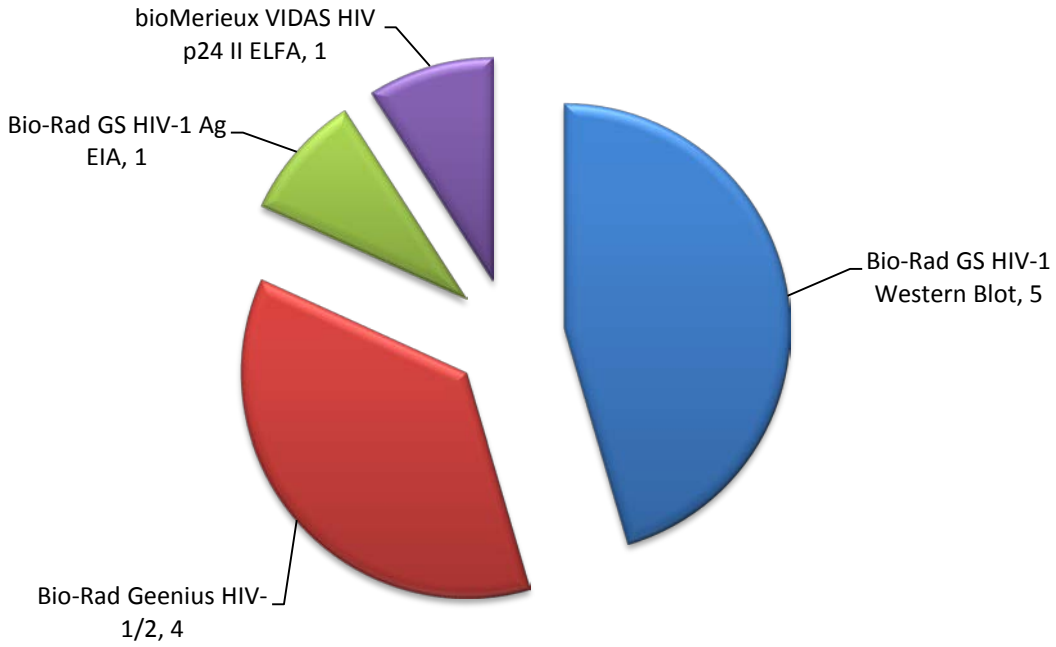

Figure 2: Breakdown of the confirmatory assays use by the participants in the NLHRS 2016Oct28 HIV serology panel (excludes the NLHRS)

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

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

Table 3: 2016Oct28 HIV Serology Panel final status reported from participants using screening assay only.

LAB	SAMPLE A Negative	SAMPLE B HIV-1 Ab Positive	SAMPLE C HIV-1 Ag Positive	SAMPLE D Negative	SAMPLE E HIV-1 Ab Positive
HV03	HIV-1/2 Ag/Ab Negative	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]
HV04	HIV-1/2 Ag/Ab Negative	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]
HV05	HIV-1/2 Ag/Ab Negative	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]
HV07	HIV-1/2 Ag/Ab Negative	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]
HV12	HIV-1/2 Ag/Ab Negative	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]
HV14	HIV-1/2 Ag/Ab Negative	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]
HV17	HIV-1/2 Ag/Ab Negative	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]
HV20	HIV-1/2 Ag/Ab Negative	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]
HV23	HIV-1/2 Ag/Ab Negative	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]
HV24	HIV-1/2 Ag/Ab Negative	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]
HV26	HIV-1/2 Ag/Ab Negative	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]
HV27	HIV-1/2 Ag/Ab Negative	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]
HV28	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]
HV30	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]
HV31	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive[1]
HV43	HIV-1/2 Ag/Ab Negative[1]	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]
HV44	HIV-1/2 Ag/Ab Negative	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]
HV45	HIV-1/2 Ag/Ab Negative	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]
HV48	HIV-1/2 Ag/Ab Negative	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]
HV49	HIV-1/2 Ag/Ab Negative	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]
HV50	HIV-1/2 Ag/Ab Negative	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]
HV53	HIV-1/2 Ag/Ab Negative	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]
HV54	HIV-1/2 Ag/Ab Negative	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]
HV55	HIV-1/2 Ag/Ab Negative	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]
HV56	HIV-1/2 Ag/Ab Negative	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]
HV57	HIV-1/2 Ag/Ab Negative	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]
HV59	HIV-1/2 Ag/Ab Negative	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]
HV63	HIV-1/2 Ag/Ab Negative	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]
HV64	HIV-1/2 Ag/Ab Negative	Did not provide status[1]	Did not provide status[1]	HIV-1/2 Ag/Ab Negative	Did not provide status[1]
HV68	HIV-1/2 Ag/Ab Negative	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]
HV74	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive[1]
HV76	HIV-1/2 Ag/Ab Negative	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]
HV79	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Positive[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 Ab Negative[1]	HIV-1/2 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: 2016Oct28 HIV Serology Panel final status reported from participants (include the NLHRS) using screening and confirmatory assays.

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

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

Results

- *Return rate* - Results were returned from 100% of participants excluding the NLHRS (42/42).
- *Group Analysis(Excluding the NLHRS)*

  2016Oct28 Panel (Table 3 and Table 4)

  - *Sample A (HIV-1/2 Ag/Ab negative)* – All participants provided either a correct serology status and/or recommendation
    - ***HV74:*** Did not provide the S/Co result yet provided final serology status
  - *Sample B (HIV-1 Ab Positive)* – 41/42 participants provided either a correct serology status and/or recommendation
    - ***HV64***: Did not submit final serology status but made a recommendation
    - ***HV74:*** Did not provide the S/Co result yet provided final serology status
    - ***HV15***: Provided HIV-1/2 Ab positive but used HIV-1 WB for confirmation
  - *Sample C (HIV-1 Ag positive)* – 39/42 participants provided either a correct serology status and/or recommendation.
    - ***HV13, HV15, HV74*:** Missed the HIV-1 Ag (ran 3rd gen.) and did not provide recommendation/refer to reference/provincial laboratory for further testing.
    - ***HV22, HV48, HV55, HV64***: Did not provide final serology status but referred sample for further testing
    - ***HV74:*** Did not provide the S/Co result yet provided final serology status

Result *(continued)*

- *Sample D (HIV-1/2 Ag/Ab negative)* – All participants provided either a correct serology status and/or recommendation
    - ***HV74:*** Did not provide the S/Co result yet provided final serology status
- *Sample E (HIV-1 Ab positive)* – 41/42 participants provided either a correct serology status and or recommendation
    - ***HV48, HV55, HV64***: Did not provide final serology status but referred sample for further testing
    - ***HV15***: Provided HIV-1/2 Ab positive but used HIV-1 WB for confirmation for HIV-1 Ab
    - ***HV74:*** Did not provide the S/Co result yet provided final serology status

- *Using Incorrect Final Status Terminology*: ***HV15***
  Labs continue to provide interpretations that are not accurate based on the assays being used.
  This lab reported the final status as HIV-1/2 Ab positive based on the HIV-1 western blot which is incapable of distinguishing HIV-2 antibodies.
- *Failed to entered required result of the assay*: ***HV74***
  This lab reported the final status of each panel samples but failed to provide the S/Co results to support their diagnosis.
- *Inability to detection a potential pre-seroconversion sample:* ***HV13, HV15, HV74***
  Labs continuing to use a 3rd Generation EIA were incapable of detecting the HIV-1 Ag in Sample C which led to misinterpretation and reported as false negative.

Conclusion

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 report of the 2016Apr21 HIV Serology panel and this issue is again highlighted in this panel. There were 3 participants that used a 3rd generation EIA in this panel and 4 participants use the rapid test as their primary screening assay.

All 7 participants were incapable of detecting the HIV-1 Ag in sample C. However, the participants that utilized the rapid test (4 of 7) as their primary screening assay referred sample C to a provincial laboratory/reference laboratory for further testing.

Conclusion *(continued)*

The other 3 participants did not perform further testing on sample C after the initial screening nor did they refer sample C to a provincial laboratory/reference laboratory for further testing which resulted in an incorrect diagnosis. The inability to detect a pre-seroconversion (acute) infection due to the high viral load and increased transmission capacity could potentiate secondary transmission resulting in negative public health implications.

In this panel, we observed several participants have begun to use the recently approved Bio-Rad Geenius HIV-1/2 supplemental Assay. This addressed the issue raised in the last report on the ability of identifying HIV-2 infection and the poor performance of the HIV-1 Western Blot. 4 participants have started to use the Bio-Rad Geenius HIV-1/2 Supplemental Assay while 5 participants still continue to use the Bio-Rad GS HIV-1 Western Blot.

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 and post examination stages.

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

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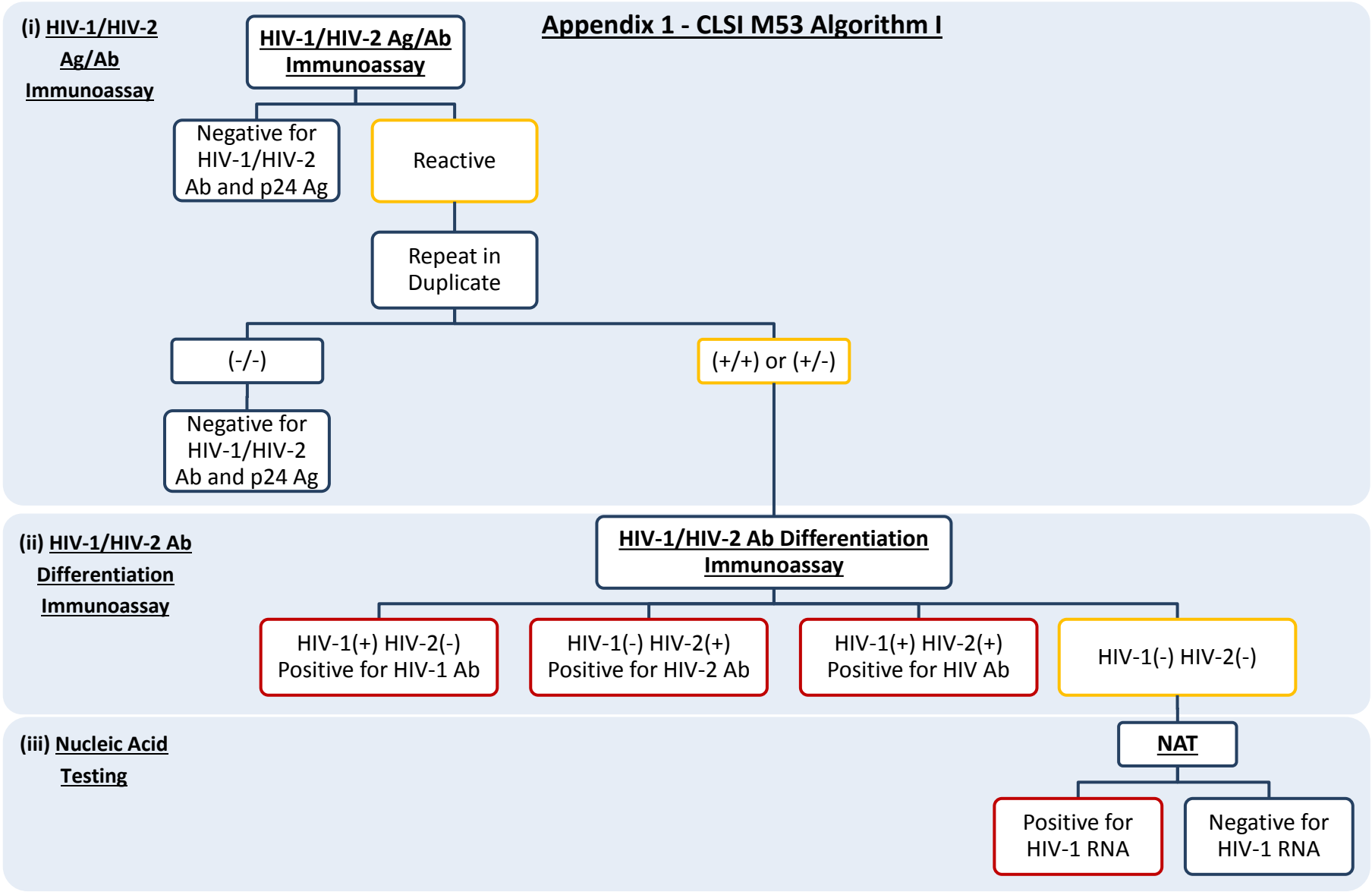

Appendix 1: Adaptation of the Clinical and Laboratory Standards Institute (CLSI) M53-*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline* Algorithm I.

Appendix 2: Characterization

Summary of NLHRS Characterization of the NLHRS 2016Oct28 HIV Panel Samples

Sample		A/D (Duplicate)	B	C	E
		Negative	**HIV-1 Ab positive**	**HIV-1 Ag positive**	**HIV-1 Ab positive**
Final Status		HIV-1/2 Ag/AbNegatve	HIV-1 Ab positive	HIV-1 Ag positive	HIV-1 Ab Positive
bioLytical INSTI HIV-1/2 Rapid Test	**Result**	NR	R	NR	R
Bio-Rad GS HIV-1 p24	**Result**	Neg	Neg	Pos	Neg
Bio-Rad GS HIV-1 Western Blot	**Result**	Neg	HIV-1	Neg	HIV-1
	gp160	-	++	-	++
	gp120	-	++	-	++
	p65	-	++	-	++
	p55	-	++	-	++
	p51	-	++	-	-
	gp41	-	++	-	++
	p40	-	++	-	++
	p31	-	++	-	++
	p24	-	++	-	+
	p18	-	++	-	+/-
Fujirebio INNO-LIA HIV-I/II Score	**Result**	Neg	HIV-1	Neg	HIV-1
	sgp120	-	+++	-	+++
	gp41	-	+++	-	+++
	p31	-	+++	-	+++
	p24	-	+++	-	++
	p17	-	+++	-	+
	sgp105	-	-	-	-
	gp36	-	-	-	-
Bio-Rad Geenius HIV-1/HIV-2 Supplemental Assay	**Result**	Neg	HIV-1	Neg	HIV-1
	gp36	-	-	-	-
	gp140	-	-	-	-
	p31	-	+	-	+
	gp160	-	+	-	+
	p24	-	+	-	+
	gp41	-	+	-	+

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.