



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 2017Apr19

2017Apr19 HIV Serology Panel			
Panel Sample	True Status	Labs Reporting Incorrect Status	
A	HIV-1 Ag Positive	Incorrect Final Status	<ul style="list-style-type: none"> • HV01 • HV15 • HV74
B	HIV-1 Ab Positive	Incorrect Final Status	<ul style="list-style-type: none"> • HV01
C	HIV-1/2 Ag/Ab Negative	Incorrect Final Status	<ul style="list-style-type: none"> • HV20 • HV21 • HV22 • HV63
D	HIV-1 Ab Positive	Incorrect Final Status	<ul style="list-style-type: none"> • HV01
E	HIV-1/2 Ag/Ab Negative	Incorrect Final Status	<ul style="list-style-type: none"> • HV20 • HV21 • HV22 • HV63

Incorrect interpretations based on their assay result(s):

HV01, HV20, HV21, HV22

Did not provide a recommendation for further action for samples reported with an unresolved serology status

HV13

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

HV15, HV74

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

HV63

Incorrect final status: HIV-1/2 Ab positive was reported (Sample C, E) but results submitted are HIV-1/2 Ab negative.



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Final Report for Panel HIVSER 2017Apr19

Issued 2017-06-27

Introduction

The NLHRS distributed the 2016Oct28 panel and the 2017Apr19 panel on Oct 12th 2016. This report is specific to the 2017Apr19 panel only and this final report is publicly available; however the identity of participants is not disclosed.

Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition*
 - 2017Apr19 HIV Serology Panel: Five samples; two HIV negative (C, E), two HIV-1 Ab positive (B, D) and one HIV-1 Ag positive (A). 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 for the 2017Apr19 panel was April 19th, 2017.
- *HIV Test Kits* – Ten different assays were used by the 41 participants excluding the NLHRS who returned results (Table 1, Figure 1 and Figure 2). The majority of participants, 83% (35/41) 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. 3 labs are using the Bio-Rad HIV-1 Western Blot confirmatory assay and 6 labs use the 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.

Table 1: Summary of the assays used in the 2016Apr21, 2016Oct28 and 2017Apr19 HIV Panels (excludes the NLHRS).				
Type	Assay	# of Users		
		2016Apr21	2016Oct28	2017Apr19
Screen – 4 th Generation	Abbott ARCHITECT HIV Ag/Ab Combo CMIA	31	31	30
	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
Screen – 3 rd Generation	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA	2	2	2
	Abbott AxSYM HIV HIV 1/2 gO MEIA	--	--	--
Screen – 3 rd 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	1	2
	Bio-Rad Genscreen HIV-1 Ag EIA	1	1	1
Confirmatory-Ab	Bio-Rad Multispot HIV-1/2 Rapid Test	1	--	--
	Bio-Rad Genetic System HIV-1 Western Blot	8	5	3
	Fujirebio INNO-LIA HIV-I/II Score	0	0	0
	Bio-Rad Geenius HIV-1/2 Supplemental Assay	0	4	6

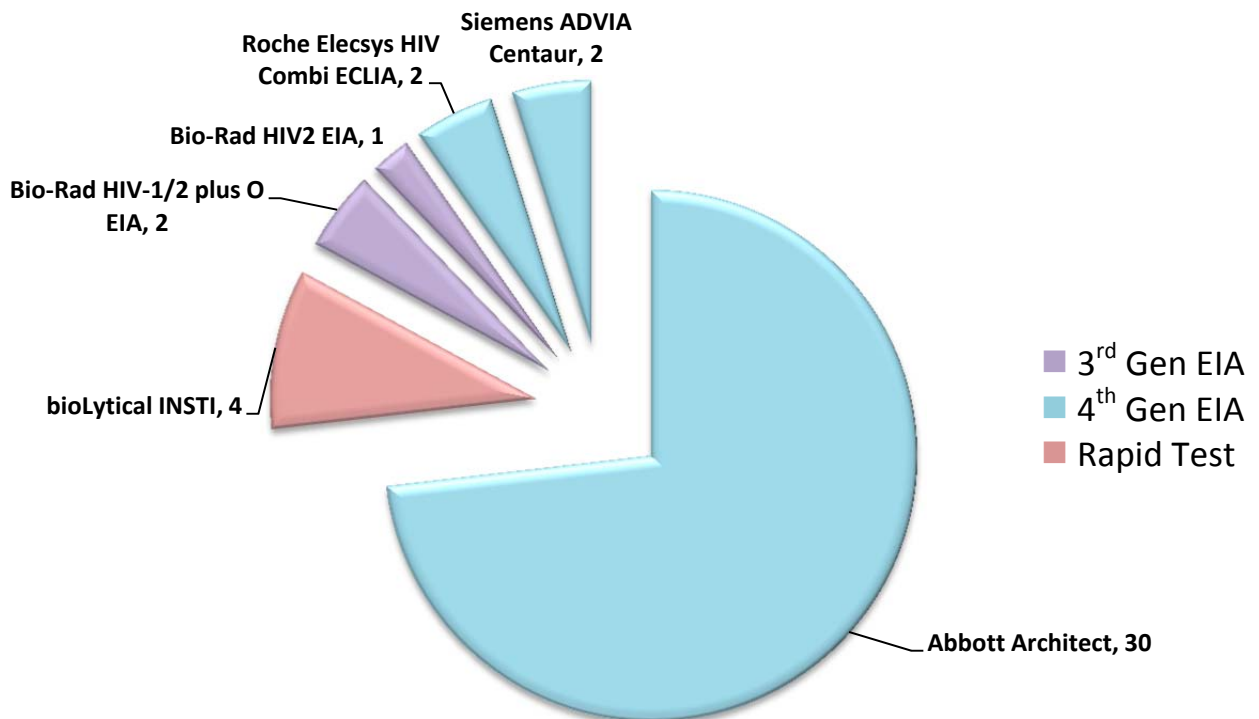


Figure 1: Breakdown of the screening assays used by the 41 participants in the NLHRS 2017Apr19 HIV serology panel (excludes the NLHRS)

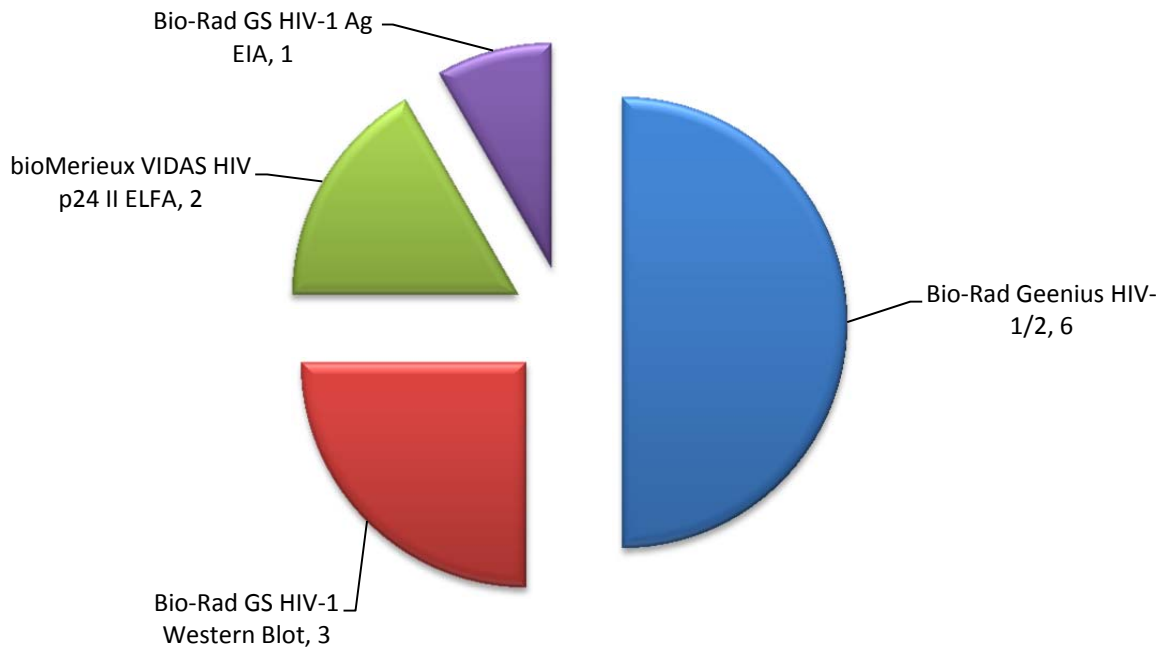


Figure 2: Breakdown of the confirmatory assays use by the participants in the NLHRS 2017Apr19 HIV serology panel (excludes the NLHRS)

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: 2017Apr19 HIV Serology Panel final status reported from participants using screening assay only.

LAB	SAMPLE A HIV-1 Ag Positive	SAMPLE B HIV-1 Ab Positive	SAMPLE C Negative	SAMPLE D HIV-1 Ab Positive	SAMPLE E Negative
HV03	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
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	Would not report based on result ¹	Would not report based on result ¹	HIV-1/2 Ab Negative, HIV-1 Ag Negative	Would not report based on result ¹	HIV-1/2 Ab Negative, HIV-1 Ag Negative
HV14	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
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	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
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 Ag/Ab Negative 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
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	Would not report based on result ¹	HIV-1/2 Ag/Ab Negative
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	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
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 Ag Positive	HIV-1/2 Ag/Ab Positive ¹ HIV-1 Ag Positive	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative	HIV-1/2 Ag/Ab Positive ¹ HIV-1 Ag Positive	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative
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 Ab Positive	Did not provide final status ¹	HIV-1/2 Ab Positive
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
HV74	HIV-1/2 Ab Negative ¹	HIV-1/2 Ab Positive ¹	HIV-1/2 Ab Negative	HIV-1/2 Ab Positive ¹	HIV-1/2 Ab Negative
HV76	HIV-1/2 Ag/Ab Positive ¹ HIV-1 Ag Positive	HIV-1/2 Ag/Ab Positive ¹ HIV-1 Ag Positive	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative	HIV-1/2 Ag/Ab Positive ¹ HIV-1 Ag Positive	HIV-1/2 Ag/Ab Negative, HIV-1 Ag 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".

Legend: Major Intermediate Minor

Table 4: 2017Apr19 HIV Serology Panel final status reported from participants (include the NLHRS) using screening and confirmatory assays.

LAB	SAMPLE A HIV-1 Ag Positive	SAMPLE B HIV-1 Ab positive	SAMPLE C Negative	SAMPLE D HIV-1 Ab Positive	SAMPLE E Negative
HV01	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
HV02	HIV-1 Ab Negative ¹	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative
HV13	HIV-1/2 Ab Negative HIV-1 Ag Positive	HIV-1/2 Ab Positive ¹	HIV-1/2 Ag/Ab Negative HIV-1 Ag Negative	HIV-1/2 Ab Positive ¹	HIV-1/2 Ag/Ab negative HIV-1 Ag Negative
HV15	HIV-1/2 Ab Negative	HIV-1 Ab Positive	HIV-1 Ab Negative	HIV-1 Ab Positive	HIV-1 Ab Negative
HV16	HIV-1/2 Ab Negative, HIV-1 Ag Positive	HIV-1 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	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative
HV19	HIV-1/2 Ab Negative, HIV-1 Ag positive ¹	HIV-1 Ab Positive ¹	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive ¹	HIV-1/2 Ag/Ab Negative
HV20	Did not provide final status ¹	HIV-1 Ab Positive ¹	Not Tested	HIV-1 Ab Positive ¹	Not Tested
HV21	HIV-1/2 Ab Negative ¹	HIV-1 Ab Positive ¹	Not Tested	HIV-1 Ab Positive ¹	Not Tested
HV22	Would not report based on result ¹	HIV-1 Ab Positive	Not Tested	HIV-1 Ab Positive	Not Tested
HV75	HIV-1/2 Ab Negative, HIV-1 Ag Positive	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative	HIV-1 Ab Positive	HIV-1/2 Ag/Ab Negative

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 97.6% of participants excluding the NLHRS (41/42).
 - HV64** did not submit results for the 2017Apr19 panel.

- Group Analysis(Excluding the NLHRS)

2017Apr19 Panel (Table 3 and Table 4)

From this panel and onward, the NLHRS will no longer flag participant who reported without a serology status but made a recommendation for further action by the participants.

- Sample A (HIV-1 Ag Positive) – 38/41 participants provided either a correct serology status and/or recommendation

- HV15 and HV74:** Missed the HIV-1 Ag (ran 3rd gen) and did not provide recommendation/refer to reference/provincial laboratory for further testing.
- HV01:** Did not provide a recommendation/refer to reference/provincial for further testing with an unresolved serology status.
- HV13:** Participant reported HIV-1 Ag status in the result but use a rapid test to that only detects HIV-1/2 Ab.
- HV56 and HV76:** Participants reported HIV-1 p24 status but did not perform HIV-1 p24 Ag confirmatory testing.
- HV16:** Participant did not provide HIV-1 Ab confirmatory result to support the reported final serology status.

Result (continued)

- *Sample B (HIV-1 Ab Positive)* – 41/41 participants provided either a correct serology status and/or recommendation
 - **HV13:** Participant reported HIV-1/2 Ab positive but used HIV-1 WB for confirmation for HIV-1 Ab
 - **HV56 and HV76:** Participants reported HIV-1 p24 status but did not perform HIV-1 p24 Ag confirmatory testing.
 - **HV16:** Participant did not provide HIV-1 Ab confirmatory result to support the reported final serology status.
 - **HV31:** Participant reported HIV-1 Ag status in the result but use a rapid test that only detects HIV-1/2 Ab.
 - **HV01:** Participant performed HIV-1 Ab confirmatory testing but did not report the result from the HIV-1 Ab confirmatory testing. In addition, it did not make a recommendation for further testing or requesting a follow up sample.

- *Sample C (HIV-1/2 Ag/Ab Negative)* – 37/41 participants provided either a correct serology status and/or recommendation.
 - **HV63:** Participant reported “HIV-1/2 Ab Positive” even though the result submitted is HIV-1/2 Ab negative
 - **HV20, HV21, and HV22:** Participants reported “not tested” as final serology status without any recommendation even though it was screened non-reactive on 4th gen.
 - **HV31:** Participant reported HIV-1 Ag status in the result but use a rapid test that only detects HIV-1/2 Ab.
 - **HV12, HV56 and HV76:** Participants reported HIV-1 p24 status but did not perform HIV-1 p24 Ag confirmatory testing.
 - **HV20, HV21, and HV22:** Participants reported “not tested” as final serology status and did not make a recommendation for further testing or requesting a follow up sample

Result (continued)

- *Sample D (HIV-1 Ab positive)* – 40/41 participants provided either a correct serology status and/or recommendation
 - **HV56 and HV76:** Participants reported HIV-1 p24 status but did not perform HIV-1 p24 Ag confirmatory testing.
 - **HV13:** Participant reported HIV-1/2 Ab positive but used HIV-1 WB for confirmation for HIV-1 Ab
 - **HV31:** Participant reported HIV-1 Ag status in the result but use a rapid test that only detects HIV-1/2 Ab.
 - **HV16:** Participant did not provide HIV-1 Ab confirmatory result to support the reported final serology status.
 - **HV01:** Participant performed HIV-1 Ab confirmatory testing but did not report the result from the HIV-1 Ab confirmatory testing. In addition, it did not make a recommendation for further testing or requesting a follow up sample.

- *Sample E (HIV-1/2 Ag/Ab negative)* – 37/41 participants provided either a correct serology status and or recommendation
 - **HV63:** Participant reported “HIV-1/2 Ab Positive” even though the result submitted is HIV-1/2 Ab negative
 - **HV20, HV21, and HV22:** Participants reported “not tested” as final serology status without any recommendation even though it was screened non-reactive on 4th gen.
 - **HV31:** Participant reported HIV-1 Ag status in the result but use a rapid test that only detects HIV-1/2 Ab.
 - **HV56 and HV76:** Participants reported HIV-1 p24 status but did not perform HIV-1 p24 Ag confirmatory testing.

- **Using Incorrect Final Status Terminology: HV01, HV13, HV31, HV56, HV76**

Labs continue to provide interpretations that are not accurate based on the assays being used. HV01 reported the final status for panel member B and D as HIV-1/2 Ag/Ab positive but confirmed it is HIV-1 Ab positive with a HIV-1 Ab confirmatory test. HV13 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. HV31 reported HIV-1 p24 Ag status but used a rapid test that only detects HIV-1/2 Ab. HV56 and HV76 did not perform HIV-1 p24 Ag confirmatory testing but reported a HIV-1 p24 status.

Result (*continued*)

- Entering incorrect Final status: HV63

HV63 reported Sample C and E as HIV-1/2 Ab positive but the results provided are HIV-1/2 Ab negative.

- Failed to enter required result of the assay: HV16

This participant reported the final HIV-1 serology status of HIV-1 Ab on Sample A, B, and D but failed to provide the results to support the status reported

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

Participants continuing to use a 3rd Generation EIA were incapable of detecting the HIV-1 Ag in Sample A which led to misinterpretation and reported as false negative.

- No recommendation for samples with unresolved serology status : HV01, HV20, HV21, HV22

HV01 did not provide a recommendation for panel member A, B, and D with an unresolved status. It was screened reactive on 4th gen but negative on HIV-1 Ab confirmatory testing. HV20, HV21 and HV22 reported sample C and E as “Not Tested” without any recommendation

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. This issue is again highlighted in this panel and the 2016Oct28 panel. There were 3 participants that used a 3rd generation EIA in this panel and 4 participants use only the rapid test as their primary screening assay. The participants that utilized the rapid test (4 of 7) as their primary screening assay referred sample A to a provincial laboratory/reference laboratory for further testing.

Of the 3 participants that used 3rd generation EIA as the primary screening method, only one was capable of detecting the HIV-1 Ag in sample A. Because the participant performed a standalone HIV-1 p24 Ag test on samples that were initially screened non-reactive, they were able to detect the HIV-1 Ag in sample A. The other 2 participants did not perform further testing on sample A after the initial screening nor did they refer sample A to a provincial laboratory/reference laboratory for further testing which resulted in an incorrect diagnosis.

Conclusion (Continued)

It is noted that these 2 participants have failed to detect the HIV-1 Ag in panels. 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. The NLHRS would like to recommend these 2 participants to consider switching to a 4th generation EIA as the primary screening method or supplement their testing with a standalone HIV-1 p24 Ag test as one participant did.

In this panel, the NLHRS observed an increased number of participants using the Bio-Rad Geenius HIV-1/2 supplemental Assay and a decreased number of participants using the Bio-Rad HIV-1 Western Blot. This addressed the issue raised in previous report on the ability of identifying HIV-2 infection and the poor performance of the HIV-1 Western Blot.

The NLHRS noticed that an increased number of post-analytical transcription errors were made by the participants in this panel. This resulted in either incorrect status being reported or sample reported with an unresolved status without recommending for further testing or requesting a follow-up sample. The NLHRS would like to stress the importance of having a second individual to go over the results before reporting to avoid this type of transcriptional errors.

In addition, the NLHRS would like to encourage participants to report the final interpretation as outlined by the kit insert of the assay being used. Several participants have reported final interpretation that deviated from the kit insert; hence, they were flagged in this report. On the other hand, the NLHRS will no longer flag participants who reported without a serology status for a sample as long as further action is recommended by the participant.

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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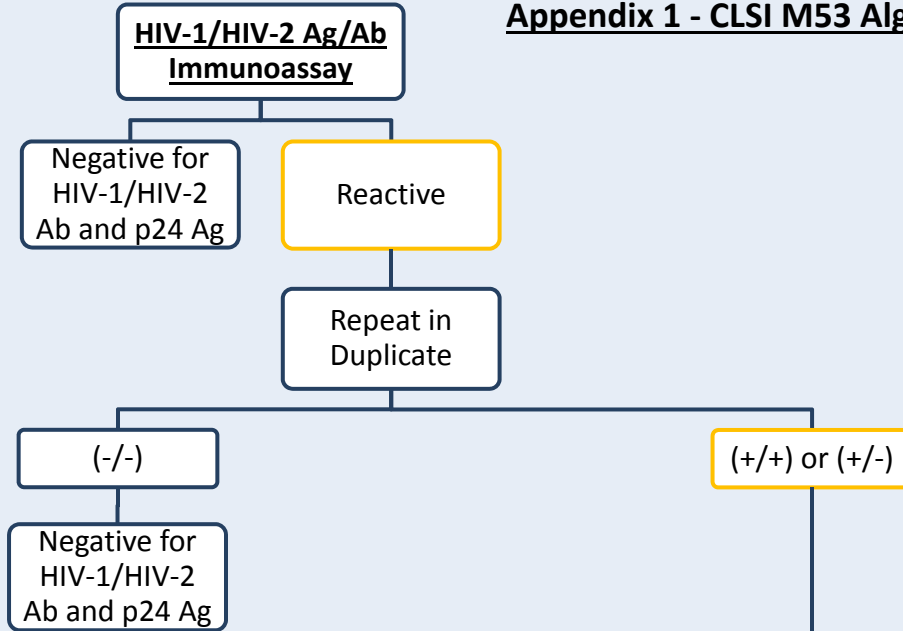


Dr. John E. Kim

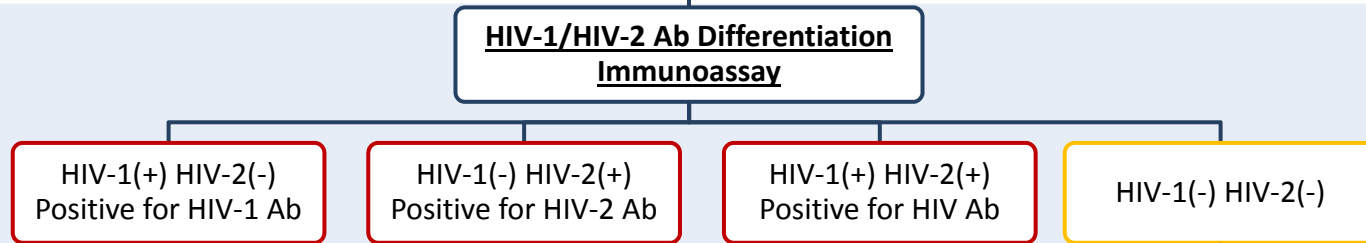
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Appendix 1 - CLSI M53 Algorithm I

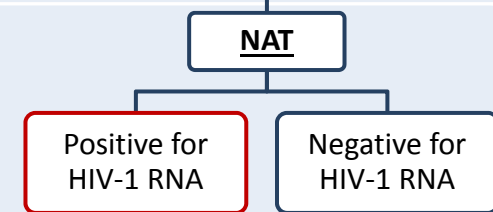
**(i) HIV-1/HIV-2
Ag/Ab
Immunoassay**



**(ii) HIV-1/HIV-2 Ab
Differentiation
Immunoassay**



**(iii) Nucleic Acid
Testing**



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 2017Apr19 HIV Panel Samples

Sample		C/E (Duplicate)	B	A	D
		Negative	HIV-1 Ab positive	HIV-1 Ag positive	HIV-1 Ab positive
Final Status		HIV-1/2 Ag/AbNegative	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)	<u>Sporadic test results identified as outlying and/or aberrant can be classified as random events. Possible causes of random error include:</u>			
	• 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)	<u>A series of test results identified as outlying and/or aberrant may be due to a systematic problem. Systematic problems may be due to:</u>			
	• 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.