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 HIVS425 2015Oct22

| 2015Oct22 Result Summary | | | |
|---|---|---|---|
| **Panel Sample** | **True Status** | **Labs Reporting Incorrect Status** | |
| A | HIV-1 Ab Positive | **Incorrect Final Status** | • HV07 • **HV12** • HV13 • HV15 • HV21 • HV22 • HV24 |
| B | HIV-1 Ab Positive | **Incorrect Final Status** | • HV07 • HV13 • HV21 • HV22 • HV24 |
| C | HIV-1/2 Ab Negative | **Incorrect Final Status** | • **HV12** • HV21 • HV22 • HV59 |
| D | HIV-1 Ab Positive | **Incorrect Final Status** | • HV07 • HV15 • HV21 • HV24 |
| E | HIV-1 Ab Positive | **Incorrect Final Status** | • HV07 • HV13 • HV21 • HV22 • HV24 |

Incorrect interpretations based on their assay result(s):

**HV12**
Incorrect test result and final status for Sample A and C, possible sample switch.

**HV13**
Provided screen test results even though a confirmatory assay was run.

**HV15**
Indeterminate final status and made no recommendation.

**HV21**
Final status indicates a confirmatory assay was run but no results were provided.

**HV22**
Reactive screen and made no recommendation.

**HV07, HV24, HV29**
Incorrect Final Status: Using 4$^{th}$ generation Ab/Ag test, final status missing Ag.

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# HIV Serology Quality Assessment Program
# Final Report for Panel HIVS425 2015Oct22

## Introduction

The NLHRS distributed 2 HIV serology panels in April 2015 with the second panel to be tested after the test event open date of October 6th, 2015.

## Panel Samples, HIV Test Kits and Data Entry

- *Panel Composition* – Panel 2015Oct22 consisted of five samples; one HIV negative sample (C) and one HIV-1 positive sample (A, B, D and E) aliquoted in 10-fold serial dilutions to test sensitivity and specificity (Table 1). NLHRS characterization prior to shipment is presented in Appendix 2.

Table 1: Serial dilution for the HIV-1 positive sample in the 2015Oct22 panel.

| Panel Sample | Sample B | Sample E | Sample A | Sample D |
|---|---|---|---|---|
| Dilution Factor | Neat | $10^{-1}$ | $10^{-2}$ | $10^{-3}$ |

- *Data entry* - The NLHRS HIV Serology Quality Assessment Program used the computerized web based system Oneworld Accuracy to capture and analyze results. After the October 22nd, 2015 deadline for submission of results, a preliminary Laboratory Specific Report (LSR) reflecting the statistical analysis of the data was then issued by Oneworld Accuracy to all participants November 28th, 2015.

Table 2: Summary of the assays used by the 42 participants in the 2015 HIV panels. *(Excludes the NLHRS)*

| Type | Assay | # of Users | |
|---|---|---|---|
| | | 2015Apr23 | 2015Oct22 |
| Screen – 4th Generation | Abbott ARCHITECT HIV Ag/Ab Combo CMIA | 29 | 29 |
| | Abbott AxSYM HIV Ag/Ab Combo MEIA | 3 | 2 |
| | Roche Elecsys HIV Combi ECLIA | 2 | 2 |
| | Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) ChLIA Assay | 2 | 2 |
| Screen – 3rd Generation | Bio-Rad GS HIV-1/HIV-2 PLUS O EIA | 2 | 2 |
| | Siemens ADVIA Centaur HIV1/O/2 Enhanced (EHIV) | 1 | -- |
| | Abbott AxSYM HIV HIV 1/2 gO MEIA | -- | 1 |
| Screen – Rapid | bioLytical INSTI HIV-1/HIV-2 Antibody Test Kit | 4 | 4 |
| Screen – HIV-2 | Bio-Rad Genetic Systems HIV-2 EIA | 1 | 1 |
| Confirmatory – p24 | bioMerieux VIDAS HIV p24 II ELFA | 1 | 2 |
| | Bio-Rad Genscreen HIV-1 Ag EIA | 1 | 1 |
| Confirmatory | Bio-Rad Multispot HIV-1/2 Rapid Test | 1 | 1 |
| | Genetic Systems HIV-1 Western Blot | 7 | 6 |
| | Fujirebio INNO-LIA HIV I/II Score | -- | 1 |

**Panel Samples, HIV Test Kits and Data Entry *(continued)***

- *HIV Test Kits* – Twelve different assays were used by the 42 participants excluding the NLHRS who returned results (Table 2, Figure 1). The majority of participants, 83% (35/42) reported using one screen test only. Of these 35 participants, 83% (29/35) used 4th generation assays. One participant reported using two screen tests and the remaining 6 participants performed confirmatory testing through a combination of tests. Seven participants continue to use 3rd generation assays. This raises potential issues with the ability of labs to detect acute infections.

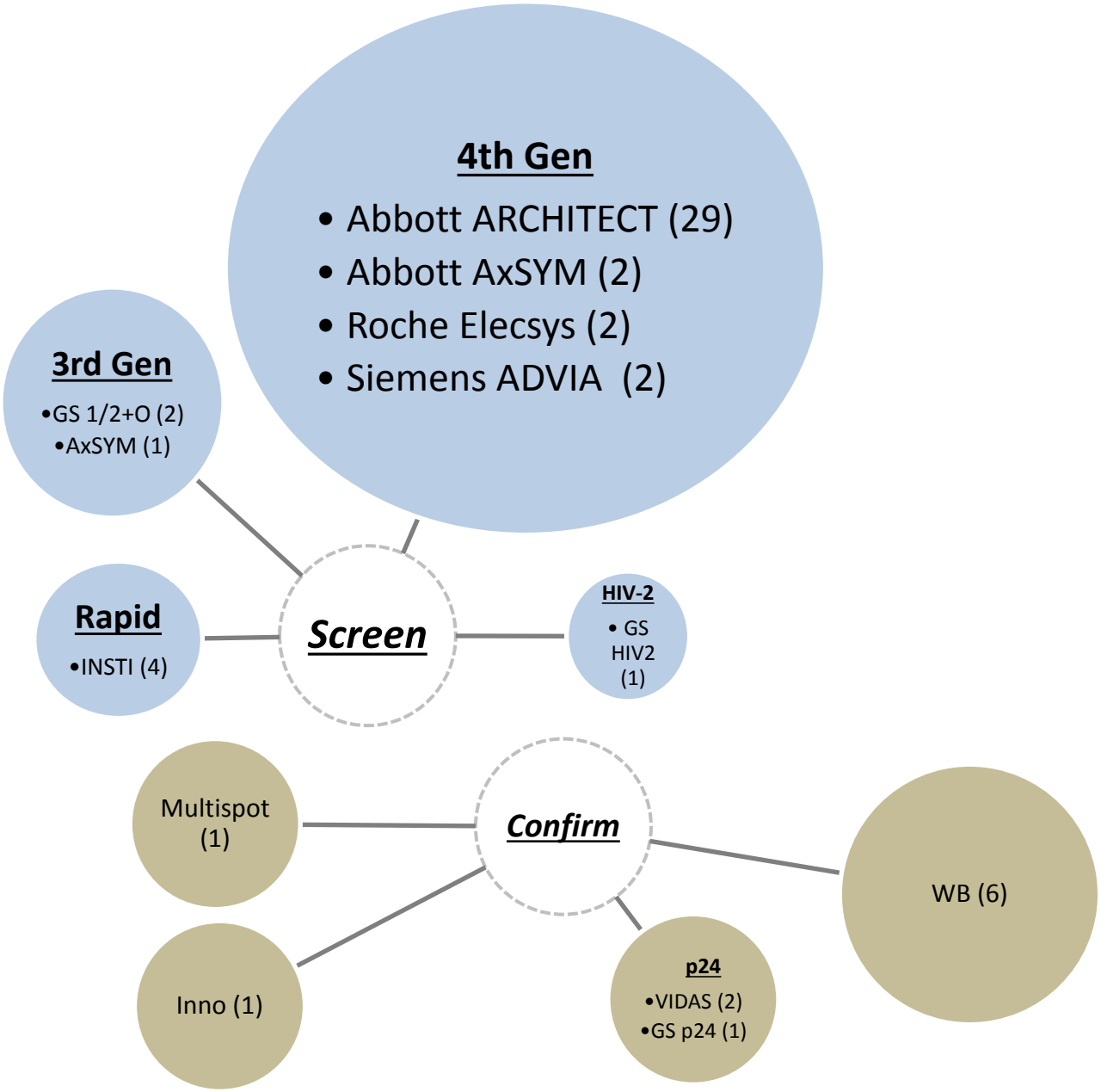


Figure 1: Breakdown of the assays used by the 42 participants in the NLHRS 2015Oct22 HIV Panel *(Excludes the NLHRS)*

**Results**

- *Return rate* - Results were returned from 95% of participants (42/44).
  - Two labs, HV69 and HV78 were unable to provide results prior to the test event closing date.

- *Group Analysis* (Table 4)
  - *Sample A (HIV-1 Ab positive, Dilution $10^{-2}$)*

    40/42 participants provided either a correct serology status and/or recommendation.
    - **HV07, HV24:** Final status for Antibody only instead of Antibody/Antigen.
    - **HV12:** Negative results on the HIV positive sample.
    - **HV13:** Final status based on screen results even though confirmatory testing was done.
    - **HV15:** Indeterminate final status with no recommendations.
    - **HV21:** Provided confirmatory final status without confirmatory test results.
    - **HV22:** Ran screen test only but did not provide any recommendations.
  - *Sample B (HIV-1 Ab positive, Neat)*

    42/42 participants provided either a correct serology status and/or recommendation.
    - **HV07, HV24:** Final status for Antibody only instead of Antibody/Antigen.
    - **HV13:** Final status based on screen results even though confirmatory testing was done.
    - **HV21:** Provided confirmatory final status without confirmatory test results.
    - **HV22:** Ran screen test only but did not provide any recommendations.
  - *Sample C (HIV-1/2 Ab negative)*

    41/42 participants provided either a correct serology status and/or recommendation.
    - **HV12:** Positive results on the HIV negative sample.
    - **HV21:** Provided confirmatory final status without confirmatory test results.
    - **HV24, HV59:** Final status for Antibody only instead of Antibody/Antigen.
  - *Sample D (HIV-1 Ab positive, Dilution $10^{-3}$)*

    41/42 participants provided either a correct serology status and/or recommendation.
    - **HV07, HV24:** Final status for Antibody only instead of Antibody/Antigen.
    - **HV15:** Indeterminate final status with no recommendations.
    - **HV21:** Provided confirmatory final status without confirmatory test results.
    - **HV22:** Ran screen test only but did not provide any recommendations.
  - *Sample E (HIV-1 Ab positive, Dilution $10^{-1}$)*

    42/42 participants provided either a correct serology status and/or recommendation.
    - **HV07, HV24:** Final status for Antibody only instead of Antibody/Antigen.
    - **HV13:** Final status based on screen results even though confirmatory testing was done.
    - **HV21:** Provided confirmatory final status without confirmatory test results.
    - **HV22:** Ran screen test only but did not provide any recommendations.

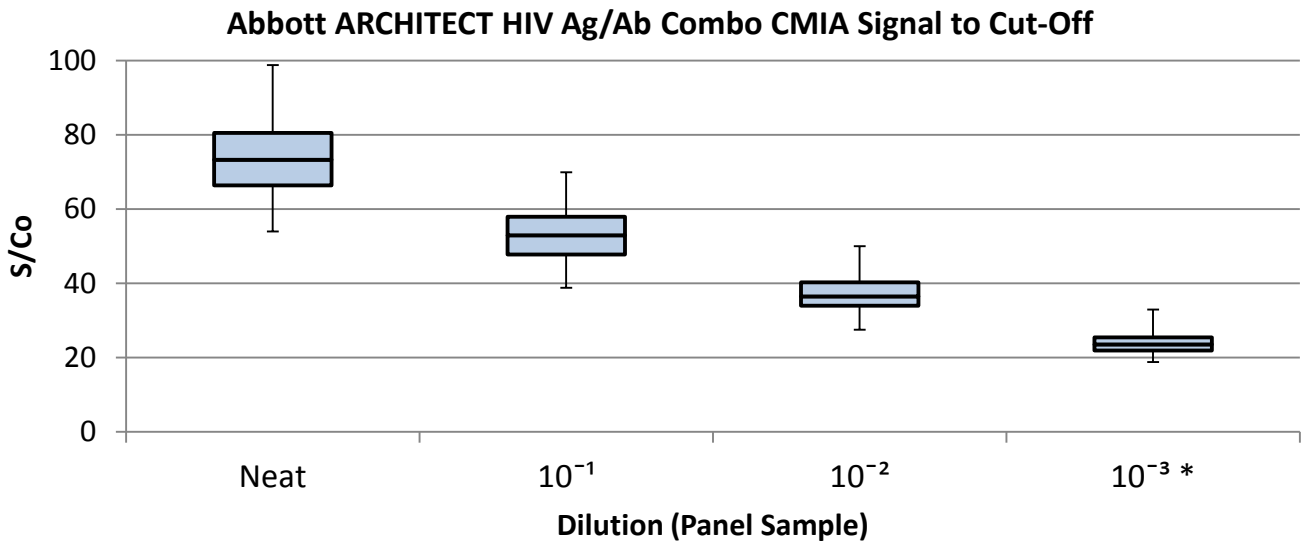


Figure 2: Abbott ARCHITECT HIV Ag/Ab Combo CMIA signal to cut-off results from the NLHRS 2015Oct22 HIV Panel.
** Two outliers (35.82, 36.69) removed (p<0.05).*

Table 3: Confirmatory Test Results from the NLHRS 2015Oct22 HIV Panel.

| Assay | | Neat | $10^{-1}$ | $10^{-2}$ | $10^{-3}$ |
|---|---|---|---|---|---|
| ***Participant Results*** | HIV-1 Western Blot | **Ind** | **Ind** | **Ind** | **Ind** |
| | | **Ind** | **Ind** | **Ind** | **Ind** |
| | | Pos | **Ind** | **Ind** | **Ind** |
| | | Pos | Pos | **Ind** | **Ind** |
| | | Pos | Pos | Pos | **Ind** |
| | | Pos | Pos | Pos | **Ind** |
| | | Pos | Pos | Pos | **Ind** |
| | HIV-1/2 Multispot | HIV-1 | HIV-1 | HIV-1 | HIV-1 |
| | HIV-1/2 INNO-LIA | HIV-1 | HIV-1 | HIV-1 | HIV-1 |
| | | | | | |
| ***NLHRS Result*** | HIV-1/2 Geenius | HIV-1 | HIV-1 | HIV-1 | HIV-1 |
| | HIV-1/2 INNO-LIA | HIV-1 | HIV-1 | HIV-1 | HIV-1 |
| | HIV-1 Western Blot | **Ind** | **Ind** | **Ind** | **Ind** |

**Discussion**

- *Effect of Decreasing Antibody*

  In contrast to the HIV-1 Western Blot, every other supplementary assay, including the recently approved Bio-Rad Geenius, confirmed all the samples as HIV-1 Antibody positive. Of the 7 participants that ran the HIV-1 Western Blot, none of the samples (including the neat) were consistently diagnosed as HIV-1 positive. Only 2 labs ran other confirmatory assays (the Multispot and the Inno-LIA), both of which were able to diagnose all dilutions as HIV-1 positive. All the screening assays were successfully able to detect HIV in the 4 samples despite the decreasing antibodies (Figure 2). The group analysis demonstrates the superior performance of alternative confirmatory assays including the recently Health Canada approved Geenius assay, compared to the HIV-1 Western Blot. The NLHRS has completed and published on the evaluation of this assay (Malloch *et.al.* J Clin Virol. 2013) and it is a welcome replacement to the HIV-1 Western Blot.

**Discussion *(continued)***

- *Sample Mix-up:* **HV12**

  Based on the test results, it would appear that one lab may have mixed up samples A and C.
  - HIV positive sample A was missed by the screen test and reported as HIV negative.
  - HIV negative sample C was a false positive on the screen test and reported as HIV-1/2 positive.

- *Using Incorrect Final Status Terminology:* **HV07, HV24, HV59**

  Labs continue to provide interpretations that are not accurate based on the assays being used.
  - Labs using only a 4th generation screen assay should provide a final status of HIV-1/2 Ag/Ab;

**Conclusion**

The publication of the CLSI M53 HIV testing guideline is anticipated to have a major impact in industrialized countries including Canada. The strength of these guidelines addresses several weaknesses from the original 1989 guidelines, which included the inability to diagnose acute infections, discriminate HIV-2 and the poor performance of the HIV-1 Western Blot. Most Canadian laboratories use the 4th generation EIA screen test, however, the seven labs that continue to use 3rd generation assays as their primary/only screening method could miss a pre-seroconversion sample as demonstrated in a publication and previous panels (Kadivar *et al.* J Clin Virol. 2013 and Panels 2015Apr23, 2014Oct23, 2013Oct24 and 2013Apr25).

While the recently approved Bio-Rad Geenius HIV assay does not address the ability to confirm acute infections, it significantly improved the capacity to confirm 4th generation HIV antibody positive samples and discriminate HIV-2.

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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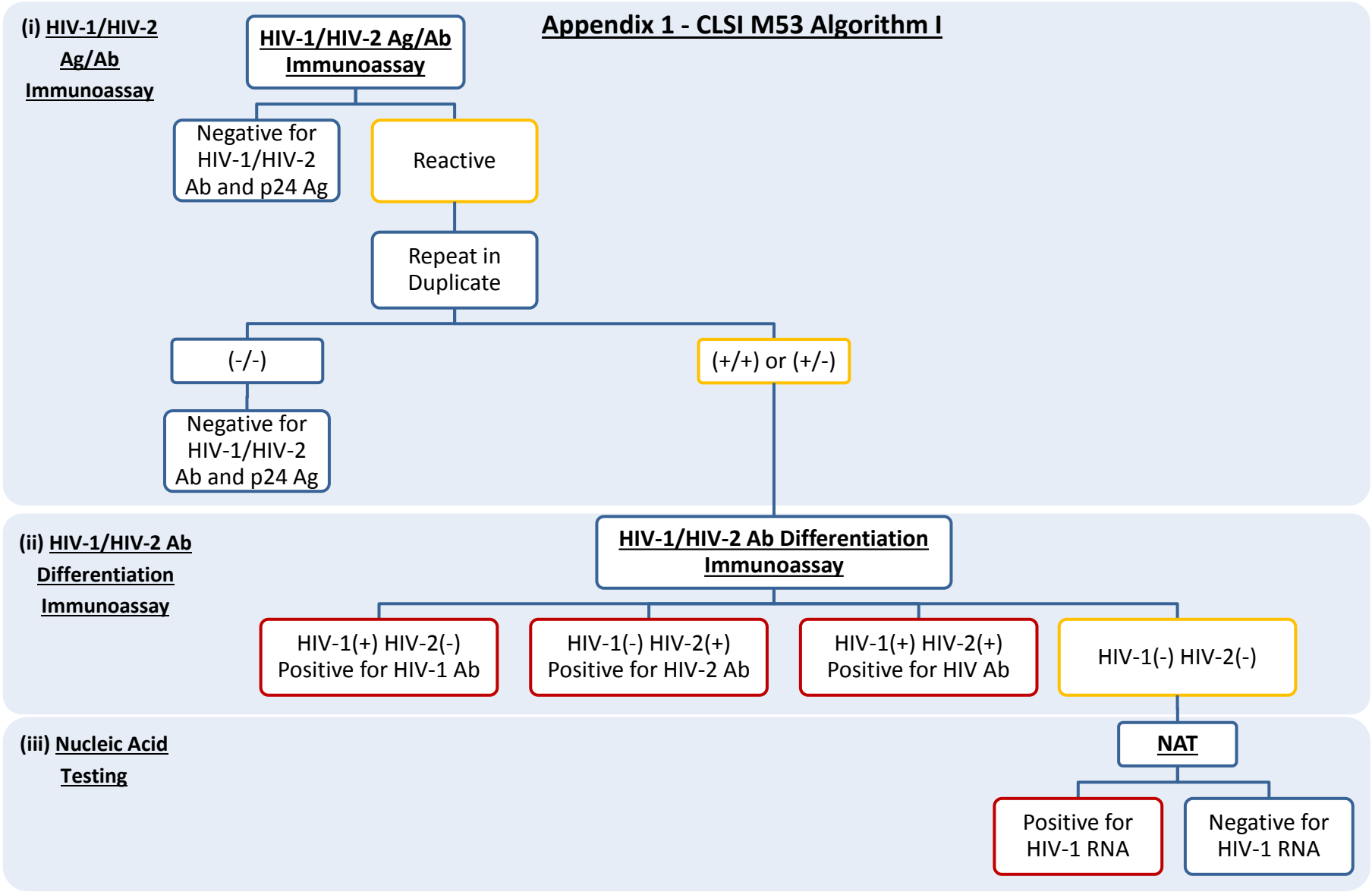
Table 4: 2015Oct22 HIV Panel final status reported from participants.

| LAB | SAMPLE A<br>HIV-1 Positive | SAMPLE B<br>HIV-1 Positive | SAMPLE C<br>Negative | SAMPLE D<br>HIV-1 Positive | SAMPLE E<br>HIV-1 Positive |
|---|---|---|---|---|---|
| HV01 | HIV-1 Ab IND[1] | HIV-1 Ab IND[1] | HIV-1/2 Ag/Ab negative[1] | HIV-1 Ab IND[1] | HIV-1 Ab IND[1] |
| HV02 | 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 positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| HV07 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ag/Ab negative | HIV-1/2 Ab positive[1] | HIV-1/2 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 positive[1] | HIV-1/2 Ag/Ab positive[1] |
| HV13 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative | HIV-1 Ab positive<br>HIV-1 p24 Ag negative[1] | HIV-1/2 Ab positive[1] |
| HV14 | Would not report[1] | Would not report[1] | HIV-1/2 Ag/Ab negative | Would not report[1] | Would not report[1] |
| HV15 | HIV-1 Ab IND | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative | HIV-1 Ab IND | HIV-1 Ab positive |
| HV16 | HIV-1 Ab positive[1] | HIV-1 Ab positive[1] | HIV-1/2 Ag/Ab negative | HIV-1/2 Ab IND[1] | HIV-1 Ab positive[1] |
| 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 positive[1] |
| HV18 | HIV-1/2 Ab/Ag IND[1] | HIV-1 Ab positive[1] | HIV-1/2 Ag/Ab negative | HIV-1/2 Ab/Ag IND[1] | HIV-1/2 Ag/Ab IND[1] |
| HV19 | HIV-1 Ab positive<br>HIV-1 p24 Ag negative | HIV-1 Ab positive<br>HIV-1 p24 Ag positive[1] | HIV-1/2 Ag/Ab negative<br>HIV-1 p24 Ag negative | HIV-1 Ab positive<br>HIV-1 p24 Ag negative | HIV-1 Ab positive<br>HIV-1 p24 Ag positive[1] |
| HV20 | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab negative | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |
| HV21 | HIV-1 Ab positive[1] | HIV-1 Ab positive[1] | HIV-1 Ab negative | HIV-1 Ab IND[1] | HIV-1 Ab IND[1] |
| HV22 | 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 positive |
| 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 positive[1] |
| HV24 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| HV28 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |
| HV30 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |
| HV31 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[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 positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| HV48 | Would not report[1] | Would not report[1] | HIV-1/2 Ag/Ab negative | Would not report[1] | Would not report[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 positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| 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 positive[1] |
| HV55 | 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 positive[1] |
| HV56 | 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 positive[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 positive[1] |
| HV59 | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ab negative | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab positive[1] |
| 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 positive[1] |
| HV64 | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab positive[1] | HIV-1 Ag/Ab negative | HIV-1/2 Ag/Ab positive[1] | HIV-1/2 Ag/Ab positive[1] |
| 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 positive[1] |
| HV74 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |
| 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 positive[1] |
| HV79 | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab negative[1] | HIV-1/2 Ab positive[1] | HIV-1/2 Ab positive[1] |

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




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**

Summary of NLHRS Characterization of the NLHRS 2015Oct22 HIV Panel Samples

| The NLHRS 2015Oct22 HIV Panel Sample Serology Testing Results | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sample** | | | **A** | **B** | **C** | **D** | **E** |
| | | | **$10^{-2}$** | **Neat** | **Negative** | **$10^{-3}$** | **$10^{-1}$** |
| Final Status | | | HIV-1 Ab Positive | HIV-1 Ab Positive | HIV-1/2 Ag/Ab Negative | HIV-1 Ab Positive | HIV-1 Ab Positive |
| NLHRS Testing | **GS HIV-1/2 plus O EIA** | **Result** | **R** | **R** | **NR** | **R** | R |
| | **bioLytical INSTI HIV-1/2 Rapid Test** | **Result** | R | R | NR | R | R |
| | **Bio-Rad GS HIV-1 p24** | **Result** | *N/T* | *N/T* | Neg | *N/T* | *N/T* |
| | **Bio-Rad GS HIV-1 Western Blot** | **Result** | IND | IND | Negative | IND | IND |
| | | gp160 | +/- | + | - | +/- | + |
| | | gp120 | - | - | - | - | - |
| | | p65 | - | - | - | - | - |
| | | p55 | + | ++ | - | +/- | ++ |
| | | p51 | - | - | - | - | - |
| | | gp41 | - | - | - | - | - |
| | | p40 | + | ++ | - | + | ++ |
| | | p31 | - | - | - | - | - |
| | | p24 | ++ | ++ | - | ++ | ++ |
| | | p18 | - | - | - | - | - |
| | **Fujirebio INNO-LIA HIV-I/II Score** | **Result** | HIV-1 | HIV-1 | Negative | HIV-1 | HIV-1 |
| | | sgp120 | - | - | - | - | - |
| | | gp41 | + | + | - | + | + |
| | | p31 | - | - | - | - | - |
| | | p24 | +++ | +++ | - | +++ | +++ |
| | | p17 | + | + | - | + | + |
| | | sgp105 | - | - | - | - | - |
| | | gp36 | - | - | - | - | - |
| | **Bio-Rad Geenius HIV-1/HIV-2 Supplemental Assay** | **Result** | HIV-1 | HIV-1 | *N/T* | HIV-1 | HIV-1 |
| | | gp36 | - | - | *N/T* | - | - |
| | | gp140 | - | - | | - | - |
| | | p31 | - | - | | - | - |
| | | gp160 | + | + | | + | + |
| | | p24 | - | + | | - | + |
| | | gp41 | + | + | | + | + |

*N/T: Not tested*

**Appendix 3**

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

| Type of Error | Possible Cause(s) | Pre-Examination Stage | Examination Stage | Post-Examination Stage |
|---|---|---|---|---|
| Sample mix-up | Two or more samples may have been interchanged, resulting in both outlying and aberrant results. Sample mix-up may occur during specimen reception or during testing. | √ | √ | |
| Transcription | Common causes of transcription errors include: | | | |
| | • Ordering of incorrect test by physician; | √ | | |
| | • Shipment of sample to incorrect laboratory; | √ | | |
| | • Selecting the wrong assay at laboratory; | √ | | |
| | • Interchanging the 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 log10 IU/mL); | | | √ |
| | • Using a comma instead of a dot to denote a decimal point; | | | √ |
| | • Selecting the incorrect assay interpretation. | | | √ |
| | • Failure to recommend follow-up testing where necessary. | | | √ |
| | It is recommended all results that are manually transcribed or entered (including Oneworld Accuracy) be checked by a second individual in order to avoid transcription errors. | | | |
| Outlying and/or aberrant test results due to random error. | Sporadic test results identified as outlying and/or aberrant can be classified as random events. Possible causes of random outlying and/or aberrant results include: | | | |
| | • Insufficient mixing of sample, especially following freezing; | | √ | |
| | • Poor pipetting; | | √ | |
| | • Ineffective or inconsistent washing; | | √ | |
| | • Transcription errors; | √ | | √ |
| | • Sample mix-up; | √ | √ | |
| | • Cross-contamination or carryover; | √ | √ | |
| | • Presence of inhibitors to PCR | | √ | |
| Outlying and/or aberrant test results due to 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.