



HIV Validation Panel Summary

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MTN Virology Core

Regional Meeting Lab Breakout

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Outline

- Purpose
- Panel Composition
- Panel Issues and Resolutions
- Geenius Issues
- Lessons Learned Discussion

Purpose

- To validate new HIV diagnostic tests for use by sites in MTN protocols

Panel Composition

- Panel Type
 - Pre-Qualification Panel (16 samples)
 - Main Validation Panel (80 samples)
- Unique panel for each of 14 sites + extras at Virology Core for future sites created using commercially available and leftover samples from MTN studies
- **1508** tests run for panel creation, internal QC and testing

Validation Panel Site Results

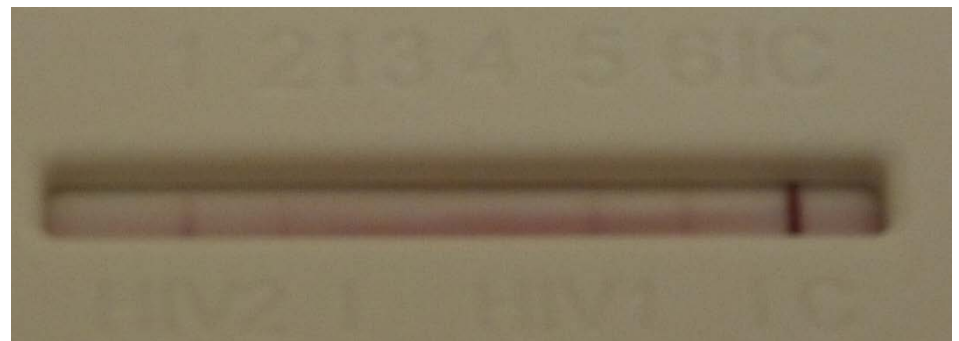
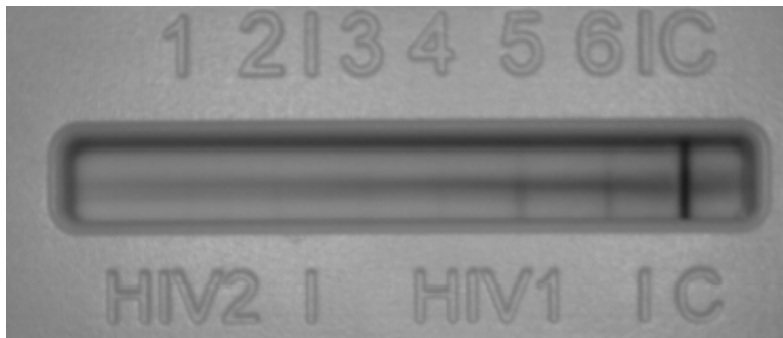
| Category | # Sites | |
|-----------------------------------|----------|---------|
| | PRE-QUAL | MAIN |
| No issues | 6 (40%) | 6 (40%) |
| Additional Testing Needed | 3 (20%) | 6 (40%) |
| Corrected Documentation Requested | 5 (33%) | 3 (33%) |
| Procedural errors discovered | 1 (7%) | 1 (7%) |

Panel Issues and Resolutions

| Issue | # of Occurrences | Resolution |
|-----------------------------------|------------------|-------------------------------------------------------------------------------------------------------------|
| Incorrect Documentation Practices | 8 | Ranged from re-submission of corrected document to assignment of online GCLP documentation training course. |
| Reporting an Invalid Result | 1 | Re-test samples assigned. |
| Reporting an Indeterminate Result | 12 | Re-test samples assigned. |
| Reporting an Incorrect Result | 2 | Investigation by LC and re-test samples assigned. |
| Procedural Issues | 1 | After discussion and identification of the problem, re-test samples were assigned. |

Genenius Horizontal Banding

- Red horizontal banding at cassette reading
 - Ensure procedure is being followed exactly – note that second incubation time may need to be closer to 30 minutes instead of 20.
 - Ensure buffer volumes are accurate.



Bio-Rad is aware of this problem and has suggested that for some lots, letting the second incubation run closer to 30 minutes rather than 20 and the band may dissipate.

Geenius HIV-2 Indeterminates

- 10 HIV-2 indeterminate results were obtained on HIV Negative samples in these panels.
- Package insert: 1.7%
- Validation Panel: 1.6%

| HIV-2 Indeterminate Results-Main Validation Panel (for HIV Negative samples) | | |
|------------------------------------------------------------------------------|--------------------------|---------------------|
| Sample ID | # of times Indeterminate | # of times Negative |
| Master-02 | 1 | 13 |
| Master-30 | 1 | 7 |
| Master-48* | 4 | 3 |
| Master-58 | 2 | 4 |
| Master-84 | 1 | 6 |
| Master-91 | 1 | 6 |

*Master 48 was removed from panel.

Lessons Learned

- Describe one challenge you faced from the validation and how you solved it.
- Share with the group.



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