



Geenius™ HIV 1/2 Supplemental Assay

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Geenius HIV-1/2 Supplemental Assay

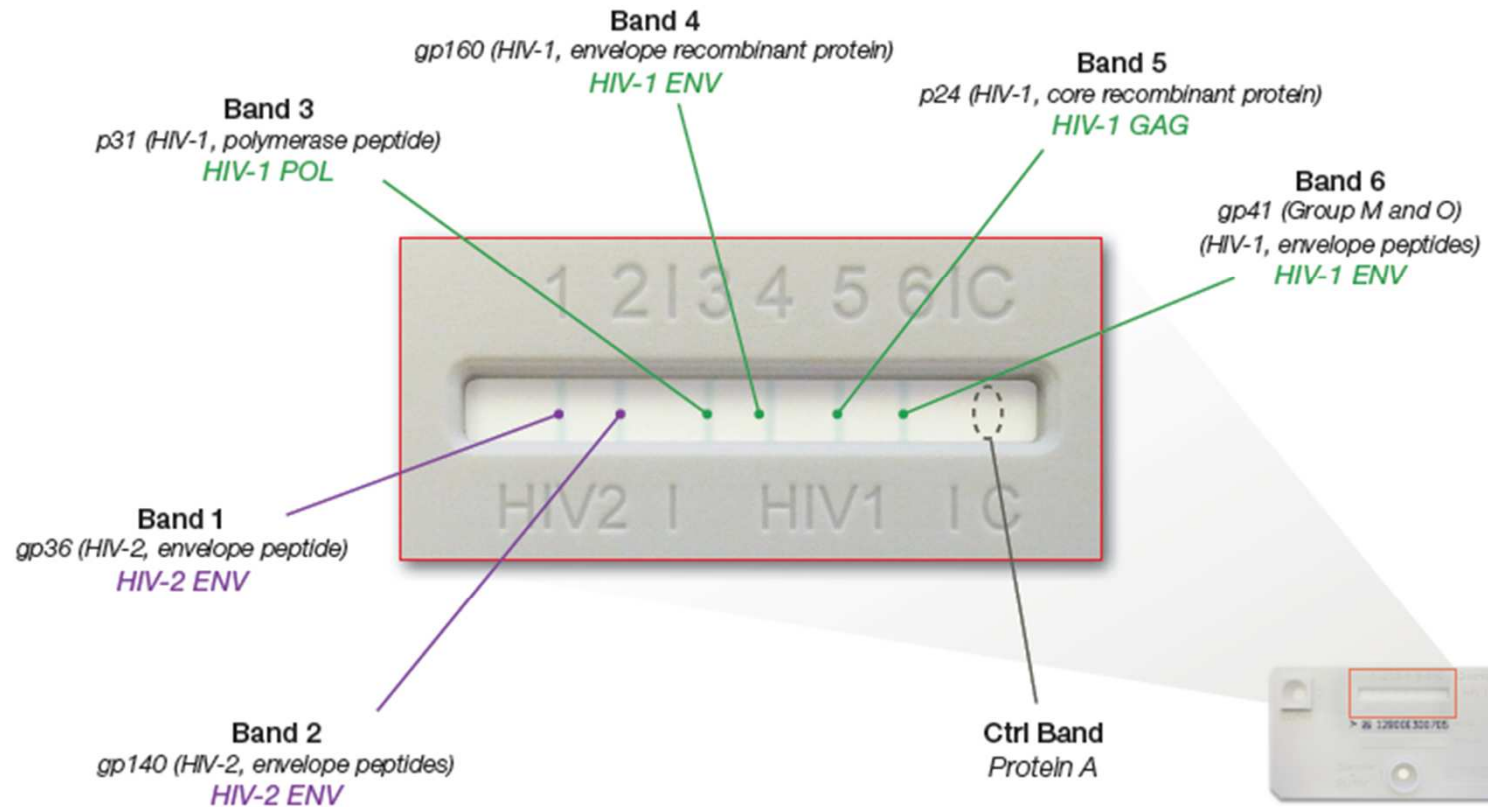


Geenius HIV-1/2 Cassette
Geenius Reader
Computer with Geenius software

The Geenius™ HIV-1/2 Lines




HIV-1 & HIV-2 Associated Lines



The Geenius™ protocol




1 Dispense 15 μ l of whole blood or 5 μ l of serum/plasma to the center of the Well 1




Whole Blood 15 μ l **OR** Serum/Plasma 5 μ l


2 Buffer Add 2 Drops into Well 1




Wait 5-7 minutes
All the blue colored test lines should have disappeared from the **Test** and **Control** window




3 Buffer Add 5 Drops into Well 2



Wait 15 to 20 minutes



4 Read, Interpret and Report Results
Do not read results later than 30 minutes after the addition of the buffer to Well 2



Reader Software Device

Geenius HIV-1/2 Interpretation Criteria



HIV-1 Positive = Any two of the four HIV-1 lines with at least one HIV-1 envelope (gp160 and/or gp41) line present

HIV-1 Indeterminate = Any HIV-1 line(s) that does not meet the requirements of HIV-1 positive

HIV-2 Positive = Both HIV-2 envelope lines (gp36 and gp140) present

HIV-2 Indeterminate = Only one HIV-2 envelope line (gp36 or gp140) present

HIV Negative = No test lines present

Valid assays = (HIV positive, HIV indeterminate and HIV negative) must have a control line present

Geenius HIV-1 and HIV-2 Result Categories



- HIV-1 Positive
- HIV-1 Indeterminate
- HIV-2 Positive
- HIV-2 Positive with HIV-1 cross reactivity
- HIV-2 Indeterminate
- HIV Indeterminate
- HIV Negative
- HIV Positive Untypable

The Geenius Software



- ✓ No visual reading
- ✓ USB reader connection to Laptop computer containing Geenius Software
- ✓ Automated Reader calibration
- ✓ Automated reading and interpretation using proprietary algorithm
- ✓ Full traceability of sample ID and test ID
- ✓ Archiving of test results including a picture of each cassette
- ✓ LIS Connectivity

Geenius HIV-1/2 Sensitivity (1)



- A total of 140 HIV-1 (Group M and O) known positive samples were tested on Geenius
 - ✓ 100% (95% CI, 97.2-100%) were found to be HIV-1 positive

- A total of 232 HIV-2 known positive samples from Africa, U.S. and Europe were tested on Geenius
 - ✓ 100% (95% CI, 98.4-100%) were found to be HIV-2 positive
 - ✓ 95% were classified as HIV-2 positive with HIV-1 crossreactivity
 - ✓ 5% demonstrated HIV-1 cross reactivity and were classified as HIV Untypable

- A total of 4 samples from patients infected with both HIV-1 and HIV-2 viruses were correctly classified as HIV-1 positive and HIV-2 positive (HIV Untypable)

Geenius HIV-1/2 Sensitivity (2)



- A total of 154 samples from 32 commercial HIV-1 seroconversion panels were tested on Geenius and the FDA licensed Bio-Rad HIV-1 Western blot assay
- Geenius testing demonstrated greater sensitivity on 13 of the 32 (or 41%) seroconversion panels tested when compared to the Western blot assay

	GS HIV-1 Western Blot	Geenius HIV 1/2 Supplemental Assay
Negative	63	73
Indeterminate	42	16
HIV-1 Positive	49	65
Total	154	154

Geenius Specificity Testing



- A total of 530 negative serum samples from blood bank and hospitals were tested with Geenius cassettes

530/530 or 100% specificity (95% CI 99.2-100%)

(No false positive)

3.5 % were indeterminate for blood bank samples and 2% for patients samples

- Typically 15-25% of negative samples are HIV-1 Western blot indeterminate

Summary and Conclusion



Geenius™ HIV-1/2 Supplemental Assay A Complete Solution for HIV Confirmation & Differentiation



- ✓ Test Results in less than 30 minutes
- ✓ Automated reading and interpretation using proprietary algorithms
- ✓ Full traceability of sample ID and patient results
- ✓ 100% HIV-1 Sensitivity
- ✓ 100% HIV-2 Sensitivity with 90% HIV-2 differentiation
- ✓ 100% specificity
- ✓ CE marking pending
- ✓ FDA PMA approval planned
- ✓ CLIA Waiver (POC) approval planned