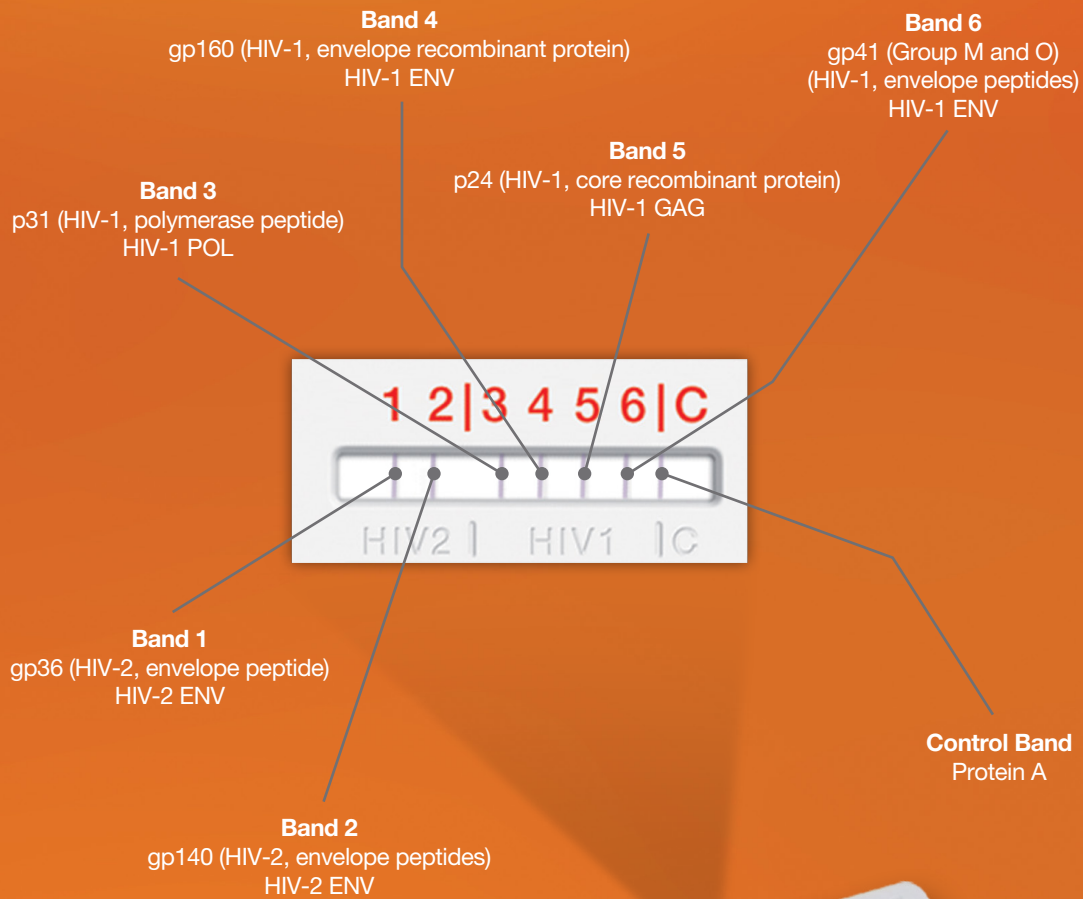


Geenius HIV 1/2 Supplemental Assay

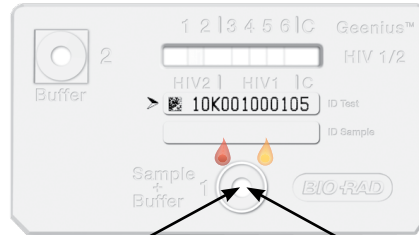


Band Identification with HIV 1/2 Differentiation



Simple, Fast, and Accurate

Dispense 15 μ l of whole blood or 5 μ l of serum/plasma into Well 1



Whole Blood – 15 μ l or Serum/Plasma – 5 μ l

Add 2 drops of buffer into Well 1



Wait 5 to 7 minutes after adding drops



Add 5 drops of buffer into Well 2



Wait 15 to 20 minutes after adding drops



Read, interpret and report results



Genieus Reader

Notebook (validated for Genieus Software)

Automated Interpretation

Proprietary software used for results interpretation.

- Bands read by Geenius Reader
- Band interpretation by validated software

Geenius Software (BIO-RAD)

Run

Sample ID: ATEST001
Cassette ID: 19A001140001
Kit Lot: 9A0011
Test: Geenius HIV 1/2 (2.0-US)

HIV-1	HIV-1 Criteria
HIV-2	HIV-2 Criteria

Control	Last Control
Positive Control	✓ 09/04/2019 12:30:44
Negative Control	✓ 09/04/2019 12:31:28

Preview:

Band Detection

Automated

	Band	Reader detected
1	gp36	<input type="checkbox"/>
2	gp140	<input type="checkbox"/>
3	p31	<input checked="" type="checkbox"/>
4	gp160	<input checked="" type="checkbox"/>

Interpretation

Conclusion HIV-1 POSITIVE (HIV-1 Ab reactive/HIV-2 Ab
Status Validated
 Blocked

Comment:

Operator: JJ Reader: Connected Calibration: OK QC: ● Database size: OK

Traceability

Printable report with detailed results and patient information.

- Unique 2D barcode on each cassette
- Positive identification of controls and patients
- Results report with picture of cassette

Patient Cassette ID and Lot # Details

Geenius HIV 1/2

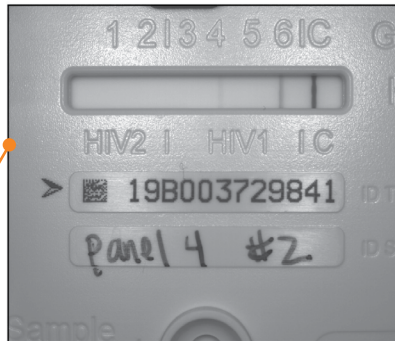
Sample ID: Panel4-2
Cassette ID: 19B003729841
Kit Lot - Exp. Date: 9B0037 - 01/14/2021
Order date: 07/22/2019 08:26:43
Analysis date: 07/22/2019 08:26:44
Test run by: Supervisor -
Test version: 2.0-US
Rule(s): HIV-1 Criteria - HIV-2 Criteria

Reader S/N: DP7K105005
Geenius version: 2.0.203.002
Last Calibration: 07/22/2019 07:49:57

Controls

Lot number: PC18H0023200807
Last run on: 07/22/2019 07:18:29
Lot number: NC18H0023200806
Last run on: 07/22/2019 07:19:14

Image



Interpretation

Interpretation type: Automatic

Band analysis:

#	Name	Result
1	gp36	Absent
2	gp140	Absent
3	p31	Absent
4	gp160	Present
5	p24	Absent
6	gp41	Present
7	CTRL	Present

HIV-1 Result: HIV-1 Ab reactive
HIV-2 Result: HIV-2 Ab nonreactive
Conclusion: HIV-1 POSITIVE (HIV-1 Ab reactive/HIV-2 Ab nonreactive)

Status: Validated **by:** Supervisor -

Cassette Picture

Automated
Conclusion

Band Detection

Intended Use

The Bio-Rad Geenius HIV 1/2 Supplemental Assay is a single-use immunochromatographic assay for the confirmation and differentiation of individual antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2) in fingerstick whole blood, venous whole blood, serum, or plasma samples (EDTA, heparin, and sodium citrate).

The Geenius HIV 1/2 Supplemental Assay is intended for use as an additional, more specific test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by diagnostic screening procedures or by an FDA licensed HIV-1/HIV-2 blood donor screening test.

For diagnostic testing the assay may also be used to confirm the presence of antibodies to HIV-1 and/or HIV-2 in pediatric subjects (i.e. children as young as 2 years of age).

The results of the Geenius HIV 1/2 Supplemental Assay must be read and interpreted only by the Geenius Reader with dedicated software.

Restrictions

- Sale of the Geenius HIV 1/2 Supplemental Assay for diagnostic testing is restricted to clinical testing laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met, and where there is assurance that operators will receive and use the instructional materials.
- The Geenius HIV 1/2 Supplemental Assay is approved for diagnostic testing only by an agent of a clinical testing laboratory.

Ordering Information

Catalog No.	Description
72461	Geenius HIV 1/2 Supplemental Assay for Diagnostic Testing
72480	Geenius HIV 1/2 Supplemental Assay for Donor Testing
72339	Geenius HIV 1/2 Supplemental Controls for Diagnostic and Donor Testing

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**Bio-Rad
Laboratories, Inc.**

**For further information, please contact the Bio-Rad office nearest you
or visit our website at www.bio-rad.com/diagnostics**

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Diagnostics Group**

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