

Geenius™ HIV 1/2 Supplemental Assay **Quick Reference Guide**

For further information, please refer to the Geenius™ HIV 1/2 Supplemental Assay Instructions for Use.

Procedure

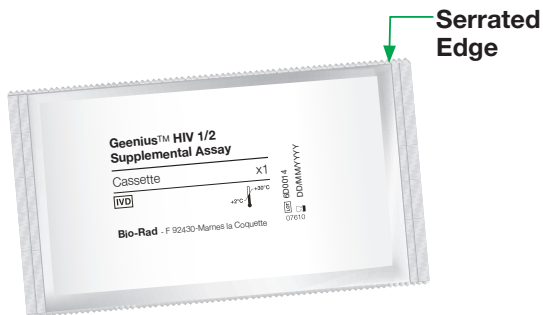
Step 1: Start the Geenius™ Reader



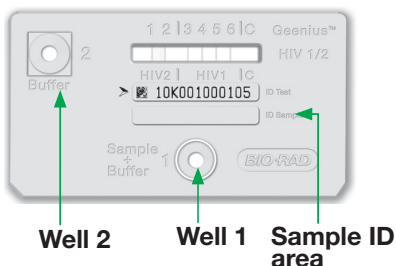
Step 2: Prepare cassette

WARNING: Perform test at room temperature (18° to 30°C, 64° to 86°F).

Hold package tightly and cut or tear open at serration near the edge.



Label cassettes with the Sample ID. Use permanent marker, or barcode labels.



Step 3: Add sample to Well 1

Add the following volume of Serum/Plasma or Whole Blood.

Serum/Plasma	5 uL
Whole Blood	15 uL

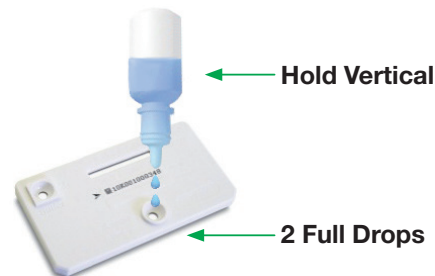
Caution: Do not pick up or tilt the cassette during procedure. Keep on flat, level surface.



Step 4: Add buffer to Well 1 (2 drops or 60 µl with a pipettor).

Mix Buffer bottle. When adding drop-wise, invert bottle to vertical and squeeze.

CAUTION: Ensure **2 full, free-falling drops** are added. Do not touch tip of dropper bottle to cassette well or membrane.



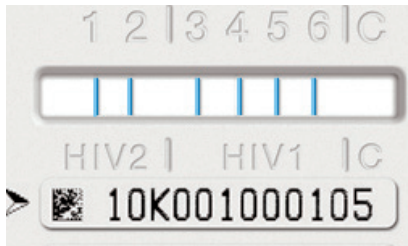
Step 5: Wait 5 – 7 minutes



Continue to Step 6...

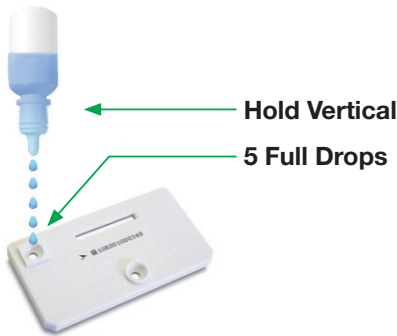
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Step 6: WARNING: If blue lines remain after 7 minutes, discard the cassette.



Step 7: Add Buffer to Well 2 (5 drops or 150 µl with a pipettor).

Caution: Ensure **5 full, free-falling drops** are added. Do not touch tip of dropper bottle to cassette well or membrane.



Step 8: Wait 15 – 20 minutes



WARNING: If any smudges or streaks are present at 20 minutes, wait an additional **10 minutes**.

Do not read results after **30 minutes**.
Do not read a Geenius™ cassette with the presence of any background color.
Test results must be read with the Geenius™ Reader.

Reporting Results

Step 9: Read Processed Cassette:

Click the **Run** button to open the Run window in the Geenius™ Software.




Insert processed cassette into the Geenius™ Reader.

The system detects the cassette.


Step 10: Sample IDs:

The Geenius™ Reader reads Sample ID barcode, or requests Sample ID, which should be typed into the **Sample ID** field.

Click the  **Run/OK** button. The corresponding test order appears in the worklist.

Step 11: Read Final Result:

Results appear in the right side of the window.

Click the  button to save the result and initiate reading of another cassette. The test is complete. Remove the cassette from the reader.

QC

- At each new shipment or lot
- If storage area falls outside 2° – 30°C
- If testing area falls outside 18° – 30°C
- At intervals established by your laboratory

When a new kit lot is introduced to the Geenius™ Reader, the software will automatically require that the corresponding controls be tested.

The **QC Indicator** in the status bar changes from green to red (blinking) when new controls need to be run.

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