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HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 and 2

(Recombinant and Synthetic Peptides)

Geenius™ HIV 1/2 Supplemental Assay

Immunochromatographic Assay for the Confirmation and Differentiation of Individual Antibodies to Human Immunodeficiency Virus Types 1 (Groups M and O) and/or 2 (HIV-1 and/or HIV-2) in Serum or Plasma Specimens from Blood Donors

For In Vitro Diagnostic Use **72480 ● 20 Tests**

This IFU is effective beginning with Geenius™ Reader Software V2.0 and APF (Assay Protocol File) V2.0

LEXICON

	Catalog Number
	Lot Number
	Manufactured by
	Number of Tests
	Use by (YYYY-MM-DD)
	For In Vitro Diagnostic Use
	Temperature Limit
	Danger

CONTENTS

1 – INTENDED USE

The 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 serum or plasma samples (EDTA, lithium heparin, sodium citrate, and CPD) from blood donors.

The Geenius™ HIV 1/2 Supplemental Assay is intended for use as an additional, more specific test for human serum and plasma samples with repeatedly reactive results by an FDA licensed blood donor screening test for antibodies to HIV-1/HIV-2. The results of the Geenius™ HIV 1/2 Supplemental Assay are read and interpreted only with the Geenius™ Reader with dedicated software.

2 – SUMMARY AND EXPLANATION OF THE TEST

Acquired immunodeficiency syndrome (AIDS) is caused by viruses transmitted by sexual contact, exposure to blood (including sharing contaminated needles and syringes) or certain blood products, or transmitted from an infected mother to her fetus or child during the perinatal period.[1] Additionally, transmission of these viruses can occur through tissue transplantation.[2] Human Immunodeficiency Virus Type 1 (HIV-1) has been isolated from patients with AIDS and AIDS-related complex (ARC).[3-5] HIV-1 was thought to be the sole causative agent of these syndromes until 1986, when a second type of Human Immunodeficiency Virus (HIV-2) was isolated and also reported to cause AIDS.[6-7] Since the initial discovery, hundreds of cases of HIV-2 infection have been documented worldwide, including cases of AIDS related to HIV-2.[8] In the United States, there have been more than 80 cases of infection with HIV-2 reported, including three potential blood donors.[9-15]

This second immunodeficiency virus is similar to, but distinct from, HIV-1. Both viruses have similar morphology and lymphotropism,[16] and the modes of transmission appear to be identical.[8,17] The HIV-1 and HIV-2 genomes exhibit about 60% homology in conserved genes such as gag and pol, and 39-45% homology in the envelope genes.[18] Serologic studies have also shown that the core proteins of HIV-1 and HIV-2 display frequent cross-reactivity whereas the envelope proteins are more type-specific.[19]

Within the two major HIV types, there is significant variation, as well. By analyzing sequences of representative strains, HIV-1 has been divided into four groups: group M (for major), including at least 9 subtypes, 3 sub-subtypes of A, and 2 sub-subtypes of F (A1, A2, A3, B, C, D, F1, F2, G, H, J, and K); group O (for outlier); group N (for non-M, non-O), and group P.[20-24] Similarly, the HIV-2 strains have been classified into at least five subtypes (A through E).[25] Some HIV-1 variants share ≤50% homology in their envelope genes with the sequences of more common prototype strains.

Despite some degree of immunological cross-reactivity between types and subtypes of HIV, reliable detection of the more divergent strains may only be achieved by incorporating specific sequences into the assay design. In one study, detection of HIV-2 positive samples by licensed HIV-1 antibody kits ranged from 60% to 91%, depending on the test used.[26] Detection of HIV-1 Group O samples by HIV-1 and HIV-1/HIV-2 assays varied from 0% to 100% in studies with U.S.-licensed and European test kits.[27-28]

The Geenius™ HIV 1/2 Supplemental Assay is an immunochromatographic test that incorporates highly conserved recombinant proteins and synthetic peptides representing HIV-1 and HIV-2 proteins. The Geenius™ HIV 1/2 Supplemental Assay is simple and easy to use for the detection and differentiation of individual antibodies to HIV-1 and HIV-2 in serum or plasma.[29]

3 – BIOLOGICAL PRINCIPLES OF THE TEST

The Geenius™ HIV 1/2 Supplemental Assay cassette contains antibody-binding protein A, which is conjugated to colloidal gold dye particles, and HIV-1 and HIV-2 antigens, which are bound to the membrane solid phase. The sample is applied to the Sample + Buffer well. After the sample and buffer have migrated onto the test strip, additional buffer is added to the Buffer well. The buffer causes the specimens and reagents to flow laterally and facilitates the binding of antibodies to the antigens. In a reactive sample, the antibodies are captured by the antigens immobilized in the Test area.

The protein A-colloidal gold binds to the captured antibodies, causing development of pink/purple bands. When there are no HIV antibodies, there are no pink/purple bands in the Test area. The sample continues to migrate through the membrane and a pink/purple band develops in the Control (C) area, which contains Protein A. This

built-in procedural control provides evidence that the test was performed properly and that the sample and reagents have migrated through the cassette.

4 – REAGENTS

Component	Contents	Preparation
Cassette (20)	Cassette with nitrocellulose membrane containing HIV-1 and HIV-2 antigens in Test area, protein A in Control area and protein A-colloidal gold conjugate in Buffer well area.	Ready to Use
Buffer (5 ml)	Diluent (Contains bovine and goat sera, with preservatives: < 0.1% sodium azide, 0.125% gentamicin sulfate and 0.125% streptomycin sulfate.)	Ready to Use

STORAGE

Store kit at 2 to 30°C (36 to 86°F).

5 – WARNINGS FOR USERS

For In Vitro Diagnostic Use

WARNING: FDA has licensed this test for use with serum or plasma specimens only. Use of this licensed test kit with specimens other than those specifically approved for use with this test kit may cause inaccurate test results.

1. The Geenius™ HIV 1/2 Supplemental Kit REF 72480 is intended for use as a supplemental test in blood donor screening procedures. For supplemental testing in diagnostic procedures, use the Geenius™ HIV 1/2 Supplemental Kit REF 72461.
2. These Instructions For Use must be read completely before performing the test. Failure to follow these instructions may give inaccurate test results.
3. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
4. This test should be performed at room temperature (18 to 30°C, 64 to 86°F). If the cassette, samples, controls and/or kit components have been refrigerated, bring to room temperature (18 to 30°C, 64 to 86°F) before use.
5. In the event that the test kit is stored at temperatures outside the temperature range of 2 to 30°C (36 to 86°F), the Geenius™ HIV 1/2 Controls (REF 72339) should be used to ensure the assay is performing properly. (Note that if this occurs, the Geenius™ HIV 1/2 Controls should be included in every test run that is performed using test kit lots that have been stored in that area.)
6. A clean new pipette or pipette tip should be used with each sample. Caution should be used when opening sample near cassette to eliminate possible cross-contamination from aerosol.

6 – PRECAUTIONS FOR USERS

SAFETY PRECAUTIONS

The Buffer Contains 0.125% gentamicin sulfate and 0.125% streptomycin sulfate:

H334:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317:	May cause an allergic skin reaction.
H361:	Suspected of damaging fertility or the unborn child.
P202:	Do not handle until all safety precautions have been read and understood.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P342 + P311:	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P304 + P341:	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P302 + P352:	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313:	If skin irritation or rash occurs: Get medical advice/attention.
P308 + P313:	IF exposed or concerned: Get medical advice/attention.
P405:	Store locked up.
P501:	Dispose of contents/container to in accordance with local/regional/ national regulation.

1. Handle the samples and materials contacting samples as if capable of transmitting infection.
2. Wear protective clothing, including lab coat, eye/face protection and disposable gloves (synthetic, non-latex gloves are recommended) while handling kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
3. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
4. Biological spills: Human source material spills should be treated as potentially infectious; spills should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment, with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the samples involved (commonly a 1:10 dilution of household bleach, 70-80% Ethanol or Isopropanol, an iodophor [such as 0.5% Wescodyne™ Plus, EPA Registration #4959-16-52], or a phenolic, etc.), and wiped dry.[30-33]

   NOTE: DO NOT PLACE SOLUTIONS CONTAINING BLEACH INTO THE AUTOCLAVE.
5. Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
6. For additional information refer to: Centers for Disease Control (CDC): Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis.[34]
7. Complete hazard information and precautions are located in the Safety Data Sheet (SDS) available at www.Bio-Rad.com, or upon request.

HANDLING PRECAUTIONS

1. The Geenius™ HIV 1/2 Supplemental Assay Cassette is for single use only.
2. Do not use the test cassettes or kit reagent beyond their stated expiration dates.
3. Do not use the test cassette if the cassette pouch does not contain a desiccant packet. Discard the test cassette and use a new cassette from a pouch that contains a desiccant.
4. Do not use any test cassette if its pouch has been perforated. Do not open the cassette's sealed foil pouch until just prior to use.
5. Do not mix components from different lot numbers of kits.

7 – REAGENT PREPARATION AND STORAGE

All components of the Geenius™ HIV 1/2 Supplemental Assay are ready to use as supplied. The Geenius™ HIV 1/2 Supplemental Assay cassettes and Buffer should be stored at 2 to 30°C. If the samples and / or kit components have been refrigerated, bring to room temperature (18 to 30º C) prior to testing.

Do not open cassette pouches until performing a test. Do not freeze pouches. The Buffer should not be removed from its original bottle. When stored as indicated, test cassettes and reagent are stable until their printed expiration dates. Do not use beyond the stated expiration date.

8 – SPECIMEN COLLECTION, PREPARATION, AND STORAGE

The Geenius™ HIV 1/2 Supplemental Assay can be performed on serum or plasma samples.

Serum or plasma samples collected by standard laboratory procedure may be used in the test. The following anticoagulants may be used for collecting plasma samples: EDTA, lithium heparin, sodium citrate, or CPD. Be sure that the tube of serum or plasma is well mixed after collection and before testing. Use a laboratory pipette to withdraw 5µL of the sample (note: SST tubes are acceptable). Perform the test following the Assay Procedure instructions below.

For long-term storage, the serum and plasma specimens should be frozen (at -20°C or colder). Samples should not be used if they have incurred more than 5 freeze-thaw cycles. Mix samples thoroughly and gently after thawing, and bring to room temperature. It is also recommended to centrifuge thawed specimens to remove gross particulate matter. Serum and plasma samples may be stored at 2-8°C for up to 7 days or up to 48 hours at room temperature (18-30°C).

SPECIMEN SHIPPING

If specimens are to be shipped they should be packed in compliance with regulations covering the transportation of etiologic agents. Serum and plasma specimens can be shipped at ambient conditions (18-30°C) for up to 2 days or samples can be shipped refrigerated with cold packs or wet ice.

9 – GEENIUS™ HIV 1/2 SUPPLEMENTAL ASSAY PROCEDURE

MATERIALS PROVIDED

See Reagents Section.

MATERIALS REQUIRED BUT SOLD SEPARATELY

- Geenius™ Reader and dedicated software
- Geenius™ HIV 1/2 Controls: Each package contains a Positive Control vial, a Negative Control vial, and 5 µL Microtube pipettes

MATERIALS REQUIRED BUT NOT PROVIDED

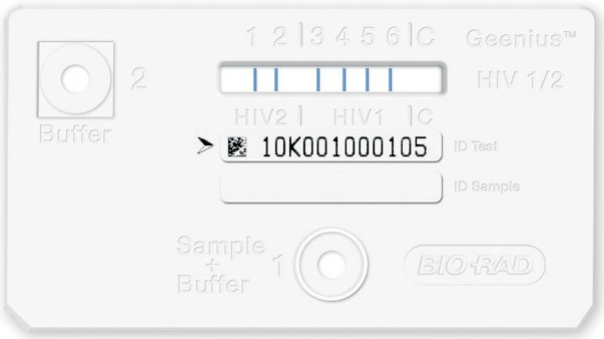
- Clock, watch or other timing device
- Pipettor capable of delivering 5 µL of sample
- Pipettor(s) capable of delivering 60 µL and 150 µL Buffer (optional)
- Disposable gloves
- Biohazard disposal containers

ASSAY PROCEDURE

WARNING: This test should be performed at room temperature (18 to 30°C, 64 to 86°F). If the cassette, samples, controls and/or kit components have been refrigerated, bring to room temperature (18 to 30°C, 64 to 86°F) before use.

1. Remove the Geenius™ HIV 1/2 Supplemental Assay cassette from its pouch and place it on a flat surface. **NOTE:** Do not use the cassette if the desiccant packet is missing from the pouch; discard the cassette and use a new test cassette. Label the cassette with sample ID or test number.

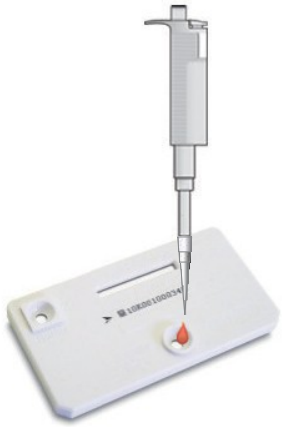
NOTE: the Geenius™ HIV 1/2 Supplemental Assay cassette has six (6) blue colored lines in the Test area; if any of the 6 colored lines are absent or are present but show any defects, DO NOT USE. Discard the cassette and use a new test cassette.



WARNING: The cassette should not be picked up or tilted during the testing procedure, including during the incubation steps.

Testing should be performed on a flat and level surface.

2. Using a laboratory pipette, dispense 5 µL of serum / plasma / control to the center of the Sample + Buffer Well 1 of the cassette.



3. Immediately following the addition of the sample **(but no longer than 5 minutes)**, use the dropper bottle to add 2 drops or a calibrated laboratory pipette to add 60 µL of Buffer into the Sample + Buffer Well 1.

Note : When dispensing buffer into the cassette Sample+Buffer well 1, it is essential that the dropper be held vertically. Buffer drops should fall freely from the tip, onto the membrane in the center of the well, to ensure the full amount is delivered. Do not touch the drop to the membrane, as this may prevent the required amount from being delivered.

4. **Wait 5 to 7 minutes.**

   Wait until the blue lines in the cassette window completely disappear **(minimum and maximum wait times of 5-7 minutes respectively)** before going to the next step.

   If any blue lines, or any portion of the blue lines, remain after 7 minutes from dispensing buffer into Well 1, the cassette is invalid, and a new cassette must be used to repeat the assay.

NOTE: A slight bluish-greenish color may remain on the membrane, but none of the actual colored lines should be seen at this point.

Use the dropper bottle to add 5 drops or a laboratory pipette to add 150 µL of Buffer to Buffer Well 2.

Note: When dispensing buffer into the cassette wells, it is essential that the dropper be held vertically. Buffer drops should fall freely from the tip, onto the membrane in the center of the buffer well 2, to ensure the full amount is delivered. Do not touch the drop to the membrane, as this may prevent the required amount from being delivered.

5. **Read the test result 15-20 minutes** after adding the Buffer to Buffer Well 2.

After adding buffer to Well 2, and before reading the cassette, wait until all fluid has migrated across test strip and no streaks or background remains (at least 15 minutes). If any background or streaks remain, allow migration to continue up to 30 minutes. Do not read cassettes after 30 minutes of buffer addition to Well 2.

In some cases test bands may appear in less than 15 minutes; however, a minimum of 15 minutes is needed to report results.

Do not read a Geenius™ cassette that contains smudges or background in the band Test area that may interfere with test interpretation. The sample should be retested with a new Geenius™ HIV 1/2 Supplemental Assay cassette.

Test results must be read with the Geenius™ Reader and associated Geenius™ software.

Refer to the Geenius™ Reader User Manual for instructions regarding the operation of the Geenius™ Reader.

NOTE: Discard the used pipette tips, cassette, and any other test materials into a biohazard container.

10 – QUALITY CONTROL – VALIDATION OF RESULTS

INTERNAL QUALITY CONTROL

Each Geenius™ HIV 1/2 Supplemental Assay cassette has a control band that is used to determine validity of the assay and confirm that sample has been added to the cassette. When the test has been performed correctly, a pink/purple band will appear in the Control (C) area to indicate the cassette is working properly (Refer to Interpretation of Test Results section of this product insert).

EXTERNAL QUALITY CONTROL

Geenius™ HIV 1/2 Controls are available separately for use with the Geenius™ HIV 1/2 Supplemental Assay to verify the performance of the test. The Positive Control will produce a positive test result for both HIV-1 and HIV-2. The Negative Control will produce a negative test result. Run the controls as described in the Assay Procedure section for a serum / plasma sample and follow the directions in the Interpretation of Test Results section of this product insert. It is the responsibility of each facility using the Geenius™ HIV 1/2 Supplemental Assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

Test the Geenius™ HIV 1/2 Controls under the following circumstances:

- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F) (Note that if this occurs, the Geenius™ HIV 1/2 Controls should be included in every test run that is performed using test kit lots that have been stored in that area).
- If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F).
- At periodic intervals as indicated by the user facility.

11 – INTERPRETATION OF TEST RESULTS

Results must be interpreted with the Geenius™ Reader (REF 92465) and the dedicated software. Refer to the Geenius™ Reader User Manual for instructions regarding the operation of the Geenius™ Reader.

The Geenius™ HIV 1/2 Supplemental Assay cassette contains a Control band (C) and six (6) test bands in the Test area that are numbered on the cassette corresponding to the following:

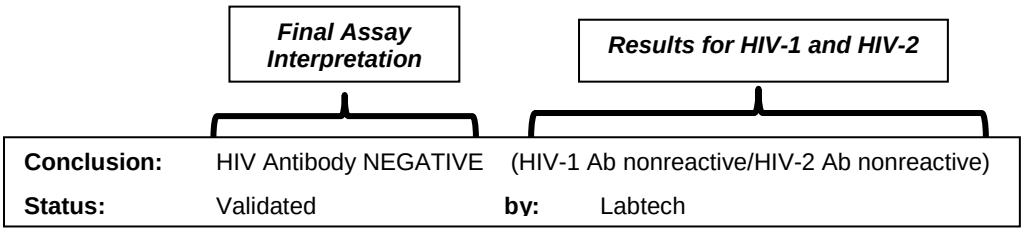
Band 1:	gp36 (HIV-2 envelope peptide)	HIV-2 ENV
Band 2:	gp140 (HIV-2 envelope peptides)	HIV-2 ENV
Band 3:	p31 (HIV-1 polymerase peptide)	HIV-1 POL
Band 4:	gp160 (HIV-1 envelope recombinant protein)	HIV-1 ENV
Band 5:	p24 (HIV-1 core recombinant protein)	HIV-1 GAG
Band 6:	gp41 (Group M and O) (HIV-1 envelope peptides)	HIV-1 ENV
Control Band	Protein A	

Note: A pink/purple band should always appear in the Control (C) area, whether or not a band appears in the Test area. If there is no distinct pink/purple band visible in the Control (C) area, then the test is INVALID. A test that is INVALID cannot be interpreted. It is recommended that the test be repeated with a new cassette.

ASSAY INTERPRETATION BY THE GEENIUS™ SOFTWARE

The Geenius™ Software detects the presence or absence of Bands 1-6 above and the Control band, determines the presence or absence of antibodies to HIV-1 and/or HIV-2, and generates an “HIV-1 Result” that is Ab reactive, indeterminate, or nonreactive, and an “HIV-2 Result” that is Ab reactive, indeterminate, or nonreactive. These results are used in combination to determine the Final Assay Interpretation.

The Geenius report generated for each sample contains the Final Assay Interpretation, printed in the Conclusion section. The individual antibody results are also provided in parentheses on the report. **The Final Assay Interpretation should always be reported to the ordering healthcare provider**.



The following table indicates the criteria employed by the Geenius™ Software to interpret the HIV-1 Result and HIV-2 Result and provide a “Final Assay Interpretation”. The detection and differentiation features are managed by proprietary algorithm. The cassettes should not be interpreted by visual inspection.

Final Assay Interpretation = Final specimen status	**HIV-1 result**	**HIV-2 result**	**Notes**
HIV Antibody NEGATIVE	Ab nonreactive	Ab nonreactive	No HIV-1 or HIV-2 bands were detected. ***The sample is non-reactive for HIV antibodies.***
HIV-1 INDETERMINATE	Ab indeterminate	Ab nonreactive	HIV-1 band(s) were detected but did not meet the criteria for HIV-1 Positivity. No HIV-2 bands were detected.
HIV-2 INDETERMINATE	Ab nonreactive	Ab indeterminate	One HIV-2 band was detected but did not meet the criteria for HIV-2 Positivity. No HIV-1 bands were detected.
HIV INDETERMINATE	Ab indeterminate	Ab indeterminate	HIV-1 and HIV-2 bands were detected but did not meet the criteria for HIV-1 Positivity or HIV-2 Positivity.
HIV-1 POSITIVE	Ab reactive	Ab nonreactive	HIV-1 bands were detected and met the criteria for HIV-1 Positivity. No HIV-2 bands detected. ***Antibodies to HIV-1 confirmed in the sample.***
HIV-1 POSITIVE	Ab reactive	Ab indeterminate	HIV-1 bands were detected and met the criteria for HIV-1 Positivity. One HIV-2 band was detected but did not meet the criteria for HIV-2 Positivity. ***Antibodies to HIV-1 confirmed in the sample.*** *HIV-2 Indeterminate result is likely due to cross-reactivity of HIV-1 antibodies on HIV-2 antigens and confirmation of HIV-2 is not required.*
HIV-2 POSITIVE	Ab nonreactive	Ab reactive	HIV-2 bands were detected and met the criteria for HIV-2 Positivity. No HIV-1 bands were detected. ***Antibodies to HIV-2 confirmed in the sample.***
HIV-2 POSITIVE	Ab indeterminate	Ab reactive	HIV-1 bands were detected and did not meet the criteria for HIV-1 Positivity. HIV-2 bands were detected and met the criteria for HIV-2 Positivity. ***Antibodies to HIV-2 confirmed in the sample.*** *HIV-1 Indeterminate result is likely due to cross-reactivity of HIV-2 antibodies on HIV-1 antigens and confirmation of HIV-1 is not required.*
HIV-2 POSITIVE with HIV-1 cross-reactivity	Ab reactive (cross-reactivity)	Ab reactive	HIV-1 bands were detected and met the criteria for HIV-1 Positivity. HIV-2 bands were detected and met the criteria for HIV-2 Positivity. ***Antibodies to HIV-2 confirmed in the sample.*** *HIV-1 band intensities are reactive but below a specified index. The HIV-1 Ab Reactive result is likely due to cross-reactivity of HIV-2 antibodies on HIV-1 antigens and confirmation of HIV-1 is not required.*
HIV POSITIVE Untypable	Ab reactive	Ab reactive	HIV-1 bands were detected and met the criteria for HIV-1 Positivity. HIV-2 bands were detected and met the criteria for HIV-2 Positivity. ***Antibodies to HIV-1 and HIV-2 confirmed in the sample.*** *Further testing is indicated.*

12 – LIMITATIONS OF THE TEST

1. The Geenius™ HIV 1/2 Supplemental Assay (REF 72480) must ONLY be used with serum or plasma. Using other types of samples or testing of samples collected using a tube containing an anticoagulant other than EDTA, lithium heparin, sodium citrate, and CPD may not yield accurate results. For serum samples, collect blood without anticoagulant.
2. The instructions in this product insert must be followed in order to obtain accurate results with the Geenius™ HIV 1/2 Supplemental Assay.
3. If results are read earlier than 15 minutes or later than 30 minutes after the addition of Buffer into Buffer Well 2, the results may be erroneous.
4. The Geenius™ HIV 1/2 Supplemental Assay **must** be interpreted using the Geenius™ Reader and Software.
5. A Geenius™ HIV 1/2 Supplemental Assay test result that is INVALID should not be reported and the sample(s) should be retested with a new cassette.
6. A positive assay result interpretation using the Geenius™ HIV 1/2 Supplemental Assay confirms the presence of specific antibodies to HIV-1 and/or HIV-2 in the sample. HIV and AIDS-related conditions are clinical syndromes caused by HIV-1 and HIV-2 and their diagnoses can only be established clinically.
7. False negative results may occur in individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART), post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).
8. For a positive Final Assay Interpretation, the intensities of the test bands do not necessarily correlate with the titer of antibody in the sample.
9. A negative or indeterminate Final Assay Interpretation does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to a recent exposure may take several months to reach detectable levels. Follow-up testing with an HIV-1 NAT test should be considered when results of an HIV donor screening assay are reactive and the Geenius assay result is nonreactive or indeterminate.
10. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus; however, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.
11. Assay Interpretation Limitations:
    - A Geenius™ HIV 1/2 Supplemental Assay cassette that contains smudges or background in the band area that may interfere with test interpretation should not be read. The sample should be retested with a new Geenius™ HIV 1/2 Supplemental Assay cassette.
    - An “Indeterminate” Final Assay Interpretation does not exclude the possibility of early seroconversion of the test subject or a cross-reaction with other retroviruses.
    - The homology between HIV-1 and HIV-2 viruses can lead to cross reactivity between anti-HIV-1 and anti-HIV-2 antibodies.
    - Samples with a Final Assay Interpretation of HIV-1 Positive may, in some rare cases, show cross reactivity on one of the HIV-2 envelope bands. In most of the cases, this profile confirms an HIV-1 infection. However, it does not exclude the rare possibility of a secondary HIV-2 seroconversion (co-infection).
    - Samples with a Final Assay Interpretation of HIV-2 Positive may, in some rare cases, show cross reactivity on one or more HIV-1 bands. In most cases, this profile confirms an HIV-2 infection. However, it does not exclude the rare possibility of a secondary HIV-1 seroconversion (co-infection).
    - Samples that have a Final Assay Interpretation of HIV-2 Positive with HIV-1 cross-reactivity, and are both HIV-1 Ab reactive and HIV-2 Ab reactive, are generally HIV-2 positive samples which show HIV-1 cross reactivity. This represents 54% of the cases in the clinical study of 200 samples characterized as HIV-2 only infections. Such profiles do not exclude the rare possibility of HIV-1 and HIV-2 co-infection.
    - Samples with a Final Assay Interpretation of HIV Positive Untypable were identified in clinical studies as HIV-2 positive samples with HIV-1 reactivity that cannot be differentiated. Such samples represent 6% of the cases in the clinical study of 200 samples that have been characterized as HIV-2 only

infections. Such profiles do not exclude the possibility of HIV-1 and HIV-2 co-infection, which is rare, or the possibility of HIV-1 positive samples with significant cross-reactivity on HIV-2 antigens.

- Final Assay Interpretations of HIV-2 Indeterminate for samples from persons without any risk factors for HIV-2 infections should be confirmed by retesting with a new Geenius™ HIV 1/2 Supplemental Assay cassette before reporting. If the result of repeat testing is Ab negative for both HIV-1 and HIV-2, the sample should be reported as HIV Antibody Negative.

13 – PERFORMANCE CHARACTERISTICS

SPECIFICITY

Reactivity in Blood Donors

Two hundred (200) samples that had been collected from random blood and plasma donors were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 1.

Table 1. Specificity of Geenius™ HIV 1/2 Supplemental Assay in Blood and Plasma Donors

Sample Type	Number	Geenius™ HIV 1/2 Supplemental Assay		
		NEG	IND	POS
Serum	100	97	3[1]	0
Plasma	100	94	6[2]	0
TOTAL	200	191	9[3]	0

[1] One sample was HIV Indeterminate and two samples were HIV-1 Indeterminate. Two of the three samples were Negative on an HIV-1/HIV-2 differentiation test and one sample that was HIV-1 Indeterminate on the Geenius assay was also HIV-1 Indeterminate on the HIV-1/HIV-2 differentiation test.
[2] Five samples were HIV-2 Indeterminate and one sample was HIV-1 Indeterminate. All of these samples were Negative on an HIV-1/HIV-2 differentiation test.
[3] Five samples were HIV-2 Indeterminate, three samples were HIV-1 Indeterminate, and one sample was HIV Indeterminate.

The overall indeterminate rate in the low risk population for the Geenius™ HIV 1/2 Supplemental Assay was 4.50% (9/200) for all sample types combined.

Note: All samples from the 200 random blood donors were negative on an FDA licensed HIV-1/HIV-2 EIA reference test, and would not normally be tested using the Geenius™ HIV 1/2 Supplemental Assay.

False Reactive Blood Donor Samples

A panel of one hundred (100) retrospective samples that were false reactive on FDA licensed HIV-1/HIV-2 tests were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 2.

Table 2. Specificity of Geenius™ HIV 1/2 Supplemental Assay in False Reactive Blood Donor Samples

Sample Type	Number Tested	Manufacturer (Number Tested)	Geenius™ HIV 1/2 Supplemental Assay		
			NEG	IND	POS
Serum	50	Licensed HIV-1/HIV-2 Test #1 (N = 30)	27	3[1]	0
		Licensed HIV-1/HIV-2 Test #2 (N = 20)	20	0	0
Plasma	50	Licensed HIV-1/HIV-2 Test #1 (N = 39)	39	0	0
		Licensed HIV-1/HIV-2 Test #2 (N = 11)	10	1[1]	0
TOTAL	100	N = 100	96	4[1]	0

[1] Sample(s) were HIV-2 Indeterminate when tested on the Geenius™ HIV 1/2 Supplemental Assay and Negative on an HIV-1/HIV-2 differentiation test.

No sample in this population tested positive on the Geenius™ HIV 1/2 Supplemental Assay.

The overall indeterminate rate for this population was 4.00% (4/100).

Reactivity in Low Risk Population

Two hundred forty (240) samples prospectively collected from one hundred twenty (120) individuals at low risk for HIV infection (military recruits, soldiers, and civilians) were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 3.

Table 3. Specificity of Geenius™ HIV 1/2 Supplemental Assay in a Low Risk Population

Matched Sample Type	Number	Geenius™ HIV 1/2 Supplemental Assay		
		NEG	IND	POS
Serum	120	118	2[a] (1.67%)	0
Plasma EDTA	60	60	0	0
Plasma Heparin	60	56	4[b] (6.66%)	0
TOTAL	240	234	6	0

[a] Both of the Indeterminate serum samples were HIV-1 Indeterminate.

[b] Of the 4 Indeterminate heparin plasma samples, 2 were HIV-2 Indeterminate, 1 was HIV-1 Indeterminate and 1 was HIV Indeterminate.

The overall Indeterminate rate in the low risk population was 2.50% (6/240) for all matched sample types combined.

Note: All samples from the 120 prospective low risk subjects were negative on an FDA licensed HIV-1/HIV-2 EIA reference test, and would not normally be tested using the Geenius™ HIV 1/2 Supplemental Assay.

False Reactive Sample Panel

A panel of one hundred (100) retrospective samples that were false reactive on FDA licensed or approved HIV tests were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 4.

Table 4. Specificity of Geenius™ HIV 1/2 Supplemental Assay in False Reactive Samples

Assay	Number of False Reactives Tested	Geenius™ HIV 1/2 Supplemental Assay		
		NEG	IND	POS
HIV Ag/Ab Combo	50	49	1[a] (2.00%)	0
HIV 1/2 EIA	43	40	3[b] (6.98%)	0
HIV 1/2 Differentiation Test	7	5	2[c] (28.57%)	0
TOTAL	100	94	6 (6.00%)	0

[a] One (1) false reactive sample was HIV-1 Indeterminate.

[b] Of three (3) false reactive samples, two (2) were HIV-1 Indeterminate and one (1) was HIV-2 Indeterminate.

[c] Two (2) HIV-1/2 differentiation test false reactive samples were HIV-1 Indeterminate.

No sample in this population tested Positive on the Geenius™ HIV 1/2 Supplemental Assay. The overall Indeterminate rate in this population was 6.00% (6/100).

Medical Conditions Unrelated to HIV Infection

A panel of 140 retrospective samples, representing 14 categories of medical conditions unrelated to HIV infection were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 5.

Table 5. Medical Conditions Unrelated to HIV Infection

Unrelated Medical Condition	Number Tested	Geenius™ HIV 1/2 Supplemental Assay		
		NEG	IND	POS
Autoimmune disease patients	10	10	0	0
Dialysis patients	10	9	1[a]	0
EBV infection	10	10	0	0
HBsAg infection	10	10	0	0
HCV infection	10	10	0	0
Hemophilia patients	10	10	0	0
High rheumatoid factor	10	10	0	0
HTLV I/II antibody positive	10	10	0	0
Multiparous (pregnant) females	10	10	0	0
Multiple transfusions	10	10	0	0
Post-Influenza vaccine recipients*	10	10	0	0
Pre-Influenza vaccine recipients *	10	10	0	0
Vaccinia vaccine samples	10	10	0	0
Yeast (Candida) reactive	10	9	1[a]	0
TOTAL	140	138/140 (98.57%)	2/140 (1.43%)	0/140 (0.00%)

* The 10 pre-Influenza vaccine and 10 post-Influenza vaccine specimens tested in the study were matched.

[a] HIV-2 Indeterminate.

The overall Indeterminate rate was 1.43% (2/140). Of the 140 unrelated medical condition samples, 139 were negative on an FDA licensed HIV-1/HIV-2 screening assay (historical data) and one was not tested.

Note: All of these specimens were non-reactive on an FDA licensed HIV-1/HIV-2 EIA test, and would not normally be tested using the Geenius™ HIV 1/2 Supplemental Assay.

In a previous cross-reactivity study performed in Europe, a panel of 227 potentially cross-reactive samples, representing 29 different disease states, was tested on the Geenius™ HIV 1/2 Supplemental Assay. Of the

227 different samples, 223 specimens tested HIV Antibody Negative, and 4 specimens, from 3 different medical conditions tested HIV-1 or HIV-2 Indeterminate, due to reactive bands at trace level [1 HCV, 1 HBs Ag, and 2 Malaria]. The overall Indeterminate rate was 1.8% (4/227).

SENSITIVITY

HIV Positive Blood Donors

Two hundred (200) samples collected from HIV positive blood donors were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 6.

Table 6. Sensitivity of Geenius™ HIV 1/2 Supplemental Assay in Known HIV-1 Positive Blood Donors

Matrix Type	Number Tested	Geenius™ HIV 1/2 Supplemental Assay Results						HIV-1 IFA		
		HIV-1 POS	HIV-2 POS	IND	NEG	Sensitivity	Wilson 95% CI	POS	IND	NEG
Serum	100	100	0	0	0	100%	96.30 – 100%	94	1[1]	5[1]
Plasma	100	100	0	0	0	100%	96.30 – 100%	98	0	2[1]
TOTAL	200	200	0	0	0	100%	98.12 – 100%	192	1[1]	7[1]

[1] All samples that were Indeterminate or Negative on the HIV-1 IFA were HIV-1 Positive on an HIV-1/HIV-2 differentiation test and HIV Positive on a NAT test.

For HIV-1 Positive serum samples, the sensitivity of the Geenius™ HIV 1/2 Supplemental Assay was 100% (100/100) with a 95% CI of 96.30% to 100%. For HIV-1 Positive plasma samples, the sensitivity of the Geenius™ HIV 1/2 Supplemental Assay was 100% (100/100) with a 95% CI of 96.30% to 100%. For all sample types from this known HIV-1 positive population the sensitivity of the Geenius™ HIV 1/2 Supplemental Assay was 100% (200/200) with a 95% CI of 98.12% to 100%.

All samples from the known HIV-1 positive population were HIV-2 negative when tested on the Geenius™ HIV 1/2 Supplemental Assay.

HIV Positive Population

Five hundred ninety-eight (598) samples prospectively collected from two hundred ninety-nine (299) known HIV-1 positive/AIDS patients were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 7.

Table 7. Sensitivity of Geenius™ HIV 1/2 Supplemental Assay in Prospective Known HIV-1 / AIDS Positive Patients

Matched Sample Type	Number Tested	Geenius™ HIV 1/2 Supplemental Assay Results					Rapid HIV 1/2 Supplemental / Differentiation Assay	HIV-1 Western Blot	FDA Licensed (3rd Gen) HIV-1/HIV-2 EIA
		POS	IND	NEG	Sensitivity	Wilson 95 % CI			
Serum	299	297	2[a]	0	99.33% (297/299)	97.59% - 99.82%	*99.00% (296/299)	**99.00% (296/299)	100% (299/299)
EDTA Plasma	151	150	1[b]	0	99.34% (150/151)	96.34% - 99.88%	NA	NA	NA
Heparin Plasma	148[c]	147	1[b]	0	99.32% (147/148)	96.27% - 99.88%	NA	NA	NA

[a] Two (2) AIDS patient serum samples were HIV-1 Indeterminate on the Geenius™ HIV 1/2 Supplemental Assay.

[b] Of the 2 AIDS patient samples that had HIV-1 Indeterminate results for serum, 1 had an HIV-1 Indeterminate EDTA plasma sample and the second AIDS patient had an HIV-1 Indeterminate heparin plasma sample.

[c] For the plasma Heparin, 150 samples were collected, 2 test results were invalid and 1 was double enrolled and was excluded.

* Three (3) samples were Indeterminate on the Rapid HIV 1/2 Supplemental Differentiation Assay, including the 2 AIDS patient serum samples that were Indeterminate on the Geenius™ Supplemental Assay.

** Three(3) samples were Indeterminate on the HIV-1 Western blot, including the 2 AIDS patient serum samples that were Indeterminate on the Geenius™ HIV 1/2 Supplemental Assay.

All 299 serum samples from the HIV positive/AIDS patients were repeatedly reactive when tested on a third generation FDA licensed HIV-1/HIV-2 EIA. Three (3) of these serum samples were HIV-1 Indeterminate on either an FDA approved Rapid HIV-1/HIV-2 Supplemental and Differentiation assay or a FDA licensed HIV-1 Western blot. Therefore the sensitivity of these comparator assays was 99.00% (296/299) for this population.

CDC Stage 3 AIDS Patients

Four hundred twenty-four (424) prospectively collected samples from two hundred twelve (212) known AIDS patients, categorized as CDC Stage 3, were tested with the Geenius™ HIV 1/2 Supplemental Assay. Results are presented in Table 8.

Table 8. Sensitivity of Geenius™ HIV 1/2 Supplemental Assay in Prospective Known CDC Stage 3 AIDS Patients

Sample Type	Number Tested	POS	IND	NEG	Sensitivity	95% Wilson CI	Rapid HIV-1 /2 Supp. / Diff. Test Results	HIV-1 Western Blot	FDA Licensed (3rd Gen) HIV-1/ HIV-2 EIA
Serum	212	210	2[a]	0	99.06% (210/212)	96.62% - 99.74%	*98.58% (209/212)	*98.58% (209/212)	100% (212/212)
EDTA Plasma	89	88	1[b]	0	98.88% (88/89)	93.90% - 99.80%	NA	NA	NA
Heparin Plasma	123[c]	122	1[b]	0	99.19% (122/123)	95.53% - 99.86%	NA	NA	NA

[a] Two (2) patient serum samples were HIV-1 Indeterminate.

[b] Of the 2 patient samples that had HIV-1 Indeterminate results for serum, 1 had an HIV-1 Indeterminate EDTA plasma sample. The second had an HIV- 1 Indeterminate heparin plasma sample.

[c] For plasma heparin, 124 samples were collected; 1 was double enrolled and was excluded.

* Three (3) samples were Indeterminate on either the Rapid HIV 1/2 Supplemental Differentiation Assay or the HIV-1 Western Blot, including the two samples that were Indeterminate on the Geenius™ Supplemental Assay.

Two (2) CDC Stage 3 AIDS patients (diagnosed in 2002 and 2004 respectively) had Indeterminate results on the Geenius™ HIV 1/2 Supplemental Assay.

All 212 serum samples from the AIDS patients were reactive when tested on a third generation FDA licensed HIV-1/HIV-2 EIA. Three (3) samples were HIV-1 Indeterminate on either an FDA approved Rapid HIV-1/HIV-2 Supplemental and Differentiation assay or a FDA licensed HIV-1 Western blot. Therefore, the sensitivity of the two comparator assays in this population was 98.58% (209/212).

HIV-2 Positive Samples

Sensitivity Performance with Known HIV-2 Positive Samples

Two hundred (200) known HIV-2 antibody positive samples obtained from individuals from different geographic locations (161 from Ivory Coast, 20 from Guinea Bissau, and 19 from USA) were tested with the Geenius™ HIV 1/2 Supplemental Assay.

Of the two hundred (200) known HIV-2 antibody positive samples, 38.50% (77/200) were interpreted as only HIV-2 Positive, 54.00% (108/200) were interpreted as HIV-2 with HIV-1 cross reactivity, 6.00% (12/200) were interpreted as HIV Positive Untypable (undifferentiated), and 1.50% (3/200) were interpreted as HIV-2 Indeterminate.

All samples from the known 200 HIV-2 positive subjects were positive on a third generation FDA licensed HIV-1/HIV-2 EIA reference test (historical data).

HIV-1 and HIV-2 Co-infected Patient Samples

Sensitivity Performance with Known HIV-1 and HIV-2 Co-infected Patient Samples

Three (3) samples from patients known to be co-infected with both HIV-1 and HIV-2 viruses were obtained from France and were tested with the Geenius™ HIV 1/2 Supplemental Assay.

The reactivity of the Geenius™ HIV 1/2 Supplemental Assay with the three (3) samples was 100%. All the samples were found to be HIV Positive Untypable (undifferentiated), which means that they were found positive for both HIV-1 and HIV-2 antibodies.

HIV-1 Group M Subtype Samples

Sensitivity Performance with Known HIV-1 Group M Subtype Positive Samples

The reactivity of the Geenius™ HIV 1/2 Supplemental Assay with HIV-1 Group M subtype samples was determined by testing one hundred thirty-six (136) HIV-1 antibody positive Group M subtype specimens (A, A1, B, C, D, F, F2, G, A/E, A/G, H, J, K, U, CRFs) collected from individuals in Cameroon.

The reactivity of the Geenius™ HIV 1/2 Supplemental Assay for the 136 HIV-1 Group M Subtype samples tested was 100% (136/136) HIV positive (135 HIV-1 Positive and 1 HIV Positive Untypable), with a 95% confidence interval of 97.25% to 100%.

HIV-1 Group O Subtype Samples

Sensitivity Performance with Known HIV-1 Group O Subtype Positive Samples

Fifteen (15) specimens known to be positive for antibodies to HIV-1 Group O were tested with the Geenius™ HIV 1/2 Supplemental Assay.

The Geenius™ HIV 1/2 Supplemental Assay was HIV-1 Positive for 13 and HIV-1 Indeterminate for 2 of the 15 known positive HIV-1 Group O samples. None of the specimens was found to be HIV Antibody Negative.

PERFORMANCE PANELS

HIV-1 Incidence / Prevalence Panel

An HIV-1 Incidence / Prevalence panel containing seven (7) known HIV-1 positive incidence (new infections) members and eight (8) known HIV-1 positive prevalence (long-standing infections) members was tested with the Geenius™ HIV 1/2 Supplemental Assay.

The Geenius™ HIV 1/2 Supplemental Assay was reactive with 100% (15/15) of the HIV-1 incidence / prevalence panel members with a 95% confidence interval of 79.57% - 100%. All 15 panel members were HIV-1 Positive.

HIV-1 / HIV-2 Performance Panel

An HIV-1 / HIV-2 Performance Panel containing seven (7) HIV-1 positive and seven (7) HIV-2 positive panel members was tested with the Geenius™ HIV 1/2 Supplemental Assay.

The Geenius™ HIV 1/2 Supplemental Assay gave correct results for the seven HIV-1 panel members (“HIV-1 Positive”) and five of the HIV-2 panel members (“HIV-2 Positive”) for all three lots tested. One HIV-2 panel member was HIV-2 Indeterminate on all three lots tested. Additionally, one HIV-2 panel member was HIV-2 Positive on two of three lots tested and HIV-2 Indeterminate on the remaining lot. None of the panel members was found to be HIV Antibody Negative on any lot tested.

HIV-1 Seroconversion Panels

Twenty-six (26) commercially available seroconversion panels were tested with the Geenius™ HIV 1/2 Supplemental Assay. The reactivity with the two hundred thirty (230) specimens in the panels is presented in Table 9.

Table 9. Reactivity in HIV-1 Seroconversion Panels

Note: The number of positive panel members found to be repeatedly reactive or positive is listed for each test.

Panel ID	Number of Panel Members Tested	HIV-1 RNA Positive Panel Members	Automated (4th Gen) HIV Ag/Ab Combo EIA	FDA Licensed (3rd Gen) HIV 1/2 EIA	Geenius™ HIV-1/HIV-2 Supplemental Assay Results	Rapid HIV-1 /2 Supp. / Diff. Test Results	HIV-1 WB Results
001	9	6	6	5	3	2	3
002	13	7	5	4	2	2	3
003	10	6	5	3	2	2	2
004	8	6	3	2	0	0	0
005	7	4	5	5	5	3	4
006	8	3	2	2	0	0	0
007	3	1	1	1	1	1	1
008	14	11	5	5	3	3	2
009	6	4	4	3	2	3	2
010	10	5	3	3	1	2	0
011	27	17	16	14	14	13	13
012	25	18	17	14	13	9	11
013	6	4	3	2	2	2	2
014	5	4	5	2	1	2	0
015	8	4	4	3	1	0	0
016	6	2	2	2	1	2	0
017	6	5	4	2	2	2	2
018	9	5	4	4	4	4	1
019	8	8	7	6	5	5	1
020	6	5	4	2	1	1	0
021	6	5	3	2	0	0	0
022	4	4	3	3	0	0	1
023	6	5	4	0	1	1	2
024	7	5	2	1	1	0	0
025	7	7	7	0	4	4	4
026	6	6	5	3	2	2	2
Total	230	157	129 / 157	93 / 157	71 / 157	65 / 157	56 / 157
% HIV-1 RNA Positives detected			82.17%	59.24%	45.22%	41.40%	35.67%
95% Confidence Interval			75.43% - 87.36%	51.42% - 66.61%	37.64% - 53.04%	33.98% - 49.23%	28.59% - 48.43%

* Historical data on the Rapid HIV 1/2 Supplemental and Differentiation Assay was evaluated using a new diagnostic algorithm interpretation approved by FDA in March 2013.

The Geenius™ HIV 1/2 Supplemental Assay results were compared to previously known results obtained with the comparator assays shown in Table 9 above. The HIV Ag/Ab Combo EIA, the HIV 1/2 EIA, and the Rapid HIV-1/2 supplemental/differentiation test are FDA-approved tests.

Of the 230 seroconversion panel specimens tested, 68.26 % (157/230) had detectable HIV-1 RNA. The Geenius™ HIV 1/2 Supplemental Assay found 45.22% (71/157, 95% CI 37.64% - 53.04%) Positive compared to 41.40% (65/157, 95% CI 33.98% - 49.23%) reactive on a Rapid HIV-1/2 supplemental/differentiation assay. Also in this study the Geenius™ HIV 1/2 Supplemental Assay found 45.22% Positive compared to 35.67% (56/157, 95% CI 28.59% - 48.43%) Positive on the HIV-1 Western Blot.

REPRODUCIBILITY

A 17-member reproducibility panel for the Geenius™ HIV 1/2 Supplemental Assay was prepared at Bio-Rad Laboratories and provided to 3 sites for testing. Three clinical lots of the Geenius™ HIV 1/2 Supplemental Assay were used in the evaluation.

The 17-member reproducibility panel included 5 serum members, 5 EDTA plasma members, 5 heparin plasma members and 2 Geenius™ HIV 1/2 Supplemental Assay kit controls. The reproducibility panel was tested on the Geenius™ HIV 1/2 Supplemental Assay following the instructions for use. Each panel member was tested twice a day (AM and PM), for 5 days on 3 kit lots of the Geenius™ HIV 1/2 Supplemental Assay, at each of 3 sites, for a total of 90 replicates per panel member at all three sites combined (5 days x 2 per day x 3 lots x 3 sites = 90 replicates per panel member). Each Geenius™ HIV 1/2 Supplemental Assay test result was read and interpreted using the Geenius™ HIV 1/2 Supplemental Assay Reader and Software.

The total percent (%) agreement of the Geenius™ HIV 1/2 Supplemental Assay results was calculated for each of the 17 reproducibility panel members as the number of results that were correct compared to the known sample status, along with the 95% confidence interval. Results were reported as Positive, Indeterminate, or Negative. The results are shown in Table 10. This study demonstrated that the Bio-Rad Geenius™ HIV 1/2 Supplemental Assay is highly reproducible.

Table 10. Reproducibility Results

Panel Member	Panel Description	Replicates*	Total Results	% Agreement	95 % CI
1	HIV-1 antibody positive serum	90	90/90 HIV-1 Positive	100%	95.91% - 100%
2	HIV-1 antibody positive EDTA plasma	89	89/89 HIV-1 Positive	100%	95.86% - 100%
3	HIV-1 antibody positive heparin plasma	90	90/90 HIV-1 Positive	100%	95.91% - 100%
4	HIV-1 indeterminate serum	89	85/89 HIV-1 Indeterminate	95.51%	89.01% - 98.24%
5	HIV-1 indeterminate EDTA plasma	87	84/87 HIV-1 Indeterminate	96.55%	90.35% - 98.82%
6	HIV-1 indeterminate heparin plasma	90	85/90 HIV-1 Indeterminate	94.44%	87.65% - 97.60%
7	HIV-2 indeterminate serum	86	80/86 HIV-2 Indeterminate	93.02%	85.60% - 96.76%
8	HIV-2 indeterminate EDTA plasma	88	76/88 HIV-2 Indeterminate	86.36%	77.66% - 92.02%
9	HIV-2 indeterminate heparin plasma	89	85/89 HIV-2 Indeterminate	95.51%	89.01% - 98.24%
10	HIV-2 antibody positive serum	90	90/90 HIV-2 Positive	100%	95.91% - 100%
11	HIV-2 antibody positive EDTA plasma	90	88/90 HIV-2 Positive	97.78%	92.26% - 99.39%
12	HIV-2 antibody positive heparin plasma	89	89/89 HIV-2 Positive	100%	95.86% - 100%
13	HIV non-reactive serum	90	89/90 HIV Antibody Negative	98.89%	93.97% - 99.80%
14	HIV non-reactive EDTA plasma	90	89/90 HIV Antibody Negative	98.89%	93.97% - 99.80%
15	HIV non-reactive heparin plasma	90	90/90 HIV Antibody Negative	100%	95.91% - 100%
16	Kit Positive control serum	90	90/90 HIV-1/2 Positive	100%	95.91% - 100%
17	Kit Negative control serum	90	89/90 HIV Antibody Negative	98.89%	93.97% - 99.80%

* Replicate values for each panel member that are less than 90 are due to invalid test results excluded from analysis.

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