# One Step test Rapid Test for detection of anti-HIV in Human ~~Serum/~~Plasma/ Whole blood

# MERISCREEN HIV 1-2 WB

Meril Diagnostics

IVD For in vitro diagnostic use
Read this pack insert thoroughly before use

| Product code | Pack Size |
|---|---|
| HVWRPD-01 | 30T |
| HVWRPD-02 | 40T |

**INTENDED USE:**

MERISCREEN HIV 1-2 WB Test is a qualitative, screening, *in-vitro* diagnostic immunochromatography assay for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human serum, plasma and venous whole blood. The test is intended for use by trained competent person.

**INTRODUCTION:**

Acquired Immunodeficiency Syndrome (AIDS) is caused by two types of Human Immunodeficiency Virus, HIV-1 and HIV-2. Transmission of infection is mainly by exposure to certain infected body fluids e.g., blood and blood products, genital secretions etc. and by transplacental route. Infection by HIV-1 has been reported worldwide; HIV-2 infection has been reported as occurring mainly in West Africa and some European countries. Both these viruses show substantial antigenic cross reactivity in their core proteins, but the envelope glycoproteins are least cross reactive. Detection of antibodies against envelope proteins of both viruses ensures detection of antibodies against both types of viruses following infection. The earliest specific antibody response following infection by HIV may be of immunoglobulin M (IgM) followed by a response in immunoglobulin G (IgG). Maximum sensitivity for detection of anti-HIV sero-conversion is achieved by assays which respond to both IgM and IgG.

**PRINCIPLE:**

The MERISCREEN HIV 1-2 WB rapid test kit contains a membrane strip, which is pre-coated with HIV-1 & HIV-2 antigens on test region '1' and test region '2' respectively. Recombinant antigen gold conjugate will form a coloured band in the test region '1' and test region '2' of result window. As the test sample flows through the membrane after addition of Assay buffer, the antigen gold conjugate complexes with anti-HIV antibodies. The complex moves further on the membrane towards the test region, where HIV antigens are coated and leads to formation of reddish purple band(s) at test region(s). Absence of test bands indicates a negative test results.

The control band is used for procedural control and should always appear if the test procedure is performed correctly. The intensity of control band has nothing to do with intensity of test band(s).

**REAGENTS AND MATERIALS PROVIDED:**

Each kit contains:

1. Pouches; each contains Test device with one desiccant
2. Assay Buffer bottle
3. Capillary tubes
4. Pack insert

**STORAGE AND STABILITY:**

All reagents are ready to use as supplied. Store unopened test devices at 2-30°C. If stored at 2-8°C, allow test device to attain room temperature before opening. The test device is stable up to the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately after opening the foil. After opening the Assay buffer bottle, the buffer is stable until the expiration date if kept at 2-30°C.

**PRECAUTIONS:**

1. For *in-vitro* diagnostics and professional use only.
2. Allow all reagents and sample(s) to attain room temperature (18°C to 30°C) before use.
3. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately. Though performance of test device is not affected by the different range of humidity i.e., 40% RH, 60% RH and 75% RH, it is recommended that the test device should be used in ambient humidity i.e., between 40% RH and 60% RH.
4. Do not use the kit contents beyond the expiry date.
5. Do not use test device if pouch is lack of desiccant.

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6. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
7. Test Devices and assay buffers of different lot must not be mixed and used.
8. Do not re-use accessories like capillary tubes for testing purpose.
9. Perform the test by using kit' s assay buffers. Performing the test with any other buffer is not valid.
10. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
11. Do not use haemolysed or lipemic specimen for testing.
12. Use sufficient volume of sample for testing.
13. Do not re-use the Test Devices and pipette tips from the procedure; this may lead to aberrant results.
14. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
15. Avoid contact of reagents with eyes and skin. If either of the reagents come into contact with skin or eyes, wash thoroughly with water.
16. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Do not re-use used gloves or washed gloves.
17. Handle sample(s) and used materials as if it is capable of transmitting infection.
18. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. All remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
19. Clean up spills thoroughly using an appropriate disinfectant.
20. The test device should remain in its original sealed pouch until usage. Do not use the test device if the seal is broken or the pouch is damaged. In case desiccant pouch changes colour from blue to light pink colour or test device pouch is lack of desiccant then test device should not be used.

**SPECIMEN COLLECTION AND PREPARATION:**

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

**WHOLE BLOOD:**

Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.

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**PLASMA:**

Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.

1. Separate the plasma by centrifugation (Centrifugation time & speed: 2350-3150 x g for ~ 10 minutes).
2. Carefully withdraw the plasma into new pre-labelled tube.

**SERUM:**

1. Collect blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation. (Centrifugation time & speed: 2350-3150 x g for ~ 10 minutes).
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection.

Stored serum/plasma/whole blood specimens at 2-8°C up to 3 days can be used for testing. Serum/Plasma specimens should be frozen at -20°C for longer storage.

**TEST PROCEDURE:**

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Take sample upto the marking (of 10 µl) on Capillary tube. For serum/plasma take it one time and for whole blood take it two times.
4. Add sample to the sample well (S) using capillary tube. Dispose off used capillary tube as a bio-hazard waste.
5. Add three drops of the Assay Buffer to the Sample well (S).
6. Interpret the test results at the end of 20 minutes. **Do not read the results after 30 minutes.**

**INTERPRETATION OF RESULTS:**

Expected results are as follows:

**NEGATIVE RESULT:** If only the Control (C) band is developed, the test indicates that no detectable HIV antibodies are present in the specimen. The result is negative.


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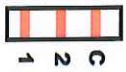
**POSITIVE RESULT:** If Control(C), HIV-1(1) and/or HIV-2(2) bands are developed, the test indicates for the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The result is HIV positive.

| | |
|---|---|
|   | Reactive for anti-HIV-1 and anti-HIV-2 antibodies (Mix infection with HIV-1 and HIV-2). |
|   | Reactive for anti-HIV-1 antibodies (Infection with HIV-1). |
|   | Reactive for anti-HIV-2 antibodies (Infection with HIV-2). |

**INVALID RESULT:** If no Control(C) band is developed, the assay is invalid regardless of colour development on '1' and '2' bands as indicated below. Repeat the assay with a new device.


**PERFORMANCE CHARACTERISTICS:**

The performance of MERISCREEN HIV 1-2 WB has been determined by testing samples of anti-HIV positive samples and HIV negative samples. In addition, its performance on commercially available seroconversion panels has been evaluated.

**Diagnostic Sensitivity:**

In-house testing:

Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was evaluated using 555 anti-HIV positive samples including 400 HIV-1 positive samples, 112 HIV-2 positive samples, and 43 HIV-1 subtypes. All samples were identified as positive when tested with MERISCREEN HIV 1-2 WB assay kit. Diagnostic sensitivity of MERISCREEN HIV 1-2 WB assay kit was calculated as 100% (95% CI: 99.34% to 100.00%) and positive predicted value was calculated as 100%.

Testing at National Institutes of Biologicals, India:

Three lots of MERISCREEN HIV 1-2 WB were tested at National Institute of Biologicals, India to find out the diagnostic sensitivity. Diagnostic sensitivity of all three lots of MERISCREEN HIV 1-2 WB was found as 100%.

Overall Diagnostic Sensitivity of MERISCREEN HIV 1-2 WB:

Total 855 anti-HIV positive samples were tested with MERISCREEN HIV 1-2 WB and all samples were detected as positive. So, Diagnostic sensitivity of MERISCREEN HIV 1-2 is calculated as 100% (95% CI: 99.57% to 100.00%).

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**Diagnostic Specificity:**

In-house testing:

Diagnostic specificity of MERISCREEN HIV 1-2 WB was evaluated using 1901 HIV negative samples including 1190 healthy blood donor samples, 204 pregnant women samples, 207 hospitalized (clinical) samples and 100 Interfering substances. All samples were identified as negative when tested with MERISCREEN HIV 1-2 WB assay kit. Diagnostic specificity of MERISCREEN HIV 1-2 WB assay kit was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%.

Testing at National Institutes of Biologicals, India:

Three lots of MERISCREEN HIV 1-2 WB were tested at National Institute of Biologicals, India to find out the diagnostic specificity. Diagnostic specificity of MERISCREEN HIV 1-2 WB having lot no.:MI111306R, lot no.: MI111307R and lot no.: MI111308R were found as 100%, 100% and 99.79% respectively.

Overall Diagnostic Specificity of MERISCREEN HIV 1-2 WB:

Total 3344 HIV negative samples were tested with MERISCREEN HIV 1-2 WB. Among 3344, 3343 HIV negative samples were detected as negative whereas 01 sample was detected as "False positive".

So, Diagnostic specificity of MERISCREEN HIV 1-2 WB is calculated as 99.97% (95% CI: 99.83% to 100%).

**Sensitivity in Seroconversion Panels:**

MERISCREEN HIV 1-2 WB assay kit was tested with 40 HIV seroconversion panels including early sero-conversion HIV samples to evaluate the sensitivity in seroconversion panels. From the results, it can be concluded that MERISCREEN HIV 1-2 WB has relatively comparable sensitivity when compared with CE marked comparator assay kit i.e., Turklab' s Rapidan® Tester Anti-HIV ½ Test, WB/S/P.

**Repeatability & Reproducibility:**

Inter-day, inter-lot, inter-operator, within-run variability were assessed by testing samples in replicates of 3 by three operators over the five days. The results have shown 100% agreement with the sample status when tested with anti-HIV positive samples and HIV negative samples. The results and data analysis showed 100% sensitivity for anti-HIV positive samples and 100% specificity for HIV negative samples.

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**Hook effect:**

30 anti-HIV high-titer positive samples were diluted to generate moderate titer and weak titer anti-HIV positive samples and these samples were tested in replicates of three (03) with MERISCREEN HIV 1-2 WB assay kit to check whether MERISCREEN HIV 1-2 WB assay kit exhibit hook effect or not. There was no intensity drop observed anywhere with high-titer anti-HIV positive samples. So, it is concluded that MERISCREEN HIV 1-2 WB does not exhibit hook effect.

LIMITATIONS OF THE TEST:

1. As with all diagnostic tests, the test result must always be co-related with clinical findings.
2. Presence of heterophile antibodies in patient' s sample with Rheumatic diseases and autoimmune disorder may lead to false results.
3. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
4. A negative result at any time does not preclude the possibility of exposure or infection.
5. Repeat the test in case of very faint band or if have any doubt for test band.
6. Other clinically available tests should be used if questionable results are obtained.
7. This test should not be used on specimens from immunosuppressed individuals.
8. Reactive samples should be confirmed by EIA and RNA HIV test or Western Blot.

**REFERENCES:**


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***Product Disclaimer:***

*Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.*

***Warning:***

*The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.*

**Disposable Capillary tube**


**QA0I-701.58**

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Symbols used on Meril Diagnostics labels:

| | | | |
|---|---|---|---|
| REF Catalogue No. | LOT Batch No. | Consult instruction for use | |
| Manufacturer | Expiry date | For single use only do not reuse | |
| Manufacturing date | Keep dry | Keep away from direct sunlight | |
| Storage temperature | Sufficient for | Do not use if box open or damaged | |
| IVD In Vitro Diagnostics | EC REP Authorized European Representative in the European Community | CE European health & safety product label | |