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 specimen 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 specimen 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 specimens should always be confirmed by EIA and RNA HIV test or Western Blot in agreement with local regulations/national or international recommendation.
9. MERISCREEN HIV 1-2 WB assay kit is tested with following interfering and cross reacting specimens: Hepatitis, Anti-Chromatine, RF Factors. Anti-TPO, Influenza virus, Herpes virus, Bilirubin, Lipid, Hemoglobin, Ascorbic acid, Acetaminophen, Ethanol, Gamma Globulin, Hepatitis C, Hepatitis B, Syphillis and the performance of the kit was not affected by these interfering and cross-reacting factors. Interfering and cross reacting factors other than these may affect the performance of the kit.

REFERENCES:

1. Robinson, N., 2002. Immunogold conjugation for IVD applications. IVD Technology, 8(3):33-36.
2. Chandler, J., Gurmin, T., Robinson, N., 2000. The place of gold in rapid tests. IVD Technology, 7(2):37-49.
3. Weiss, A., 1999. Concurrent engineering for lateral flow diagnostics. IVD Technology, 5(7):48-57.
4. O'Farrell, B., Bauer, J., 2006. Developing highly sensitive more reproducible lateral flow assay part 1: New approaches to old problems.IVD Technology, 12(5):41-49.
5. Ketema, F., Zeh, C., Edelma. D.C., Saville, R., Constantine, N.T., 2001. Assessment of the performance of a rapid, lateral flow assay for detection of antibodies to HIV. J.Acquir. Immune. Defic. Syndr. , 27(1):63:70.
6. Gayle, H.D., Hill, G.L., 2001. Global impact of HIV and AIDS. Clin. Microbiol. Rev., 14(2):327-335.
7. Neogi, U., Bontell, I., Shet, A., Decosta, A., Gupta, S., Diwan, V., Larishram, R.S., Wanchu, A., Ranga, V., Banerjea, A.C., Sonnerborg, A., 2012, Molecular epidemiology of HIV-1 subtypes in India : origin and evolutionary history of predominant subtype C. Plos one, 7(6): e39819

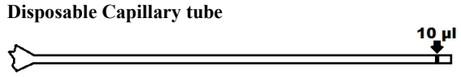
Product Disclaimer:

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



CIFU/HVWRPD01/03
Date: 18/09/2020

Digitally signed by Poiata Vitalie
Date: 2024.01.17 13:00:57 EET
Reason: MoldSign Signature
Location: Moldova

Symbols used on Meril Diagnostics labels:

REF Catalogue No.	LOT Batch No.		For single use only do not reuse
Manufacturer	Expiry date		Keep away from direct sunlight
Manufacturing date	Keep dry		Do not use if box open or damaged
Storage temperature	Sufficient for	CE	European health & safety product label
IVD In Vitro Diagnostics	Caution	CE 0197	This CE mark concerns lancets and alcohol swabs
Consult instruction for use	EC REP Authorized European Representative in the European Community		

Manufacturer of Lancets and Alcohol Swabs:
Beijing Ruicheng Medical Supplies Co. Ltd., No. 558 Zhangzikou, Yansong Town, Huairou District, 101400 Beijing, China.
Authorised Representataive of Lancets and Alcohol Swabs:
Lotus Global Co. Ltd., 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom

One Step test Rapid Test for detection of anti-HIV in Human Serum/Plasma/ Whole blood
MERISCREEN HIV 1-2 WB

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

Meril Diagnostics

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

INTENDED USE:

MERISCREEN HIV 1-2 WB Test is a single use, qualitative, screening, *in-vitro* diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for trained users (either in laboratory or in point-of-care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.

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 specimen 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:

Kit Contents	HVWRPD-01	HVWRPD-02
Test devices, pouched with desiccant	30	40
Assay buffer bottles	2 X 3.0 ml	2 X 3.0 ml
Specimen transfer device – capillary tubes (10 µl)	30	40
Sterile lancets	30	40
Alcohol swabs	30	40
Pack Insert	1	1

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Timer
2. New pair of disposable gloves
3. Pen
4. Sterile gauze/Plaster (for fingerstick whole blood specimens)
5. Centrifuge (for serum/plasma specimens only)
6. Biohazard Sharp Box
7. Non-sharp disposal biohazard container
8. Venous blood collection materials and precision pipette plus tips

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.

WARNINGS AND PRECAUTIONS:

1. For *in-vitro* diagnostics use only.
2. Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
3. Do not use any other buffer than the buffer supplied within this kit.
4. The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities.
5. Do not use any other specimens than fingerstick whole blood, venous whole blood, serum or plasma.
6. Do not use any other anticoagulants other than EDTA, heparin and citrate.
7. Allow all reagents and specimen(s) to attain room temperature (18ºC to 30ºC) before use.
8. 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.
9. Do not use the kit contents beyond the expiry date.
10. Do not use test device if pouch is lack of desiccant.
11. Do not use the lancet if the seal is broken.
12. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
13. Test Devices and assay buffers of different lot must not be mixed and used.
14. Do not re-use accessories like capillary tubes, alcohol swabs or lancets for testing purpose.
15. Perform the test by using kit's assay buffers. Performing the test with any other buffer is not valid.
16. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
17. Do not use haemolysed or lipemic specimen for testing.
18. Use sufficient volume of specimen for testing.

CE 1434
Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 13/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.
Tel.:+91-260-2408000, Fax:+91-260-2408025, Email: diagnostics@merillife.com, Web: www.merillife.com
EC REP Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

19. Do not re-use the Test Devices and pipette tips from the procedure; this may lead to inaccurate results.
20. Do not pipette reagents nor specimens by mouth and do not smoke, eat or drink while handling specimens and performing a test.
21. Avoid contact of reagents with eyes and skin. If either of the reagents come into contact with skin or eyes, wash thoroughly with water.
22. 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.
23. Handle specimens(s) and used materials as if it is capable of transmitting infection.
24. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective materials/expired kit/used kits. All remnants of specimen(s), used materials, expired materials/kits, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121ºC for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
25. Clean up spills thoroughly using an appropriate disinfectant.
26. 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.
27. In case of performance changes or product malfunction, stop using the kit immediately and contact your local distributor.

SPECIMEN COLLECTION AND PREPARATION OF FINGERSTICK WHOLE BLOOD:

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

Specimen Collection and Test Procedure for Fingerstick Whole Blood

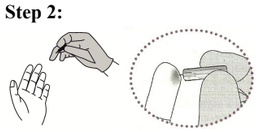
1. Bring test components and reagents to room temperature.
2. Choose a finger for the finger prick:
   - Do not choose a finger that is swollen, bruised or scarred.
   - Preferably choose the 3rd or 4th finger of the hand the patient does not use to write. Alternatively choose the heel or the earlobe for neonates.
3. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
4. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
5. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the patient's blood).
6. Take the safety-seal lancet.
7. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the fingerprint. Dispose the lancet immediately into the sharps box.
8. Make sure a well-formed drop of blood is present on the tip of the finger.
9. If there is no well-formed drop of blood, repeat the finger prick. Use a new lancet and choose a different puncture site.
10. Take the Capillary tube and suck blood up to 10µl mark from the whole blood drop. Place the circular end of the Capillary tube in the circle well (marked "S") so that it touches the strip (pad at the bottom of the well) Press down lightly to transfer the whole blood to the strip. (Repeat this step again to make specimen volume as 20 µl).
11. Put the used capillary tube into the non-sharps disposal container.
12. Add three drops of the Assay Buffer to the Specimen well (S). Buffer bottle should be held perpendicular to the test.

Interpret the test results at the end of 20 minutes. Do not read the results after 30 minutes.

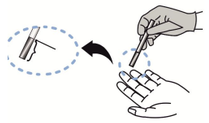
PICTORIAL REPRESENTATION OF FINGER-STICK TEST PROCEDURE:

Step 1:

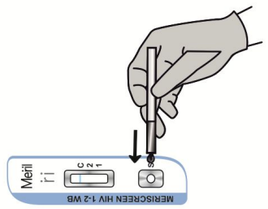
Step 2:



Step 3:

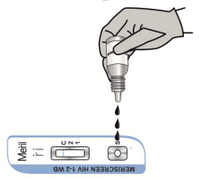


Step 4:



Add 20µl of sample (10µl whole blood-twice)

Step 5:



Dispense 3 drops of assay buffer

SPECIMEN COLLECTION AND PREPARATION OF VENOUS WHOLE BLOOD/PLASMA/SERUM/

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

VENOUS WHOLE BLOOD COLLECTION:

Collect venous whole blood specimen into collection tube containing EDTA, Citrate or Heparin by following laboratory procedure. Be sure that blood is well mixed before sampling.

PLASMA COLLECTION:

Collect blood specimen into collection tube containing EDTA, Citrate or Heparin by following laboratory procedure.

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 COLLECTION:

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 2-8ºC up to 3 days can be used for testing. For longer-term storage, Serum/Plasma specimens should be frozen at -20ºC and these specimens should not be frozen and thawed repeatedly (Not more than 3 times). Capillary whole blood shall be used/tested immediately after collection.

Test Procedure for Serum/Plasma/Venous Whole Blood

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 specimen up to the marking (of 10 µl) on Capillary tube. For serum/plasma, take 10 µl one time and for whole blood take 10 µl of specimen two times.
4. Add specimen (10 µl serum/plasma or 20 µl of whole blood) to the specimen well (S) using capillary tube. Dispose off used capillary tube as a bio-hazard waste in biohazard sharp bin. Alternately, a calibrated pipette and tips can be used in place of the capillary tube to dispense 10 µl of serum/plasma or 20 µl of venous whole blood specimen.
5. Add three drops of the Assay Buffer to the specimen well (S). **Interpret the test results at the end of 20 minutes. Do not read the results after 30 minutes.**

INTERPRETATION OF RESULTS:

Note: The faint blue line at "Control" position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation. A reddish purple band is expected at the control band if the test has been conducted properly.

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.

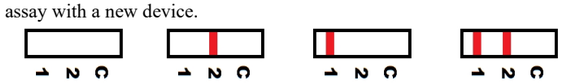
POSITIVE RESULT: If Control(C), HIV-1(1) and/or HIV-2(2) bands are developed, the test indicates for the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The result is HIV positive.

	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:

Failure of a reddish purple line to appear over the faint blue line at the control band even after the addition of specimens and assay buffer and no color development at control band, the assay is invalid as indicated below. Sometimes, color development due to red blood cells/their lysed components may cover the reading area which can affect the interpretation of results. Repeat the assay with a new device.

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 specimens of anti-HIV positive specimens and HIV negative specimens. In addition, its performance on commercially available seroconversion panels has been evaluated.

Diagnostic Sensitivity:

Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was evaluated using 555 anti-HIV positive specimens including 400 HIV-1 positive specimens, 112 HIV-2 positive specimens, and 43 HIV-1 subtypes. All specimens were identified as positive when tested with MERISCREEN HIV 1-2 WB assay kit. Entire study included testing of 412 EDTA plasma, 24 citrate plasma and 119 serum specimens. Diagnostic sensitivity of MERISCREEN HIV 1-2 WB assay kit was calculated for these specimen types are given in below table:

Specimen Type	Calculated diagnostic sensitivity	95% CI
EDTA Plasma	100%	99.08% to 100.00%
Citrate Plasma	100%	85.75% to 100.00%
Serum	100%	96.95% to 100.00%

Overall, 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%.

Diagnostic Specificity:

Diagnostic specificity of MERISCREEN HIV 1-2 WB was evaluated using 1961 HIV negative specimens including 1450 healthy blood donor specimens, 204 pregnant women specimens, 207 hospitalized (clinical) specimens and 100 Interfering substances. All specimens were identified as negative when tested with MERISCREEN HIV 1-2 WB assay kit. Entire study included testing of 509 EDTA plasma, 1210 citrate plasma, 31 Heparin plasma and 211 serum specimens. Diagnostic specificity of MERISCREEN HIV 1-2 WB assay kit was calculated for these specimen types are given in below table:

Specimen Type	Calculated diagnostic sensitivity	95% CI
EDTA Plasma	100%	99.28% to 100.00%
Citrate Plasma	100%	99.70% to 100.00%
Heparin Plasma	100%	88.78% to 100.00%
Serum	100%	98.27% to 100.00%

Overall, 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%.

Sensitivity in Seroconversion Panels:

MERISCREEN HIV 1-2 WB assay kit was tested with 30 HIV seroconversion panels including early sero-conversion HIV specimens 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 specimens in replicates of 3 by three operators over the five days. Study includes testing of plasma EDTA and Serum specimens. The results have shown 100% agreement with the specimen status when tested with anti-HIV positive specimens and HIV negative specimens. The results and data analysis showed 100% sensitivity for anti-HIV positive specimens and 100% specificity for HIV negative specimens.

Hook effect:

30 anti-HIV high-titer positive specimens were diluted to generate moderate titer and weak titer anti-HIV positive specimens and these specimens 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 specimens. So, it is concluded that MERISCREEN HIV 1-2 WB does not exhibit hook effect.

Specimen matrix equivalency:

25 anti-HIV positive and 25 HIV negative specimens were collected in eight specimen matrices: capillary whole blood by fingerstick, venous whole blood (EDTA, Citrate, Heparin), Plasma (EDTA, Citrate, Heparin) and serum. Specimens were "same day" fresh specimens (≤1 day after sampling) and tested with MERISCREEN HIV 1-2 WB assay kit. The data obtained during this study showed 100% agreement among matrices. There was no statistical difference observed among matrices.