MICROBIOLOGY EXTERNAL QUALITY ASSURANCE SCHEME

Under the aegis of Indian Association of Medical Microbiology

IAMM EQAS New Delhi

Department of Clinical Microbiology and Immunology
Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060

PC- 1029

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Result (Code No: DLH450 / ESIC Medical College & Hospital, Faridabad)

Batch Name	**28th QC, November**	**Batch Marks**	**71**
Start By Date	**17-Nov-2021**	**Submit By Date**	**24-Dec-2021**

Q 1. Smear :

1.1 : A 55 year old man who is a known case of alcoholic liver disease presented with fever & abdominal distension of 3 days duration. Smear prepared from ascitic fluid is provided to you. Perform Gram stain & report as below. (Marks: 5)

Expected Result (Cells):--Moderate no. of PMN cells seen. (Marks :2)

Participant's Answer (Cells):--3-5 pus cells/oil immersion field. (Marks :2)

Expected Result (Organism):--Moderate no. of gram negative bacilli seen. (Marks :2)

Participant's Answer (Organism):--Short, stout, encapsulated gram-negative bacilli present. (Marks :2)

Expected Result (Interpretation):--Gram negative bacterial peritonitis. (Marks :1)

Participant's Answer (Interpretation):--Peritonitis caused by gram-negative bacilli probably due to Klebsiella pneumoniae. (Marks :1)

Marks Obtained :-- 5

1.2 : A 45 year old man, HIV positive presented with loose stool. Smear from Stool specimen is provided. Perform Kinyoun stain & report as below. (Marks: 5)

Expected Result (Findings):--Few acid fast (1) oocysts seen (1). (Marks :2)

Participant's Answer (Findings):--Acid-fast oocysts 4-6 micrometer in size seen. (Marks :2)

Expected Result (Interpretation):--Suggestive of diarrhea due to Cryptosporidium. (Marks :3)

Participant's Answer (Interpretation):--Diarrhoea due to Cryptosporidium parvum. (Marks :3)

Marks Obtained :-- 5

1.3 : A 5 year old child presented with fever & shortness of breath, 5 days duration. Smear prepared from bronchoalveolar lavage is provided. Perform Gram stain & report as below. (Marks: 5)

Examiner Comments	**This question has been withdrawn from evaluation.**

Marks Obtained :-- (Not evaluated.)

Q 2. Culture/Sensitivity :

2.1 Three freeze dried (lyophilized) cultures of bacteria are provided. Identify and perform the antibiotic sensitivity testing. Use current CLSI guidelines wherever applicable for interpretation of antimicrobial sensitivity. EUCAST guideline can be used wherever CLSI guidelines are not available. A= Automated/M= Manual; tick whichever applicable. Attempt only one: Either "A" or "M". Kindly do not report both, even if done. Organism Isolated From Stool: (Marks: 15)

	Genus	Species
Expected Result (Identification of given organism)	***Vibrio* (Marks: 3)**	***cholerae* (Marks: 2)**
Participant's Answer	***Vibrio* (Marks: 3)**	***cholerae* (Marks: 2)**

Antibiotics	Cefotaxime	Ciprofloxacin	Tetracycline	Amikacin	Co-trimoxazole
Expected Result	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**R(Marks: 2)**
Participant's Answer	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**R (Marks: 2)**
Participant's Test Method	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**

Participant's Zone Size (mm) or MIC (ug/ml)	**1 microgram per millilitre**	**1 microgram per millilitre**	**2 microgram per millilitre**	**12 microgram per millilitre**	**4/76 microgram per millilitre**
Correct:-- 2 Minor Error:-- 1 Major Error:-- 0 Very Major Error:-- (-1)					
Marks Obtained: 15					

2.2 Organism Isolated From Urine: (Marks: 15)

	Genus	**Species**
Expected Result (Identification of given organism)	***Escherichia* (Marks: 3)**	***coli* (Marks: 2)**
Participant's Answer	***Escherichia* (Marks: 3)**	***coli* (Marks: 2)**

Antibiotics	**Nitrofurantoin**	**Co-trimoxazole**	**Ertapenem**	**Amikacin**	**Cefuroxime**
Expected Result	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**
Participant's Answer	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**
Participant's Test Method	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**
Participant's Zone Size (mm) or MIC (ug/ml)	**Less than or equal to 16 microgram per millilitre**	**Less than or equal to 20 microgram per millilitre**	**Less than or equal to 0.5 microgram per millilitre**	**Less than or equal to 2 microgram per millilitre**	**4 microgram per millilitre**
Correct:-- 2 Minor Error:-- 1 Major Error:-- 0 Very Major Error:-- (-1)					
Marks Obtained: 15					

2.3 Organism Isolated from Blood : (Marks: 15)

	Genus	**Species**
Expected Result (Identification of given organism)	***Enterococcus* (Marks: 3)**	***faecalis* (Marks: 2)**
Participant's Answer	***Enterococcus* (Marks: 3)**	***faecalis* (Marks: 2)**

Antibiotics	**Benzylpenicillin/ Ampicilllin**	**Teicoplanin**	**Linezolid**	**Gentamicin High Level**	**Vancomycin**
Expected Result	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**	**S(Marks: 2)**
Participant's Answer	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**	**S (Marks: 2)**
Participant's Test Method	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**	**Vitek -2**
Participant's Zone Size (mm) or MIC (ug/ml)	**2 microgram per millilitre**	**Less than or equal to 0.5 microgram per millilitre**	**2 microgram per millilitre**	**SYNERGY**	**1 microgram per millilitre**
Correct:-- 2 Minor Error:-- 1 Major Error:-- 0 Very Major Error:-- (-1)					
Marks Obtained: 15					

Q 3. : Serology:

3.1 : Please carry out following serological tests on the given samples. (Marks: 8)

Q.No.	**3.1.1**	**3.1.2**
Test	**Herpes IgM**	**ASO**
Expected Result	**Negative (Marks: 4)**	**Negative (Marks: 4)**
Participant's Answer	**NotAttempted (Not evaluated.)**	**Negative (Marks: 4)**

Center Comments	**ASO tested with Recombigen kit**

Marks Obtained :-- 4

3.2 : Perform the Blood Borne Viral (BBV) serology: HBsAg, HCV and HIV antibody on both the samples (Sample nos. 3.2.1 & 3.2.2) (Marks: 12)

Sample		HIV Antibody	HBsAg	HCV Antibody
3.2.1	Expected Result	Non-Reactive (Marks: 2)	Non-Reactive (Marks: 2)	Non-Reactive (Marks: 2)
	Participant's Answer	Non-Reactive (Marks: 2)	Negative (Marks: 2)	Negative (Marks: 2)
3.2.2	Expected Result	Reactive (Marks: 2)	Non-Reactive (Marks: 2)	Non-Reactive (Marks: 2)
	Participant's Answer	Reactive (Marks: 2)	Negative (Marks: 2)	Negative (Marks: 2)

Center Comments	HIV tested with COMBAIDS-RS Advantage kit based on Dot Immunoassay

Marks Obtained :-- 12

Grand Total Marks : 71
Marks Obtained: 71

Note : This is computer generated report, does not require signature of the EQAS provider.

----------End of Report----------

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

INTENDED USE:
MERICSCREEN HIV 1-2 WB Test is a qualitative, screening, invitro diagnostic immunochromatographic assay for detection of antibodies specific to HIV-1 and HIV-2 in human serum, plasma and whole blood. The test is intended for use by trained clinician 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 seroconversion is achieved by assays which respond to both IgM and IgG.

PRINCIPLE:
The MERICSCREEN HIV 1-2 WB rapid test kit contains a membrane strip, which is pre-coated with HIV-1 (gp41 and gp120) and HIV-2 antigens (gp36) on test region '1' and test region '2' respectively. Recombinant antigen (gp41, gp120 and gp36) 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 band 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, test device has to be brought to room temperature before opening. In case, the desiccant pouch is not present or changes colour from blue to light pink or colourless, the device should not be used.The unopened 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.

PRECAUTIONS:
1.For in-vitro diagnostics and professional use only.
2.Allow all reagents and sample(s) to attain room temperature (15°C to 30°C) before use.
3.Test Device is sensitive to humidity. Incise use the Test Device immediately once pouch is opened.
4.Do not use the kit contents beyond the expiry date.
5.Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
6.Test Devices and assay buffers of different lot must not be mixed and used.
7.Do not re-use accessories like capillary tubes for testing purpose.
8.Perform the test by using kit's assay buffers. Performing the test with any other buffer is not valid.
9.Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
10.Do not use haemolysed or lipemic specimen for testing.
11.Use sufficient volume of sample for testing.
12.Do not re-use the Test Devices and pipette tips from the procedure; this may lead to aberrant results.
13.Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
14.Avoid contact of reagents with eyes and skin.
15.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Avoid re-using gloves or use of washed gloves.
16.Handle sample(s) and used materials as if it is capable of transmitting infection.
17.Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. All remnants of samples(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.
18.Clean up spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND PREPARATION:
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
Sample: Serum/Plasma/Whole blood

A.WHOLE BLOOD:
Collect blood specimen into collection tube containing EDTA, Heparin or Sodium Citrate.

B.PLASMA:
Collect blood specimen into collection tube containing EDTA, Heparin or Sodium Citrate.

1.Separate the plasma by centrifugation, 1500 RPM for 10 minutes.
2.Carefully withdraw the plasma into new pre-labelled tube.

C.SERUM:
1.Collect blood specimen into a collection tube containing no anti-coagulants.
2.Allow the blood to clot.
3.Separate the serum by centrifugation, 1500RPM 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 test components, reagents and specimens 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 up to 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). 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

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

(CONT.)

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	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:

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, in our in-house testing. 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%.

Diagnostic Specificity:

Diagnostic specificity of MERISCREEN HIV 1-2 WB was evaluated using [illegible] HIV negative samples including [illegible] healthy blood donor samples, 200 pregnant women samples, 207 hospitalized (clinical) samples and 100 interfering substances. In our in-house testing, 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%.

Sensitivity in Seroconversion Panels

MERISCREEN HIV 1-2 WB assay kit was tested with 30 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.

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.

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.

Sample matrix equivalency

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

LIMITATIONS OF THE TEST:

1. As with all diagnostic tests, the test result must always be correlated 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 on 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 [illegible] test or Western Blot.
9. MERISCREEN HIV 1-2 WB assay kit is tested with following interfering and cross reacting samples: [illegible], Anti-Chlamydia, RF Factor, [illegible], Influenza virus, Herpes virus, Bilirubin, Lipid, Haemoglobin, Ascorbic acid, Acetaminophen, Ethanol, Gamma Globulin, Hepatitis C, Hepatitis B, Syphilis 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.

Note:

Since HIV-1 and HIV-2 share 30 to 50% similar antigenic structure (amino acid-sequence), there is a probability of cross reaction. Hence, appearance of HIV-1 and HIV-2 test line on the device does not necessarily imply co-infection from HIV-1 and HIV-2. Diagnosis of co infection must be performed by confirmatory test like PCR or NAAT.

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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.

Notice:

Every effort is made to supply ordered consignment as per the sample submitted but due to continuous development, the company reserves the right to improve / change any specifications / components without prior information / notice to the buyer.

Meril
Diagnostics

ISO 13485 & GMP Certfied

QUADRO™ HIV 1-2 Ab

4 Dot Rapid Test Device with Flow Through Technology for Detection of Anti-HIV Antibody

Evaluated by NARI

SENSITIVITY 100% • SPECIFICITY > 99.5% • NIB

Power of 2

- Synthetic Peptides coated on HIV 1 and HIV 2 individual Test Region
- Uniquely formulated Recombinant Proteins Coated on HIV 1 + 2 Test Region

Be Extra Sure

- Synthetic Peptides detects antibodies against the serotype specific linear epitopes
- Recombinant Peptides detects antibodies against the conformational epitopes

- Differential detection of HIV 1 and HIV 2
- Detects antibodies against all group of HIV (M, N and O) Including subtype 'C'
- Sensitivity : 100% and Specificity : 99.5%
- No Hook effect
- Result in **3 minutes**
- User Friendly Protocol

Meril Diagnostics Pvt. Ltd.

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Meril
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QUADRO™ HIV 1-2 Ab

4 Dot Rapid Test Device with Flow Through Technology for Detection of Anti-HIV Antibodies

TESTING PROCEDURE

3 DROPS OF BUFFER

1 DROP OF SAMPLE

3 DROPS OF BUFFER

2 DROPS OF GOLD CONJUGATE

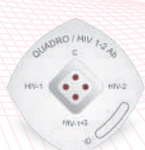
3 DROPS OF BUFFER

INTERPRET IN 3 MINUTES

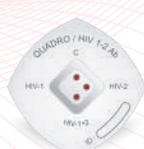
RESULT INTERPRETATION

NEGATIVE

HIV 1 REACTIVE



HIV 1 & 2 REACTIVE (MIXED INFECTION)



HIV 2 REACTIVE

INVALID

INVALID

ORDERING INFORMATION

Product Code	Product Name	Pack Size
HD4RPD-01	Quadro HIV 1 - 2 Ab	10 Tests
HD4RPD-03	Quadro HIV 1 - 2 Ab	50 Tests

QH/flyer/20170210/V1.01/IND

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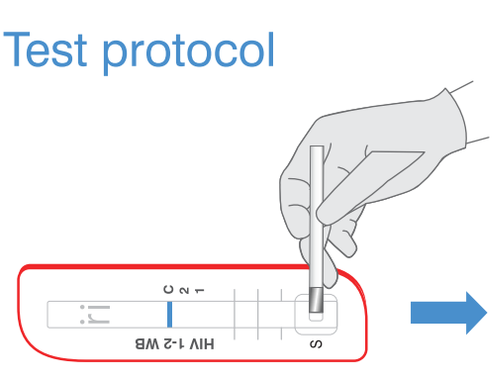
HIV 1-2 WB

One step qualitative immunochromatographic assay for detection of antibodies against HIV - 1 including subtype C and HIV - 2 in human serum, plasma and whole blood

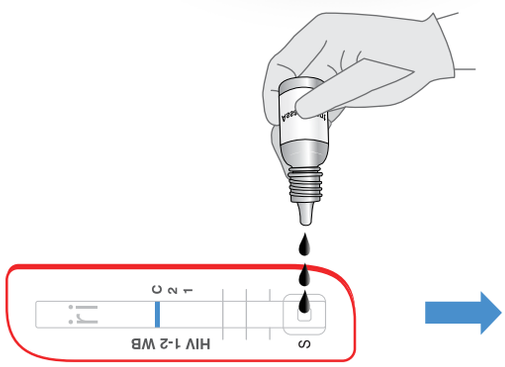
- 3rd Generation Assay
- Detection of IgM, IgG & IgA Antibodies
- Coated Ag: gp120, gp41 for HIV 1 and gp36 for HIV 2
- Specimen Type: Serum, Plasma, Whole blood
- Specimen Volume: 10 µl Serum / Plasma or 20 µl Whole Blood
- Buffer Volume: 3 drops
- Result Interpretation Time: 20 Minutes
- Diagnostic Sensitivity: > 99.5 %
- Diagnostic Specificity: > 99.0 %
- Long shelf life

Evaluated by NARI | Procured by NACO

Test protocol



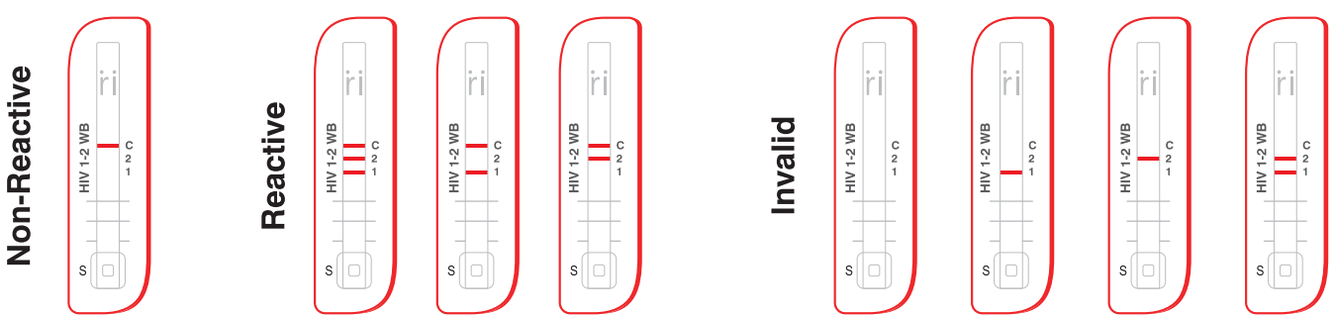
Add 10 µl of Serum / plasma or 20 µl whole blood (10µl whole blood-twice)



Dispense 3 drops of assay buffer

Read results at 20 minutes

Interpretation of test results



Product Code	Material Description	Pack Size
RPDHIV - 01	MERISCREEN HIV 1-2 WB	50 Test