MD HIV 1/2

Rapid test for the detection of HIV 1/2 in human blood, serum, or plasma

Product Code: MDHIV12001
Version: 210331

Intended use

The MD HIV 1/2 test is a rapid visual immunoassay for the qualitative detection of HIV-1 and 2. It is intended for professional use to accurately diagnose HIV in human whole blood, serum, or plasma.

HIV (Human Immunodeficiency Virus) is a pathogen causing AIDS (Acquired Immunodeficiency Syndrome). HIV/AIDS is characterized by changes in the amount of T-cell lymphocytes. The virus, in infected individuals, causes a depletion of the T-helper cells, which are a sub-population of T-cells.

This leaves patients susceptible to severe opportunistic infections and malignant neoplasias. The presence of the virus itself causes the immune system to produce antibodies, which can be detected by the MD HIV 1/2 test kit.

Principle of the test

The MD HIV 1/2 test (whole blood, serum, or plasma) detects HIV 1/2 through visual interpretation of colour development on the membrane. Capture antigens (GP41 and GP36) are immobilized on the nitrocellulose membrane. The red blood cells are held back by the blood filtration pad releasing serum which binds selectively to these antigens as the serum is wicked up the strip. The colloidal gold signal reagent is coated with specific HIV antigens which binds with the antibody-antigen complexes formed on the membrane, producing a red line. The presence of coloured lines at the test line region indicates a positive result, while their absence indicates a negative result. The presence of an upper red line (the procedural control line) demonstrates the test has been performed correctly.

Reagents and material provided in the kit

Units	Components
25	Single pouched test cassettes with desiccant
25	Disposable blood collection devices (10 µL)
25	Sterile Wipes
25	Lancets
1	Reaction Buffer 3 mL (used to ensure good flow and accuracy)
1	Instructions for use

Timer required but not provided.

Storage conditions and shelf life

The following indications must be followed to ensure accurate test performance:

1. Store kits at room temperature between 4 and 40°C.
2. Store in a dry place, humidity can affect test performance.
3. The test devices must remain pouched until usage.
4. The kits have a shelf-life of 24 months after manufacturing.
5. The expiration date printed on the kits and pouches must be verified prior to use.
6. Kits must not undergo freezing conditions.

Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure, results interpretation, and precautions precisely to get accurate results.
4. Do not open the sealed pouch unless ready to conduct the test.
5. Do not use expired tests.
6. Do not mix reagents and components from different lots.
7. Do not use the test if the pouch is damaged or if the seal is broken.
8. Do not eat, drink or smoke while handling specimens and test devices.
9. Wear protective gloves and eye protection while handling specimens.
10. Respect standard procedures to dispose of specimens and potentially contaminated material, in a biohazard container.
11. MD HIV 1/2 test does not present any risk to the user if used as recommended.

Specimen collection and storage

Collection by venipuncture

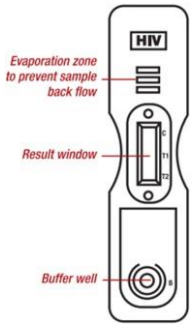
1. Collect the whole blood into the collection tube (containing EDTA, citrate, or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2 - 8°C. For storage periods greater than three days, freezing is recommended. Specimens should be brought to room temperature before use. Using an old specimen or using a control standard for an extended period, usually for more than three days, can cause non- specific reactions.
3. When stored at 2 - 8°C, the whole blood sample should be used within three days.

Collection using a lancet

1. Clean area to be lanced with an alcohol/antiseptic swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take the sample pipette provided, and while gently squeezing the tube, immerse the open end into the blood drop and then gently release the pressure to draw blood into the sample pipette up to the second line (10 µL).

Test procedure

Prior to use, allow the test in the foil pouch to reach room temperature.

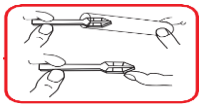


Open the foil pouch to be used, only prior to conducting the test, exposing the cassette.

Select the finger to puncture, usually the side of the third or fourth finger.
Clean with alcohol swab and allow to air dry.

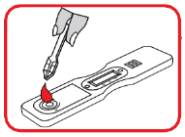
Puncture the finger with a sterile lancet. Blood will well to the surface. Re-do procedure on another finger if necessary.

Touch the collection device supplied to the blood spot and allow the blood to fill up to the second line (10 µL).



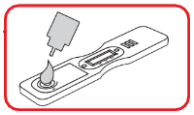
Step 1

Transfer blood/serum/plasma to the test cassette by gently touching the nozzle to the sample well.



Step 2

Place 5 drops of the reaction buffer into the sample well.



Step 3

Allow the reaction to proceed for 15 minutes.
Read the result and dispose of the cassette.

Manufactured by:
Medical Diagnostech (Pty) Ltd.
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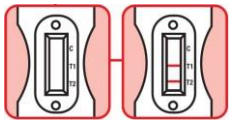
Interpretation of results

Invalid:
Either no lines are observable or either one or both test lines are present without a control line. Improper test procedure was carried out or reagents have deteriorated. Re-test.



Negative:
The control line is present but neither test line; demonstrating the test was performed correctly and no HIV antibodies are detected.

HIV-1 Positive:
The middle (T1) and top (control; C) lines are evident.

HIV-2 Positive:
The bottom and top (control) lines are evident.

Note: If all three lines are evident, this indicates a mixed infection.

Limitations of the test

1. The MD HIV 1/2 test is for professional in vitro diagnostic use. It is intended to be used for the qualitative detection of HIV-1 and 2 specific antibodies.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the existence of HIV antibodies in the blood, as the antibodies may be absent or below the minimum detectionlevel of the test. It should also be taken into account that the immune system can take up to 3 months to develop antibodies which are detected in HIV tests. If the patient is uncertain as to the time of potential exposure to HIV infection, then another test should be taken in 3 months' time.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings.

Internal quality control

The MD HIV 1/2 test includes a control line that is used as a procedural control. It should always appear confirming that the test procedure has been performed accurately.

Symbols

IVD	For in-vitro diagnostic use only	For single use only	
Σ	Content	Expiry date	
LOT	Lot number	Storage temperature	

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