# LordsMed HIV 1&2 Rapid Test

(Wholeblood/Serum/Plasma)

| Catalog No. | Pack Size | Specimen Type |
|---|---|---|
| HIVLMR01 | 25 Test Device | WholeBlood/Serum/Plasma |
| HIVLMR02 | 50 Test Device | WholeBlood/Serum/Plasma |
| HIVLMR03 | 25 Test Device | Serum/Plasma |
| HIVLMR04 | 50 Test Device | Serum/Plasma |

**INTENDED USE**

LordsMed HIV 1&2 Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of HIV-1 and HIV-2 antibodies (IgG, IgM, IgA) in human serum, plasma, and whole blood. It is used for professional use only.

**TEST PRINCIPLE**

LordsMed HIV 1 & 2 Rapid Test for qualitative detection of antibodies of HIV in human specimen. It is based on the principle of immunochromatography, a unique double antigen system immunoassay on a nitrocellulose membrane. Test device contains a test strip composed of absorbent pad, sample pad, nitrocellulose membrane and conjugate pad. Highly purified recombinant antigens of HIV (gp41 and gp120 for HIV-1 and gp-36 for HIV-2) are coated on the nitrocellulose membrane as separate test lines (1&2) and goat anti-mouse/rabbit IgG at control line region 'C'. The gold conjugate pad contains recombinant proteins of HIV representing (gp41 and gp 120 for HIV-1 and gp-36 for HIV-2) and mouse/rabbit IgG.

When a test specimen (serum/plasma/whole blood) containing HIV-1&2 antibodies is added to the sample well along with required volume of assay buffer, it makes an immune complex with recombinant antigen of HIV-1&2 conjugated with colloidal gold. The complex moves further on the nitro cellulose membrane to the test line regions, where it is captured by the HIV-1&2 antigens coated on the membrane and leads to the formation of purplish pink colored band at respective positions. The presence of colored bands in the test line regions indicates for the presence of antibodies to HIV-1&2 in the specimen. Appearance of no purplish pink band at test line regions, indicates for the absence of HIV-1&2 antibodies or level of the antibodies are below detection limit. The unreacted conjugate and unbound complex, if any, moves further on the membrane and are subsequently captured by the protein coated at the control line region 'C' forming an additional purplish pink band. This control band act as a procedural control and serves to validate the results.

**MATERIALS PROVIDED**

1. Test Device
2. Plastic dropper
3. Assay Buffer
4. Pack insert
5. Desiccant

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock or Timer

**PRECAUTIONS**

1. For professional *In - Vitro* diagnostic use only. Do not use after expiration date.
2. Do not use the components in any other type of test kit as a substitute for the components in this kit.
3. Do not use haemolysed blood specimens for testing.
4. Do not eat, drink, or smoke in the area where the specimens or kits are handled.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, mask cap, disposable gloves, and eye protection when specimens are being tested.
7. Humidity and temperature can adversely affect results.

**STORAGE AND STABILITY**

1. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum, Plasma and Whole blood specimens may be stored at 2-8°C for up to 3 days. For long term storage, serum/plasma should be kept below -20°C.
2. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

**PROCEDURE**

**For LordsMed HIV 1&2 Rapid Test**

1. Bring the specimen and test components to the room temperature before use if kept under refrigerated condition.
2. Check the expiration date of the test. If expired, do not use it but take another test from an unexpired kit.
3. Perform the test immediately after opening of pouch.
4. Take out the test device from the pouch and place on flat surface, don't bring the test device just below the fan or high blow of air.
5. Do not use the test device if pouch is damaged.
6. Mention specimen ID on test device.
7. **Add 1 drop (20 µl) of serum/plasma/whole blood** into the sample well (S) using provided dropper.
8. Hold the assay buffer vial vertically above the sample window and **add 1-2 drop (40-60 µl) of assay buffer** into the sample well (S) of the test device.
9. Interpret test results within 15-20 minutes.

**TEST INTERPRETATION (REFER TO FIGURE)**

**POSITIVE: A)** A distinct purplish pink colored line appears on the control region 'C' and on the test region '1' and '2', the specimen contains antibodies of HIV-1 and HIV-2 respectively.

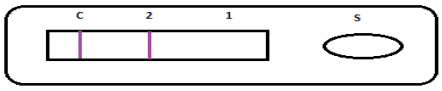



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**B)** A distinct purplish pink colored line appears on the control region 'C' and on the test region '1', the specimen contains antibodies of HIV-1.

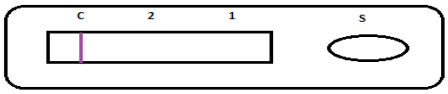



**C)** A distinct purplish pink colored line appears on the control region 'C' and on the test region '2', the specimen contains antibodies of HIV-2.



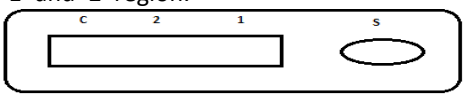

**NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HIV-1 & 2 antibodies present in the specimen.

**NEGATIVE**: One purplish pink colored line appears in the control region 'C' and no purplish pink colored line appears in '1' & '2' test region, indicates that there are no detectable level of HIV antibodies and specimen is negative for HIV-1 & 2

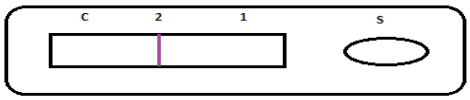



**INVALID:** The test should be considered invalid if,

A) No purplish pink colored line appears in control 'C' region test '1' and '2' region.




B) No purplish pink colored line appears in control 'C' region and in test '1' region.




C) No purplish pink colored line appears in control 'C' region and in test '2' region.




**PERFORMANCE CHARACTERISTICS**

As per National Institute of Biologicals – Noida, (NIB) the sensitivity is 100% and specificity is 100%

**SENSITIVITY & SPECIFICITY**

| | Positive sample | Negative sample | Rate |
|---|---|---|---|
| Positive sample | 54 | 00 | 99.39% (Sensitivity) |
| Negative sample | 01 | 20 | 100% (Specificity) |
| Total | 55 | 20 | 99.56% (Total accuracy) |

**LIMITATION**

1. This test should be used for the detection of antibodies to HIV in serum/plasma/whole blood. Neither the quantitative value nor the rate of increase in HIV antibody concentration can be determined by this qualitative test.
2. This test will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV 1 and/or HIV 2 infection.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or Western Blot analysis.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow up tests using other clinical methods are recommended. Negative results do not preclude the HIV infection and should be concluded with Confirmatory test.

**BIBLIOGRAPHY**

1.Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE and White, TJ. The origin of HIV-1 isolate HTLV-IIIB. Nature (1993) 3/363:466-9.
2.Arya, SK, Beaver, B, Jagodzinski, L, Ensoli, B, Kanki, PJ, Albert, J, Fenyo, EM, Biberfeld, G, Zagury, JF and Laure, F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987) 328:548-550.
3.Caetano JA Immunologic aspects of HIV infection. Acta Med Port (1991) 4 Supple 1:52S-58S.

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| REF | Catalog No | | Attention Caution |
| LOT | Batch No. | | Instruction for use |
| | Manufacturing Date | IVD | *In-vitro* Diagnostics |
| | Expiry Date | | Storage temperature |
| | Manufacturer | Σ | No. of Tests |



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