ImmunoScience INDIA

ImmunoQuick

VIRO-4

Rapid HIV 1/2 Antibody, HCV Antibody, Syphilis Antibody & HBsAg Antigen Test - Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

PRINCIPLE

HIV Test:

After addition of the serum/plasma/whole blood sample and assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant HIV 1, HIV 2 antigen and Mouse IgG. If the sample contains detectable levels of the Antibodies against HIV 1/HIV 2 or both Antigens, it reacts with the gold conjugated respective Antigen to form a complex. This complex moves further and reacts with HIV 1/HIV 2 Antigen coated as a separate test lines on the nitrocellulose membrane to form colored band. The unbound complex and the Mouse IgG conjugated colloidal gold particles move further to the goat anti-Mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result.

HCV test:

After addition of the sample and assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HCV antigen and Mouse IgG. If the sample contains detectable levels of the Antibodies against HCV Antigen, it reacts with the gold conjugated HCV Antigen to form a complex. This complex moves further and reacts with HCV Antigen coated as a test line on the nitrocellulose membrane to form colored band. The unbound complex and the Mouse IgG conjugated colloidal gold particles move further to the goat anti-Mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result.

HBsAg test:

After addition of the serum/plasma sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HBsAg specific Antibody and Rabbit IgG. If the sample contains detectable levels of the HBsAg Antigen, it reacts with the gold conjugated HBsAg specific Antibody to form a complex. This complex moves further and reacts with HBsAg specific Antibody coated as test line on the nitrocellulose membrane to form colored band (test line). The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result.

Syphilis test:

After addition of the sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Treponema pallidum specific antigens (17,47 kDA) and Rabbit IgG. If the sample contains detectable levels of the Treponema pallidum antibodies, it reacts with the gold conjugated recombinant Treponema pallidum specific antigens to form a complex. This complex moves further and Treponema pallidum specific antibodies conjugate complex reacts with recombinant Treponema pallidum specific antigens (17,47 kDA) test line on the nitrocellulose membrane area to form colored band. The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result.

CONTENTS OF KIT

1. Pouches of Test device With Desiccant
2. Assay Buffer Bottle
3. Plastic Dropper
4. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample Container
3. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all information in the pack insert carefully before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use expired test, Expiry date is printed on the foil pouch and kit.
3. Store kit in a dry place at temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the used test hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat used samples and tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION

1. This test can be performed using serum/plasma/whole blood.
2. Testing should be performed immediately after the Collection of samples. Do not leave the specimen at room temperature for prolonged periods.
3. For whole blood, Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants.
4. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to maximum three days.
5. Clotted, contaminated samples should not be used for performing the test.

TEST PROCEDURE

1. Allow the kit components and sample to reach room temperature (20°C to 30°C).
2. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
3. Remove the test device, plastic dropper and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has turned colorless or pink, discard the test and use another test.
4. Label the test with patient's identity
5. Place the device on flat plane surface and,

   HIV: add 1 drop (Approx. 30 µl) of serum/plasma or 2 drops of whole blood (Approx. 60 µl) sample in well "S". Immediately dispense one drop (Approx. 30 µl) of assay buffer into well "S", by holding the plastic dropper bottle vertically.

   HCV: add 1 drop (Approx. 30 µl) of serum/plasma or 2 drops of whole blood (Approx. 60 µl) sample in well "S". Immediately dispense one drop (Approx. 30 µl) of assay buffer into well "S", by holding the plastic dropper bottle vertically.

HBsAg: Add 2 drops (Approx. 60 µl) of serum/plasma sample in well "S" (do not add assay buffer in HBsAg test for serum/plasma specimen)

OR

Add 2 drops (Approx. 60 µl) of whole blood sample in well "S" and immediately dispense one drop (Approx. 30 µl) of assay buffer into well "S", by holding the plastic dropper bottle vertically (Use assay buffer in HBsAg test for whole blood specimen only).

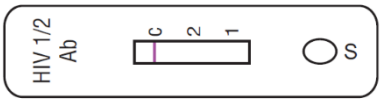
Syphilis: add 2 drops (Approx. 60 µl) of serum/plasma sample or 3 drops whole blood in well "S".
(do not add assay buffer in syphilis test)

6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

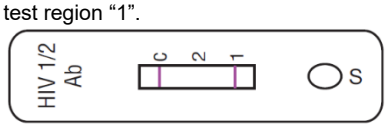
INTERPRETATION OF RESULTS

HIV:

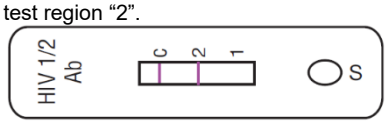
Negative: If colored line appears at the control region 'C' only.



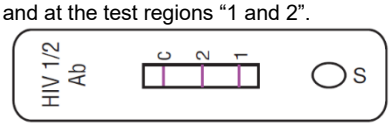
HIV 1 Positive: A distinct colored line appears at the control region 'C' and at the test region "1".



HIV 2 Positive: A distinct colored line appears at the control region 'C' and at the test region "2".

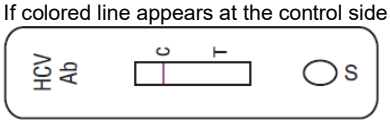


HIV 1 and 2 Positive: A distinct colored lines appears at the control region 'C' and at the test regions "1 and 2".

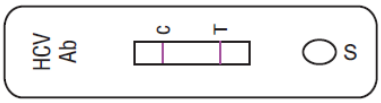


HCV:

Negative: If colored line appears at the control side 'C' only.



Positive: A distinct colored line appears at the control side 'C' and at the test side "T".



HBsAg:

Negative: If colored line appears at the control side 'C' only.

Positive: A distinct colored lines appears at the control side 'C' and at the test side "T".

Syphilis:

Negative: If colored line appears at the control side 'C' only.

Positive: A distinct colored line appears at the control side 'C' and at the test side "T".

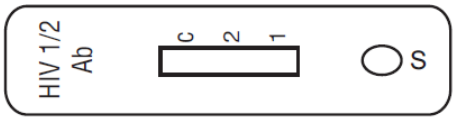
Invalid:

The test shall be considered invalid and shall be retested with using a fresh device if,

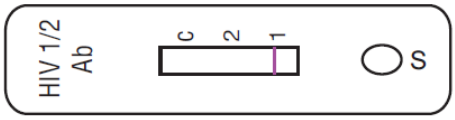
a. Control line is not appeared in any device.
b. Control line not appeared even if the test line is present in any device.

Invalid in HIV:

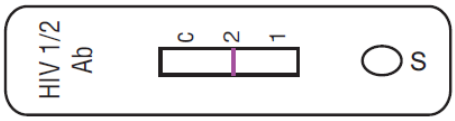
Invalid: The test should be considered invalid if,
A) No line appears at 'C', '1' and '2' regions



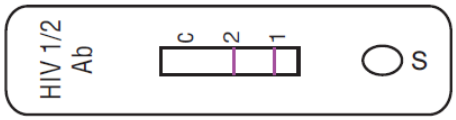
B) No line appears at 'C' and '2' region and line appears only at '1' region



C) No line appears at 'C' and '1' region and line appears only at '2' region

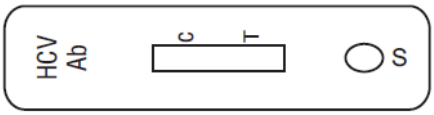


D) No line appears at 'C' region and line appears at '1' and '2' regions

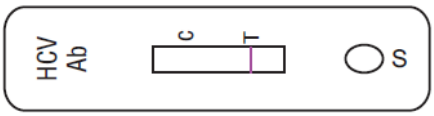


Invalid in HCV:

Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' region

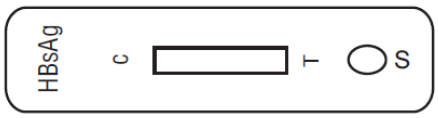


B) No line appears at 'C' region and line appear only at 'T' region



Invalid in HBsAg:

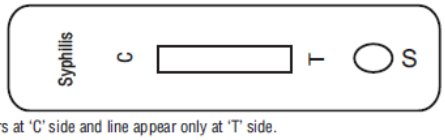
Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' side.



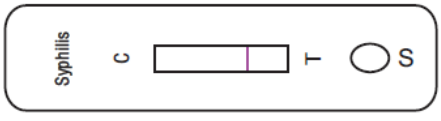
B) No line appears at 'C' side and line appear only at 'T' side.

Invalid in Syphilis:

Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' side.



B) No line appears at 'C' side and line appear only at 'T' side.



Note:

The sample may be positive or negative in one, multiple or none of the all tests depending upon the pathological status.

LIMITATIONS

This test provides presumptive diagnosis, A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. Hence, positive test needs to be confirmed by confirmatory tests.

REFERENCES

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IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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