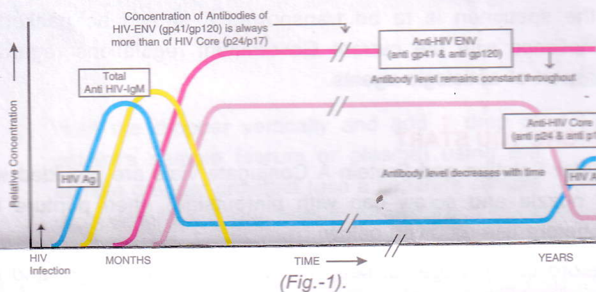
HIV TRI-DOT

Rapid Visual Test for the Qualitative Detection of Antibodies to HIV-1 & HIV-2 in Human Serum/Plasma
Separate Dots for HIV-1, HIV-2 & Control

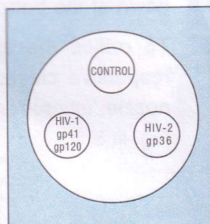
I. HISTORICAL REVIEW AND AETIOLOGY OF AIDS (Acquired Immuno Deficiency Syndrome)

First confirmed case of AIDS was identified in 1983 and by 1984 the etiologic agent, the Human Immunodeficiency Virus (HIV), subsequently named HIV-1 was isolated. Shortly afterwards in 1985 another retrovirus subsequently named HIV-2 was isolated in Africa. These two viruses belong to the retrovirus group and are slow viruses. The structure, gene organisation and serological behaviour of HIV-1 & HIV-2 and their complete nucleotide sequence has been determined. This knowledge has laid a foundation for the development of a new assay based on Recombinant DNA technology leading to the differential detection of antibodies to HIV-1 & HIV-2 (if present) in Human Serum or Plasma. Research has shown that antibodies produced against envelope gene are found in infected people as shown in graph, (Fig.-1).



(Fig.-1).

HIV TRI-DOT has been developed and designed using gp41, C terminal of gp120 & gp36 representing the immunodominant regions of HIV-1 & HIV-2 envelope gene structure respectively. The device (an immunofiltration membrane) includes a "Built-in Quality Control DOT" which will develop colour during the test, thereby, confirming proper functioning of the device, reagents and correct procedural application. This CONTROL DOT is the "Built-in Quality Control." (Fig.2)



(Fig.-2).

HIV TRI-DOT has been specially researched, developed and engineered using several thousands of serum/plasma specimens. It has also been evaluated by UNAIDS (WHO) Geneva, using samples of European, Asian, Latin American & African origin. The Sensitivity and Specificity has been extremely high in these samples of diverse origin.

The panel used for evaluation of HIV TRI-DOT by Institute of Tropical Medicine, WHO Collaborating Centre in AIDS, Belgium also included HIV-O Virus, which was found reactive with HIV TRI-DOT.

2. INTENDED USE

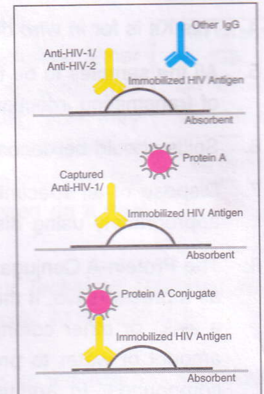
The HIV TRI-DOT Test is a visual, rapid, sensitive and accurate immunoassay for the differential detection of HIV-1 & HIV-2 antibodies (IgM, IgG & IgA) in Human Serum or Plasma using HIV-1 & HIV-2 Antigens immobilized on an immunofiltration membrane. The test is a screening test for anti-HIV-1 & anti-HIV-2 and is for *in vitro* diagnostic use only.

3. PRINCIPLE OF THE TEST

HIV antigens are immobilized on a porous immunofiltration membrane. Sample and reagents pass through the membrane and are absorbed into the underlying absorbent.

As the patient's sample passes through the membrane, HIV antibodies, if present, bind to the immobilized antigens.

Conjugate binds to the Fc portion of the HIV antibodies to give distinct pinkish purple DOT(s) against a white background. (Fig.-3)



(Fig.-3).

4. KIT DESCRIPTION

COMPONENTS	CONTENTS	PREPARATION
1. HIV TRI-DOT Test Device	Packed individually. Device has membrane with 1 Control & 2 Test Dots, one each for HIV-1 & HIV-2.	Cut open the pouch before use.
2. Buffer Solution	Buffer containing BSA and sodium azide.	Ready to use.
3. Protein-A Conjugate	Protein-A Conjugate in liquid form containing sodium azide.	Ready to use.
4. Sample Dropper	Long Plastic dropper provided for adding the sample.	

Store the kit at 2-8°C in the driest area available. Bring all reagents and test components to room temperature (20-30°C) before use. Return entire kit at 2-8°C when not in use. DO NOT FREEZE TEST COMPONENTS.

5. MATERIAL REQUIRED BUT NOT PROVIDED

The kit contains all the items required to perform this test. But if the sample is viscous/turbid/contains particulate matter, a centrifuge will be required, to separate off the suspended matter. Since the test is completed in less than 5 minutes a timer or stop watch is not essential.

6. STORAGE

Store the entire kit at 2-8°C in the coolest and driest area available. The components are stable for 15 months from the date of manufacturing, when stored at 2-8°C. Do not use the kit beyond the expiry date. DO NOT FREEZE THE KIT COMPONENTS.

7. KIT PRESENTATION

50 Test Pack
100 Test Pack
200 Test Pack

HIV TRI-DOT

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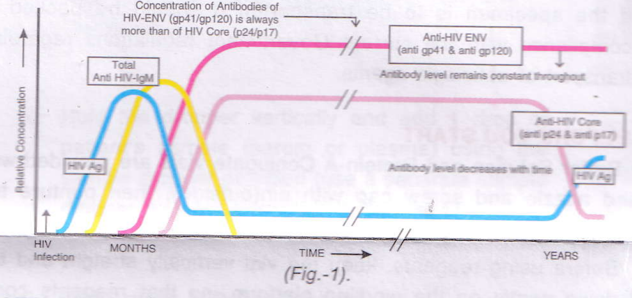

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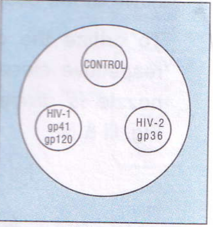

(Fig.-2).

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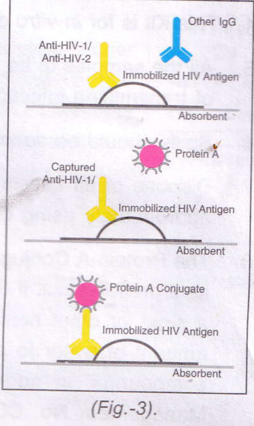
As the patient's sample passes through the membrane, HIV antibodies, if present, bind to the immobilized antigens.

Conjugate binds to the Fc portion of the HIV antibodies to give distinct pinkish purple DOT(s) against a white background. (Fig.-3)



(Fig.-3).

4. KIT DESCRIPTION

COMPONENTS	CONTENTS	PREPARATION
1. HIV TRI-DOT Test Device	Packed individually. Device has membrane with 1 Control & 2 Test Dots, one each for HIV-1 & HIV-2.	Cut open the pouch before use.
2. Buffer Solution	Buffer containing BSA and sodium azide.	Ready to use.
3. Protein-A Conjugate	Protein-A Conjugate in liquid form containing sodium azide.	Ready to use.
4. Sample Dropper	Long Plastic dropper provided for adding the sample.	

Store the kit at 2-8°C in the driest area available.
Bring all reagents and test components to room temperature (20-30°C) before use. Return entire kit at 2-8°C when not in use. DO NOT FREEZE TEST COMPONENTS.

5. MATERIAL REQUIRED BUT NOT PROVIDED

The kit contains all the items required to perform this test. But if the sample is viscous/turbid/contains particulate matter, a centrifuge will be required, to separate off the suspended matter. Since the test is completed in less than 5 minutes a timer or stop watch is not essential.

6. STORAGE

Store the entire kit at 2-8°C in the coolest and driest area available. The components are stable for 15 months from the date of manufacturing, when stored at 2-8°C. Do not use the kit beyond the expiry date. DO NOT FREEZE THE KIT COMPONENTS.

7. KIT PRESENTATION

50 Test Pack   100 Test Pack
200 Test Pack

LIMITATIONS

The HCV Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of anibodies to HCV in serum or plasma specimen.

The HCV Test Device (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteriafor the diagnosis of Hepatitis C viral infection.

As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

EXPECTED VALUES

e HCV Test Device (Serum/Plasma) has been compared with a ding commercial HCV EIA test. The correlation between these o systems is 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

e HCV Test Device (Serum/Plasma) compared with a leading nmercial HCV EIA test using clinical specimens.

Specificity

e recombinant antigen used for the HCV Test Device erum/Plasma) is encoded by genes for both structural ıcleocapsid) and non-structural proteins. The HCV Test Device erum/Plasma) is highly specific for antibodies to Hepatitis C rus compared with a leading commercial HCV EIA test.

Sample	Total No. of samples tested	Aspen HCV		sensitivity (%)	Specificity (%)
		Positive	Negative		
Negative	1500	2	1498	-	99.8
Positive	300	299	01	99.6	-

BIBLIOGRAPHY

H.J. Alter, and M. Houghton, Kuo, G., Q.L. Choo, . *An assay for rculating antibodies to a major etiologic Virus of human non-A, on-B hepatitis*. Science 1989; 244:362

H.T.M. Cuypers, H.W. Reesink, van der Poel, C. L., and N.Lelie. *Confirmation of hepatitis C Virus infection by new four-ntigen recombinant immunoblot assay*. Lancet 1991; 337:317

Wilber, J.C. *Development and use of laboratory tests for epatitis C infection: a review*. J. Clin. Immunoassay 1993; 16:204

HCV

Hepatitis C Virus Rapid Test Device (Serum/Plasma) Package Insert

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma. For professional in vitro diagnostic use only.

INTENDED USE

The HCV Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma

SUMMARY

Hepatitis C Virus (HCV) is a small, enveloped, positive sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non- B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.

The HCV Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes a combination of protein A coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV Test Device (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma specimen reacts with the Protein A coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains protein A coated particles and HCV antigen coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, nonhemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
- 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.
- If specimens are to be shipped, they should be packed in ompliance with federal regulations for transportation of etiologic agents.

MATERIALS PROVIDED

Materials Provided

- Test devices
- Disposable specimen droppers
- Buffer
- Package insert

Materials Required But Not Provided

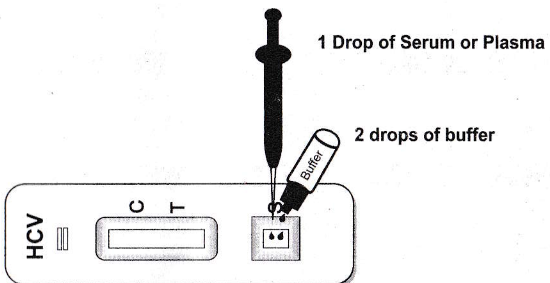
- Specimen collection container
- Pipette and disposable tips (optional)
- Centrifuge (for plasma only)
- Timer

DIRECTION OF USE

Note: Bring the test device, specimen and buffer to the room temperature if stored at 2-8°C

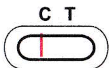
Take out the test device from the pouch and place on a clean & flat surface

- Add **1 drop** (25µl) of **serum /plasma** to the specimen well of test device using dropper / pipette. Then **add 2 drops** of **buffer** (70µl). Read result at **20 minutes**. (Do not interpret the result after 30 minutes)

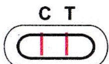


INTERPRETATION OF RESULTS

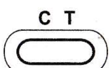
NEGATIVE: Pink/Purple line at C only



POSITIVE: Pink/Purple lines at C & T



INVALID: If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.



QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

ADDITIONAL MATERIAL REQUIRED

Slide test method: Stop watch, Variable Micropipettes.
Quantitative method: Timer, Kahn tubes / test tubes, Pipettes (0.1ml, 1ml), Physiological saline, Incubator (37^0C), Test tube rack.

PRINCIPLE

When the coloured, smooth, attenuated TYDAL® antigen suspensions are mixed / incubated with patient serum, anti-*Salmonella* antibodies present in the patient serum react with the antigen suspensions to give agglutination. Agglutination is a positive test result, indicating presence of anti-*Salmonella* antibodies in the patient serum. No agglutination is a negative test result indicating absence of anti-*Salmonella* antibodies.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The *S. typhi 'O'*, *S. paratyphi 'CO'* reagents contain 0.5% Phenol, *S. typhi 'H'*, *S. paratyphi 'AH'*, *S. paratyphi 'BH'*, *S. paratyphi 'CH'* reagents contain 0.3% Formaldehyde and *S. paratyphi 'AO'*, *S. paratyphi 'BO'* reagents contain 0.7% Ethanol along with 0.1% Sodium azide as preservatives. Avoid contact with skin and mucosa. Do not breathe vapour. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Sodium azide may react with lead and copper in plumbing and form highly explosive metal oxides, on disposal flush with large quantities of water.
3. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls. Positive control provided with the kit only for TYDAL® 4 x 5 ml set (REF.: 105200045), 2 x 5 ml set (REF.: 105210025 & REF 105200025), 2 x 2 x 5 ml set (REF.: 105210225) and TYDAL® PLUS 8 x 5 ml set (REF.: 105200085). Negative Control provided with the kit only for 8 x 5 ml (REF.: 105200085) and 2 x 5 ml (REF 105200025).
4. Shake the reagent vials well before use to disperse the antigen suspension uniformly and improve test readability.
5. Only clean and dry slides / tubes must be used. Clean the slide / tube with distilled water and dry.
6. It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop.
7. TYDAL® antigen suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded.
8. Accessories provided with the kit only must be used for optimum results. (Applicable only for TYDAL® 2 x 2 x 5 ml set (REF.: 105210225), 2 x 5 ml set (REF.: 105200025), 4 x 5 ml set REF.: 105200045) and TYDAL® PLUS 8 x 5 ml set (REF.: 105200085).
9. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

1. No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed and turbid samples.
2. Clean and dry glassware free from detergents must be used for sample collection.
3. Do not heat inactivate the serum.
4. Though freshly collected serum is preferable, store samples at 2-8^0C in case of delay in testing, for upto 72 hours.

TEST PROCEDURE

Bring reagents and samples to room temperature before testing.
Shake and mix antigens well before dispensing.

Slide Screen Method

1. Place one drop of positive control onto a reaction circle of the slide.
2. Place 50 µl of physiological saline onto the next reaction circle of the slide.
3. Place one drop of patient's serum to be tested onto each of the required number of reaction circles.
4. Add one drop of appropriate TYDAL® antigen suspension to the reaction circles containing Positive control & physiological saline.
5. Add one drop of appropriate TYDAL® antigen suspensions to the reaction circles containing the patient's serum.
6. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
7. Rock the slide gently back and forth, and observe for agglutination **macroscopically at one minute**.

Slide Semi-Quantitative Method

1. Using a pipette place 80 µl, 40 µl, 20 µl, 10 µl, and 5 µl of patient serum to be tested on 5 different reaction circles on the slide. The corresponding titres obtained will be 1:20, 1:40, 1:80, 1:160, & 1:320 respectively.
2. Follow step No. 5-7 of slide screen method.

Note: This method is recommended for obtaining quiok approximate titres only.

Quantitative Method
Tube-test Procedure

1. Take appropriate number of sets (as required; one set for each antigen suspension) of 8 Kahn tubes / test tubes and label them 1 to 8.
2. Pipette into tube No. 1 of all sets 1.9 ml of physiological saline.
3. To each of the remaining tubes (2 to 8) add 1 ml of physiological saline.
4. To tube No. 1 of all sets add 0.1 ml of serum sample to be tested and mix well.
5. Transfer 1 ml of the diluted serum sample from tube No. 1 to tube No. 2 and mix well.
6. Transfer 1 ml of the diluted serum sample from tube No. 2 to tube No. 3 and mix well. Continue this serial dilution till tube No. 7 in each set.
7. Discard 1.0 ml of the diluted serum from tube No.7 of each set.
8. Now the dilutions of the serum sample achieved from tube No. 1 to 7 respectively in each set is as follows: 1:20, 1:40, 1:80, 1:160, 1: 320, 1:640, 1: 1280. Tube No. 8 in all the sets, serves as a saline control.
9. To all the tubes (1 to 8) of each set add one drop of the respective well-mixed TYDAL® antigen suspensions from the reagent vials and mix well.
10. Cover and incubate at 37^0C overnight (approximately 18 hours).
11. Dislodge the sedimented button gently and observe for agglutination.

INTERPRETATION OF RESULTS

Slide Screen Method

Agglutination is a positive test result and indicates presence of the corresponding antibody in the patient's serum.
No agglutination is a negative test result and indicates absence of the corresponding antibody in the patient serum.

Slide Semi-Quantitative Method

Agglutination is a positive test result. The titre of the patient serum corresponds to the visible agglutination in the test circle with the least amount of serum sample.

Quantitative Method

The titre of the patient serum using TYDAL® antigen suspensions is the highest dilution of the serum sample that gives a visible agglutination.

REMARKS

1. Positive results obtained in the slide test should be confirmed with the tube test to establish whether the titres are diagnostically significant or not.
2. TAB vaccinated patients may show a high titre of antibodies to each of the antigens. Similarly, an amnestic response to other vaccines and unrelated fevers in case of patients who have had prior infection or immunization may give a false result.
3. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.
4. A rising titre is more significant than a single high titre. It is therefore necessary to evaluate two or more serum samples taken at 4- 6 days intervals after the onset of the disease.
5. 'O' being a somatic antigen brings about a coarse, compact, granular agglutination whereas 'H' being a flagellar antigen brings about larger, loose, flocculant agglutination.
6. While the 'O' antigen is species specific, the 'H' antigen is specific to the serotype.
7. Serological findings are not intended as a substitute for culture. An appropriate attempt should be made to recover and identify the etiologic organisms through various culture and biochemical tests.
8. Generally antibody titres of 1:80 or more are considered clinically and diagnostically significant. However the significant titre may vary from population to population and needs to be established for each area.

ASPEN® HBsAg

Hepatitis B Surface Antigen Test Device (Serum/Plasma) Package Insert

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum or plasma. For professional in vitro diagnostic use only.

INTENDED USE

The HBsAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum or plasma.

SUMMARY

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.[1] The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.
The HBsAg Rapid Test Cassette is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRINCIPLE

The HBsAg Rapid Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infections agent.
4. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The HBsAg Rapid Test Cassette can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens

MATERIALS

Materials Provided

- Test Device
- Droppers
- Product Insert

Materials Required But Not Provided

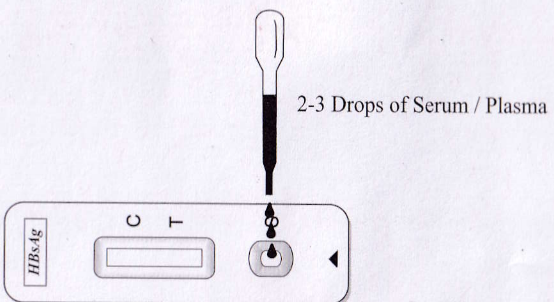
- Timer
- Centrifuge

DIRECTIONS FOR USE

Note: **Bring the test device and sample to the room temperature if stored at 2-8°C**

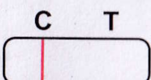
Take out the test device from the pouch and place on a clean & flat surface

- Add **2-3 drops** of **serum** / **plasma** to the specimen well of test device. Read result at **20 minutes**. (Do not interpret the result after 30 minutes)

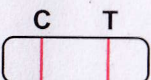


INTERPRETATION OF RESULTS

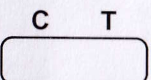
NEGATIVE: Pink/Purple line at **C** only



POSITIVE: Pink/Purple lines at **C&T**



INVALID:
If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10 ng/ml HBsAg) and a negative control (containing 0 ng/ml HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The HBsAg Rapid Test Cassette is for professional in vitro diagnostic use only. The test should be used for the detection of HBsAg in serum or plasma specimen.
2. The HBsAg Rapid Test Cassette will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection. A positive result should be correlated with other confirmatory assays as with all diagnostic tests, all results must be correlated with other clinical information available to the physician.
3. The HBsAg Rapid Test Cassette cannot detect less than 0.5ng/ml of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

EXPECTED VALUES

The HBsAg Rapid Test Cassette(Serum/Plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results on The HBsAg Rapid Test Cassette (Serum/Plasma). The test can detect 0.5ng/ml of HBsAg in serum/plasma

Specificity

Antibodies used for the HBsAg Rapid Test Cassette (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Cassette (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Sensitivity:99.8% Specificity: 99.9%

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing 0ng/ml, 0.5ng/ml and 5ng/ml of HBsAg. The negative and positive values were correctly identified.

Inter-Assay

Between-run precision has been determined by using the same three specimens of 0 ng/ml, 0.5ng/ml and 5ng/ml of HBsAg in 15 independent assays. Three different lots of the HBsAg Rapid Test Cassette (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified.

Cross-reactivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity

Interfering Substances

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

BIBLIOGRAPHY

1. Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis.* Vitro. 1971; 7: 223

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