F/C
302

TRUSTline HIV 1/2 Ab Rapid Test – Cassette

REF AR0011C IVD

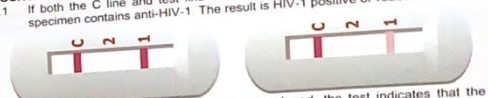
for the Detection of Antibodies to HIV 1 and 2 in Human Serum / Plasma / Whole Blood

d. The temperature used during storage of the kit falls outside of 1-30°C.
e. The temperature of the test area falls outside of 15-30°C.
f. To verify a higher than expected frequency of positive or negative results.
g. To investigate the cause of repeated invalid results.

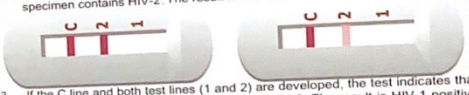
INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**
If only the C line is developed, the test indicates that the level of anti-HIV-1 and anti-HIV-2 in the specimen is undetectable. The result is negative or non-reactive for HIV-1 and negative or non-reactive for HIV-2.

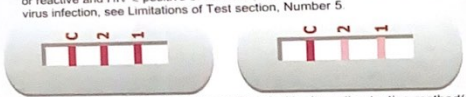
2. **POSITIVE RESULT**
2.1 If both the C line and test line 1 are developed, the test indicates that the specimen contains anti-HIV-1. The result is HIV-1 positive or reactive.



2.2 If both the C line and test line 2 are developed, the test indicates that the specimen contains HIV-2. The result is HIV-2 positive or reactive.



2.3 If the C line and both test lines (1 and 2) are developed, the test indicates that the specimen contains anti-HIV-1 and anti-HIV-2. The result is HIV-1 positive or reactive and HIV-2 positive or reactive. For differentiation of the type of HIV virus infection, see Limitations of Test section, Number 5.



Samples with reactive results should be confirmed with alternative testing method(s) such as Western Blot assay, PCR or ELISA and clinical findings before a final diagnostic decision is made.

3. **INVALID:**
If no C line is developed, the assay is invalid regardless of color development in the test lines as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance for HIV-1 Ab Test**
A total of 1308 samples from susceptible subjects were tested with the TRUSTline HIV 1/2 Ab Rapid Test and with a commercial HIV Ab ELISA Kit. Comparison for all subjects is shown in the following table.

ELISA	TRUSTline HIV 1/2 Ab Rapid Test		
	Positive	Negative	Total
Positive	326	0	326
Negative	2	980	982
Total	328	980	1308

Relative Sensitivity: 100%, Relative Specificity: 99.79%, Overall Agreement: 99.84%

2. **Clinical Performance for HIV-2 Ab Test**
A total of 195 samples from susceptible subjects were tested with the TRUSTline HIV 1/2 Ab Rapid Test and with a commercial HIV Ab ELISA Kit. Comparison for all subjects is shown in the following table.

ELISA	TRUSTline HIV 1/2 Ab Rapid Test		
	Positive	Negative	Total
Positive	49	0	49
Negative	1	174	175
Total	50	174	224

Relative Sensitivity: 100%, Relative Specificity: 99.43%, Overall Agreement: 99.55%

3. **Cross-Reactivity**
The negative sample was spiked with serum specimens of infectious diseases and then tested according to the standard procedure. The results showed that the TRUSTline HIV 1/2 Ab Rapid Test had no cross-reaction with the following tested serum specimens of infectious disease.

Specimen	Sample Size	HIV-1 Ab Reactivity	HIV-2 Ab Reactivity
HBsAg Positive Serum	10	Negative	Negative
HAV Positive Serum	10	Negative	Negative
HCV Positive Serum	10	Negative	Negative
Dengue Positive Serum	10	Negative	Negative
Syphilis Positive Serum	10	Negative	Negative
ANA Positive Serum	10	Negative	Negative
RF Positive Serum (52,500 IU/ml)	5	Negative	Negative
	5	Negative	Negative

3. **Precision**
Within run and between run precisions have been determined by testing 20 replicates with four categories of the specimens: negative, weak, medium and strong positive specimens. The negative, weak, medium and strong positive specimens were correctly identified in all of the tests performed in each run.

4. **Interference**
Common substances (such as pain and fever medication, blood components) may affect the performance of the TRUSTline HIV 1/2 Ab Rapid Test. This was studied by spiking of these substances into the three levels of the HIV-1 Ab and HIV-2 Ab standard control. The results are presented in the following table and demonstrate that the substances studied did not affect the performance of the TRUSTline HIV 1/2 Ab Rapid Test.
Note: -: Negative, +: Weak Positive, +++: Strong Positive

Potential interfering substances spiked	HIV-1 Reactivity			HIV-2 Reactivity		
	Negative	Weak Positive	Strong Positive	Negative	Weak Positive	Strong Positive
Control		+	+++		+	+++
Bilirubin 20 mg/dL		+	+++		+	+++
Creatinine 442 µmol/L		+	+++		+	+++
Glucose 55 mmol/L		+	+++		+	+++
Albumin 60g/L		+	+++		+	+++
Salicylic acid 4.34 mmol/L		+	+++		+	+++
Heparin 3000 U/L		+	+++		+	+++
EDTA 3.48 mol/L		+	+++		+	+++

LIMITATIONS OF TEST

1. The Assay Procedure and Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HIV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate test results.
2. The TRUSTline HIV 1/2 Ab Rapid Test is limited to the qualitative detection of HIV-1 or HIV-2 antibodies in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer of the specimen.
3. A non-reactive result for an individual subject indicates absence of detectable HIV-1 or HIV-2 antibodies. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
4. A non-reactive result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. As illustrated in the Interpretation of Assay Result, Section 2.3, all three test lines (1, 2 and C) may develop when tested with samples containing high titers of HIV-1 antibodies. Hence reactive test bands for both HIV-1 and HIV-2 may not indicate mixed infection but might from the cross-reactivity of HIV-1 and HIV-2 because of the similarity of their genomic structure. To differentiate and to resolve antibody cross-reactivity, dilute the test specimen with sample diluent 1:50 or 1:100, then re-test the diluted specimen with a new test device. Only test line 1 and the C line will appear if the specimen contains antibodies to HIV-1. If test line 1, test line 2 and the C line all appear, the test indicates presence of antibodies to both HIV-1 and HIV-2.
6. False negative results may arise because of hook effect due to very high titer of antibody in sample. Repeat the test by using different dilution of same sample.
7. Hemolytic samples may give reddish background even after end of the test time.
8. Infection may progress rapidly. If symptoms persist while the result from the TRUSTline HIV 1/2 Ab Rapid Test is non-reactive, it is recommended to test with an alternative test method or to re-sample the patient a few days later.
9. Unusually high titers of heterophile antibodies or rheumatoid factor in specimens may affect expected results.
10. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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 Suppl 1:52S-58S.
4. Janssen, RS, Satten, GA, Stramer, SL, Rawal,-BD, O'Brien, TR, Weiblen, BJ, Hecht, FM, Jack, N, Cleghorn, FR, Kahn, JO, Chesney, MA and Busch MP. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA (1998) 280(1): 42-4.

Index of Symbols

Consult instructions for use		REF	Catalogue number		Use-by date
IVD	For *in vitro* diagnostic use only	LOT	Batch code	N	Tests per kit
1°C 30°C	Temperature limit 1-30 °C		Do not re-use		Keep dry
	Manufacturer		Date of manufacture		
Do not use if package is damaged			Keep away from sunlight		

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road.
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

PI-AR0011C Rev. E
Effective date: 01.11.2019
English version

SPRIN
3 (2 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc.
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care - 98925 64815
Email : omkarplastic89nps@gmail.com
Web : www.omkarplasticindustries.com
Made in India

TRUSTline HIV 1/2 Ab Rapid Test – Cassette

REF AR0011C IVD

for the Detection of Antibodies to HIV 1 and 2 in Human Serum / Plasma / Whole Blood

INTENDED USE

The TRUSTline HIV 1/2 Ab Rapid Test is intended for use by healthcare professionals and is a rapid, qualitative, screening, lateral flow immunoassay for the simultaneous detection and differentiation of HIV-1 and HIV-2 antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrument. Any reactive specimen with the TRUSTline HIV 1/2 Ab Rapid Test must be confirmed with alternative testing method(s) such as ELISA, Western Blot assay or PCR.

SUMMARY AND EXPLANATION OF THE TEST

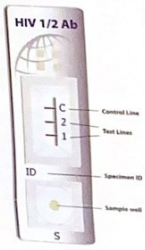
Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped, single-stranded, positive-sense RNA viruses. The causative relationship between HIV-1 and HIV-2 virus and acquired immunodeficiency syndrome (AIDS) has been established over several decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex and from healthy individuals with a high risk for developing AIDS[1]. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals[2].

The two types of HIV have significant variation in sequences. HIV-1 has been divided into three groups: group M (for major) including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O). Similarly, HIV-2 has been classified into at least five subtypes (A through E). Some HIV-1 variants share up to 50% homology in their envelope genes with the sequences of more common prototype strains.

Both HIV-1 and HIV-2 can elicit strong immune responses including the production of anti-virus antibodies[3]. Presence of specific anti-HIV-1 and/or anti-HIV-2 in blood, serum or plasma indicates exposure of an individual to HIV-1 and/or HIV-2 and thus is of great value for clinical diagnosis[4].

The TRUSTline HIV 1/2 Ab Rapid Test was developed to detect and differentiate anti-HIV-1 and anti-HIV-2 (IgG, IgM, IgA) in serum, plasma or whole blood. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment.

TEST PRINCIPLE



The TRUSTline HIV 1/2 Ab Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HIV-1 antigen conjugated with colloidal gold (HIV-1 conjugates), recombinant HIV-2 antigen conjugated with colloidal gold (HIV-2 conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (1 and 2) and a control line (C). Test line 1 is pre-coated with HIV-1 antigen for the detection of antibodies to HIV-1, test line 2 is pre-coated with HIV-2 antigen for the detection of antibodies to HIV-2, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the strip. HIV-1 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immune-complex is then captured on the membrane by the pre-coated HIV-1 antigen forming a burgundy colored line at test line 1, indicating a HIV-1 antibody positive or reactive test result. Lack of color development on test line 1 suggests an HIV-1 antibody negative or non-reactive result.

HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-2 conjugates. The immune-complex is then captured on the membrane by the pre-coated HIV-2 antigen forming a burgundy colored line at test line 2, indicating a HIV-2 antibody positive or reactive test result. Lack of color development on test line 2 suggests a HIV-2 antibody negative or non-reactive result.

The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of color development on the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Specimen transfer device
3. Sample diluent (5 mL/bottle)
4. Package insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Lancing device for whole blood test
3. Alcohol swab
4. Disposable gloves

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use the test device if pouch is not intact.
4. Do not use expired devices or components.
5. Bring all reagents to room temperature (15-30°C) before use.
6. Do not use the components of different lots and of any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Handle the negative and positive controls in the same manner as the patient specimens.
13. The test result should be read 15 minutes after a specimen is applied to the sample well of the device. Reading the test result after 20 minutes may give erroneous results.
14. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air conditioning.
15. Clean up spills thoroughly using appropriate disinfectant.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store test kit at 1-30°C. If stored at 2-8°C, ensure that all reagents are brought to room temperature before opening. The sample diluent that all reagents are brought to room temperature before opening. The sample diluent (opened and unopened) and unopened test device is stable through the expiration date printed on the label, when stored at recommended temperature. Do not freeze the kit or expose the kit to temperatures above 30°C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into a new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately. The specimens can be stored at 2-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®). Do not use hemolyzed blood for testing. Capillary blood (finger tip puncture) can be used directly without anticoagulant. Collect blood with Specimen transfer device and transfer it to sample well of device.

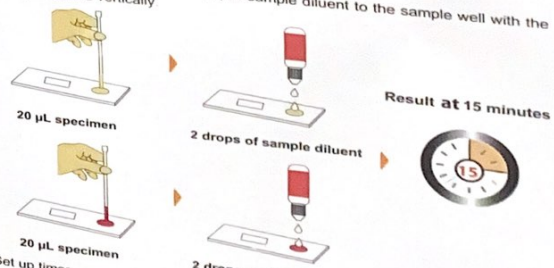
Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: Fill the specimen transfer device with specimen (about 20 µL) not to exceed the specimen line as shown in the images below. **For better precision, transfer specimen using a pipette capable of delivering a 20 µL volume.**

Holding the specimen transfer device vertically, dispense the entire specimen into the center of the sample well making sure that there are no air bubbles.

Immediately add 2 drops (60-80 µL) of sample diluent to the sample well with the bottle positioned vertically.



Step 5: Set up timer.
Step 6: Result should be read at 15 minutes.

Do not read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. If the C line does not develop, review the entire procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens
   b. A new lot of test kits is used
   c. A new shipment of test kits is used

SPRING CLIP FILE

302 - SPRING COBRA
Product Size : FC
Net Qty : 1 Pc
Mfg : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care - 98925 64815
Email : omkarplastic89sps@gmail.com
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Made in India

F/C
302

Literature files - 2021

Advantage **Dengue NS1 Ag Card**

Rapid visual test for the detection of Dengue NS1 Ag in Human Serum/ Plasma

INTRODUCTION

Dengue virus is a flavivirus found largely in areas of the tropic and sub-tropics. There are four distinct but antigenically related serotypes of dengue viruses, and transmission is by mosquito, prinicipally Aedes aegypti and Aedes albopictus.

The mosquito-borne dengue viruses (serotype 1-4) cause dengue fever, a severe flu-like illness. The disease is prevalent in third world tropical regions and spreading to sub-tropical developed countries - including the United States. WHO estimates that 50-80 million cases of dengue fever occur worldwide each year, including a potentially deadly form of the disease called dengue haemorrhagic fever (DHF) and dengue shock syndrome (DSS). Primary infection with dengue virus results in a self-limiting disease characterized by mild to high fever lasting 3 to 7 days, severe headache with pain behind the eyes, muscle and joint pain, rash and vomiting. Secondry infection is the more common form of the disease in many parts of Southeast Asia and South America. IgM antibodies are not detectable until 5-10 days in case of primary dengue infection and until 4-5 days in secondary infection after the onset of illness. IgG appear after 14 days and persist for life in case of primary infection and rise within 1-2 days after the onset of symtoms in secondary infection. This form of the disease is more serious and can result in DHF and DSS. The major clinical symptoms can include high fever, haemorrhagic evets, and circulatory failure, and the fatality rate can be as high as 40%. Early diagnosis of DSS is particularly important, as patients may die within 12 to 24 hours if appropriate treatment is not administered.

Primary dengue virus infection is characterized by elevations in specific NS1 antigen levels 0 to 9 days after the onset of symptoms; this generally persists upto 15 days. Earlier diagnosis of Dengue reduces risk of complication such as DHF or DSS, especially in countries where dengue is endemic.

INTENDED USE

Advantage Dengue NS1 Ag Card is a rapid solid phase immuno-chromatographic test for the qualitative detection of Dengue NS1 Antigen in human serum / plasma. This test is for *in vitro* diagnostic use only and is intended as an aid in the earlier diagnosis of dengue infection.

PRINCIPLE (ANTIGEN-ANTIBODY REACTION)

Advantage Dengue NS1 Ag Card is an immunoassay based on the "sandwich" principle. Dengue NS1 antigen device contains two lines; "C" (Control Line) & "T" (Dengue NS1 Antigen detection Test Line). Test line is coated with antibodies, anti-dengue NS1 Ag. When a sample is added to the device, Dengue NS1 antigen if present in the sample will bind to the anti-dengue NS1 gold colloid conjugate making antigen antibodies complex. This complex migrates along the membrane to the test region and forms the visible pink line at "T" as antibody-antigen-antibody gold conjugate complex.

The intensity of the test bands in the respective device will vary depending upon the amount of antigen/ antibody present in the sample. The appearance of any pink/red colour in a specific test region should be considered as reactive for that particular antigen and/or antibody type (IgG or IgM). A red procedural control line should always develop in the test device window to indicate that the test has been performed properly.

KIT CONTENTS

a) Dengue NS1 Ag Device
b) Sample Dropper
c) Instruction Manual

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical devices and their packing. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Manufactured By	*In vitro* diagnostic medical device
No. of tests	See Instruction for use
Lot Number / Batch Number	Temperature Limitation
Manufacturing Date	Caution, see instruction for use
Expiry Date	Catalogue Number
Do not use if package is damaged	Contains biological Material of Animal Origin
Single use only	Keep away from sunlight
Keep Dry	Country of Manufacture

KIT STORAGE & STABILITY

The kit should be stored at 2-30°C in the cool and driest area available. Expiry date on the kit indicates the date beyond which kit should not be used. Advantage Dengue NS1 Ag Card should not be frozen and must be protected from exposure to humidity.

WARNING FOR USERS

CAUTION: ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION. NO TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT HUMAN BLOOD PRODUCTS WILL NOT TRANSMIT INFECTION.

1. The use of disposable gloves and proper biohazardous clothing is STRONGLY RECOMMENDED while running the test.
2. In case there is a cut or wound in hand, DO NOT PERFORM THE TEST.
3. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
4. Tests are for in vitro diagnostic use only and should be run by competent person only.
5. Mark the test specimen with patient's name or identification number. Improper identification may lead to wrong result reporting.
6. Do not pipette by mouth.
7. All materials used in the assay and samples should be decontaminated in suitable disinfectant solution for 30-60 min. before disposal or by autoclaving at 121°C at 15psi for 60 min. Do not autoclave materials or solution containing sodium hypochlorite. They should be disposed off in accordance with established safety procedures and guidelines.
8. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. Consult a physician immediately in case of accident or contact with eyes, in the event that contaminated material are ingested or come in contact with skin puncture or wounds.
9. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
10. Do not open the foil pouch to remove the product until it attains room temperature and you are ready to perform the test.
11. Take out the cards from the pouch just before performing the test to avoid denaturation of antisera due to atmospheric exposure.

Optimal test performance requires strict adherence to the test procedure described in the insert.

SPECIMEN COLLECTION AND PREPARATION

1. Advantage Dengue NS1 Ag Card test should be performed in human serum or plasma only immediately after collection.
2. If not tested immediately, specimen should be refrigerated at 2-8°C for upto 24 hours following collection.

SPR

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care - 98925 64815
Email : omkarplastic89sps@gmail.com
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Made in India

F/C
302

3. If testing within 24 hours is not possible, specimen should be frozen at -20°C for 3 months or -70°C for longer period.
4. Specimens containing visible precipitate or cloudy specimens may give inconsistent test results. Such specimens should be clarified prior to testing by high speed centrifugation i.e. 10,000 rpm for 15 minutes before testing.
5. Heamolysed specimen or specimen with microbial contamination should be discarded and fresh aliquot should be collected.
6. Repeated freezing & thawing of the specimen should be avoided.

TEST PROCEDURE

1. Bring the required number of Advantage Dengue NS1 Ag Card foil pouches and specimen to room temperature prior to testing.
2. Remove the test card from the foil pouch prior to use.
3. Label the test card with patient's name or identification number.
4. Add 2 drops (70 μl) of sample using sample dropper to the sample well of device as shown in fig. (a).

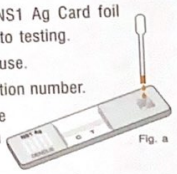
Fig. a

5. Allow reaction to occur for 20 minutes.
6. Read results at 20 minutes. Positive results may appear as early as 2-10 minutes. However, negative results must be confirmed after 20 minutes only.
7. Discard the Advantage Dengue NS1 Ag Card immediately after reading result at 20 minutes, considering it to be potentially infectious.

INTERPRETATION OF THE TEST

REACTIVE:

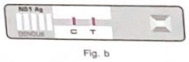
Fig. b

As shown in (Fig. b), appearance of pink coloured line, one each in test region "T" and control region "C" indicates that the sample is REACTIVE for Dengue NS1 Ag.

NON-REACTIVE:

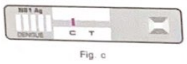
Fig. c

As shown in (Fig. c) appearance of one distinct pink line in the control region "C" only, indicates that the sample is "NON REACTIVE" for Dengue NS1 Ag.

INVALID:

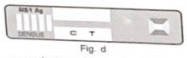
Fig. d


Fig. e

The test is invalid, if no control line appears after the completion of test, either with clear background or with complete pinkish/ purplish background Fig. (d) & (e). Invalid test are obtained due to following reasons:

(a) Improper storage at temperature other than the recommended temperature.

(b) Wrong test procedure

(c) Long atmospheric exposure of the test device after opening the pouch.

(d) Use of turbid/ lipemic/ haemolyzed sample.

In case of invalid result, the test sample should be centrifuged at 10,000 rpm for 15 minutes and retest using new Card.

LIMITATIONS OF THE TEST

1. The test is for *in vitro* diagnostic use only.
2. This test detects the presence of Dengue NS1 antigen in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. Serological cross-reactivity across the Flavivirus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.
4. As with all diagnostic tests, all results must be corelated with other clinical findings. 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 an early infection of Dengue virus.
5. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

PERFORMANCE CHARACTERISTICS

(i) The kit has been evaluated in-house with the known panel of fresh as well as frozen Dengue NS1 antigen positive and Negative samples. The performance of the test kit was evaluated and compared with the a license commercially availabel ELISA test kit. The samples included cross-reacting samples; Epstein-Barr virus, Malaria, Rheumatoid factor, Leptospirosis, Japanese encephalitis, yellow fever and West Nile viruses. Following is the in-house evaluation.

Sample Type	No. of Samples tested	Result of licensed test	Dengue NS1 Ag
Negative for Ag	4030	4030	3950
Dengue Antigen Positive	175	175	168

Sensitivity: 96% **Specificity: 98%**

(ii) Performance of Advantage Dengue NS1 Ag Card with reference to sensitivity and specificity has also been determined by NIV (National Institute of Virology), Pune, India. The evaluation indicate the following sensitivity and specificity:

Sensitivity: 93.33% **Specificity: 100%**

This information is provided for the scientific community enquiring for an independent evaluation other than company's in house evaluation. It is not for commercial or promotional purpose.

Precision: Within run (Intra assay) & between run (Interassay) precision have been determined by testing 10 replicates of eight samples - four negative, two weak positive and two strong Dengue NS1 antigen positive samples. The C.V. (%) of all the samples were within 10% of the time.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an *in vitro* diagnostic assay within the limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

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in vitro diagnostic Reagent, not for medicinal use

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R-06
VER-02
MM/DIAG/010
Rev. Date: Aug.-22

SPS
MUMBA

MADE IN INDIA

SPRING CLIP

302 - SPRING COBRA
Product Size: FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP ₹ 70.00
(Incl. of all taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98925 64815
Email : omkarplastic.ji@gmail.com
Web : www.omkarplasticindustries.com
Made in India

HBsAg Test

Rapid test for qualitative detection of HBsAg (Hepatitis B virus surface antigen) in human serum / plasma

OSCAR

Scan code on smart phone for step-by-step instruction video

- **Detection:** Detects Hepatitis B surface antigen
- **Sandwich system:** Anti HBsAg coated on NC membrane and colloidal gold conjugate
- **Specimen of choice:** Serum / plasma
- **Specimen volume:** 2-3 drops of provided dropper
- **Interpretation time:** 5-20 minutes
- **Kit presentation:** 50 tests pack
- **Storage temperature:** 2-30°C
- **Shelf life:** 24 months from date of manufacturing
- **Specificity:** 99.7%
- **Sensitivity:** 100%
- **Detection Limit:** 0.5 ng per ml
- **For in-vitro diagnostic use only**

INTENDED USE

OSCAR HBsAg test is a one step rapid, qualitative, sandwich immunoassay. It is used for the detection of Hepatitis B surface antigen in human serum/plasma specimen. For professional use only.

INTRODUCTION

Earlier known as Australia antigen, Hepatitis B surface Antigen (HBsAg), is among the first serological markers that appears in the blood of infected person two to three weeks prior to the onset of clinical symptoms. However in the symptomatic phase the levels of HBsAg are elevated and decline thereafter. It is important to detect HBV using HBsAg as the marker to screen blood donors to reduce the risk of Hepatitis B transmission by blood transfusion, screening high risk groups for HBV and for differential diagnosis of Hepatitis infection. OSCAR HBsAg is a one step test and can detect HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5ng/ml.

TEST PRINCIPLE

OSCAR HBsAg is a lateral flow test based on the principle of Immuno-chromatography, the method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose membrane. As the test sample flows laterally through nitrocellulose membrane it mixes with the gold conjugated antibodies. If the sample contains HBsAg, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. This complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody at (Test line) "T", the complex is trapped forming an antibody antigen-antibody colloidal gold complex. This forms a pink/purple band indicating the sample is positive for HBsAg. To serve as a procedural control, an additional line of anti-rabbit IgG antibody (control line) "C" has been immobilized on the strip. If the test is performed correctly, it will result in the formation of a pink/purple band upon contact with the conjugate at the control line region.

PRESENTATION

Catalogue No: HLR1050

MATERIALS PROVIDED

Each kit contains :

1. *Test device pouch: Nitrocellulose membrane coated with anti-HBsAg antibodies and anti-rabbit antibodies at the respective regions. Colloidal gold conjugate of rabbit IgG and monoclonal anti-HBsAg antibodies along with desiccant pouch.*
2. *Sample dropper*
3. *Product insert*

MATERIAL REQUIRED BUT NOT PROVIDED

1. Disinfectant
2. Disposable gloves
3. Blood collection tube
4. Timer
5. Bio-hazard waste container
6. Micro pipette
7. IPA swab
8. Syringe

STORAGE AND SHELF LIFE

The sealed pouches in the test kit may be stored between 2-30°C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE and must be protected from exposure to humidity. Once opened devices must be used immediately.

SPECIMEN COLLECTION AND STORAGE

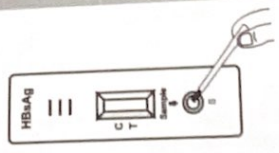
1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20°C or below. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only. **NOT FOR MEDICINAL USE.**
2. Bring all reagents and specimen to room temperature before use.
3. Do not use beyond expiration date.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as if potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink or smoke in the area where testing is done.
8. Use protective clothing and wear gloves when handling samples.
9. Use absorbent sheet to cover the working area.
10. Immediately clean up any spills with sodium hypochlorite / disinfectant.
11. Dispose off all the reagents and material used as if they contain infectious agent.
12. Do not mix components.
13. If the colour of the desiccant at the point of opening the pouch has turned from blue to white, use another test device.

Procedure: How to Do the Test

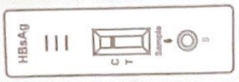
1. *Bring the sealed pouch to room temperature, open the pouch at the notch and remove the device. Once opened, the device must be used immediately.*
2. *Refrigerated specimens must be brought to room temperature prior to testing.*
3. *Add 2-3 drops of serum/plasma sample into the sample well 'S' using the dropper provided.*



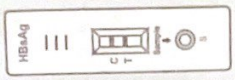
4. Read results at 20 minutes.
5. Repeat the test with a new device if the test is invalid.

Interpretation: How to Read the Result

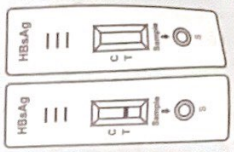
Negative:
If only one pink/purple line appears in the result window at the control line region 'C'.



Positive:
If two pink/purple line appear in the control line region 'C' and test line region 'T'.



Invalid:
The test should be considered invalid if control line does not appear.



LIMITATIONS OF THE TEST

1. OSCAR HBsAg test should not be used as a sole criterion for diagnosis of HBV infection.
2. The intensity of test lines and the control lines should not be the criteria to judge the concentration of HBsAg in the test specimen.
3. Due to the performance characteristics and antibody composition of various HBsAg tests, reactivity patterns may differ from product to product.
4. Testing of pooled samples is not recommended with OSCAR HBsAg test.
5. Most positive results develop within 15–20 minutes. Do not read results after 30 minutes.
6. It has been reported in various studies that the Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substance present in patients serum, may cause erroneous result. Though **OSCAR HBsAg test** uses sufficient amounts of heterophilic blocking reagent (HBR) to inhibit the majority of this interference; some samples with high titres may still interfere. Results that appear to be internally inconsistent or incompatible with the clinical presentation should be investigated further.
7. HBsAg is coded by the S gene, and the common antigenic epitopes of all subtypes of HBsAg are found in the same 'a' determinant. Antibodies used in **OSCAR HBsAg** are directed against this ;a, determinant so that all subtypes of HBsAg can be detected. However, a few patients infected with HBV may show negative for HBsAg inspite of a positive test for HBV-DNA or HBV polymerase chain creaction. These rare cases are due to antigenically divergent variants. Therefore, the existence of such variants should be considered before taking clinical decisions.
8. As with all diagnostics tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Internal Evaluation-I

The performance of OSCAR HBsAg device was evaluated by in-house study using a panel of ninety five known positives (of varying reactivity) and three hundred seventy five known negative specimens in comparison with two licensed ELISA kits. The results of the evaluation are as follows:

Types of Specimen	Observations			
	Oscar HBsAg Test		Commercial HBsAg ELISA	
	Positive	Negative	Positive	Negative
True Positive 95	95	00	95	00
True Negative 375	01	374	00	375

Sensitivity of OSCAR HBsAg : 100%
Specificity of OSCAR HBsAg : 99.7%

Internal Evaluation-II

OSCAR HBsAg was evaluated with a serial dilution of known concentration of HBsAg positive sample. It was observed that **OSCAR HBsAg** was able to detect all the dilutions with HBsAg concentration of > 0.5ng/ml.

Therefore the detection limit of OSCAR HBsAg is 0.5 ng/ml.

Independent External Evaluation

In another independent study, the performance of OSCAR HBsAg Test was evaluated using panel of 50 samples- 20 positives & 30 negatives, in comparison with commercially available immuno-chromatographic Test (ICT), Enzyme Immunoassay (EIA). The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	OSCAR HBsAg	Commercial ICT	EIA
Number of specimens tested	50	50	50	50
Number of Positives	20	20	20	20
Number of Negatives	30	30	30	30

The above study indicates a good correlation of the results of **OSCAR HBsAg** with that of EIA & Commercial ICT.

DISPOSAL

Discard the used test devices immediately after reading the result. Before discarding it, add few drops of disinfectant on device membrane and on all other items used for handling serum/plasma. Put all items to be disposed in disposable bags and dispose off as per local regulation for handling/ disposal of bio-medical waste.

DISCLAIMER

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside of the control of manufacturer and distributors. Various factors including storage temperature, environmental conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

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.

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SYMBOLS USED ON LABELS

	Consult instructions for use	IVD	In vitro diagnostic medical device
2	Do not reuse	Σ	Contains sufficient for <n> tests
	Storage temperature	REF	Catalogue number
	Keep away from sunlight		Manufactured By

Oscar Medicare Pvt. Ltd.
E-92, Bahadrabad Industrial Area, Haridwar-249402 (UK)
Phone No.: 01334-230204, 230051
HO: B-107, Okhla Industrial Area, Phase-I, New Delhi-110020
Phone No.: +9111-41076195, 41076196 / 97
Email: info@oscarmedcare.com

IM/HLR/01-01

ACON® hCG One Step Pregnancy Test Device (Urine) Package Insert

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional in vitro diagnostic use only.

INTENDED USE

The hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conceptions. [1,2,3,4] hCG levels continue to rise very rapidly frequently exceeding 100 mIu/mL by the first missed menstrual period [2,3,4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The hCG One Step Pregnancy Test Device (Urine) is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG One Step Pregnancy Test Device (Urine) Shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The hCG Pregnancy Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in early detection of pregnancy. The test uses two lines (C,T) to indicate results. The test line (T) is coated with anti hcg antibodies (monoclonal antibodies).The monoclonal antibody is purified agglutinating sera so making the test more reliable and accurate. The control line (C) is coated with antibodies and colloidal gold particles. The assay is conducted by adding urine specimen to the specimen well of the test device and observing the formation of red colored line (s). The specimen migrates via capillary action along the membrane to react with the antibodies at C & T lines. Positive specimens containing hCG (Antigen) when passes through the membrane, at test line reacts with the anti hCG antibody (Antigen - Antibody reaction). Positive reaction is made visible by colored conjugate. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line should always appear in the control line region(C). It indicates that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS & MATERIALS PROVIDED

- Test devices : Test line is coated with anti-hCG antibody .
- Droppers
- Package insert

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch 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

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimen may be stored at 2-8°C for up to 48 hours prior to testing. For Prolonged Storage, Specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

Materials Provided

- Test devices
- Droppers
- Package insert

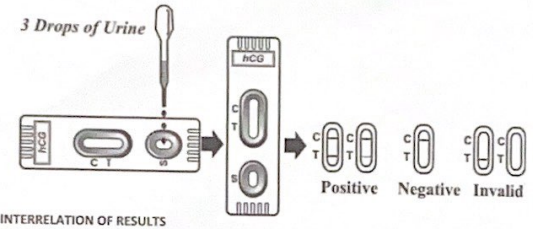
Materials Required But Not Provided

- Specimen Collection Container
- Timer

DIRECTIONS FOR USE (PROCEDURE)

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120 uL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the colored line (s) to appear. The result should be read at 5 minutes.
   NOTE: low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time; therefore, **do not interpret** the result after **10 minutes.**



INTERRELATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test line region (T).

NOTE: The intensity of the color in the test line region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line falls to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

LIMITATIONS

1. The hCG One Step Pregnancy Test Device (Urine) is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
3. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. [6,7] Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the level of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. The hCG One Step Pregnancy Test Device (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Cassette to another commercially available urine hCG Rapid test. The study included 413 urine specimens, and both assays identified 296 negative and 117 positive results. The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid test Cassette when compared to the other hCG Rapid test.

hCG Reference Method

Method		Other hCG Rapid Test		Total Result
hCG Pregnancy Rapid Test Cassette	Result	Positive	Negative	
	Positive	117	0	117
	Negative	0	296	296
Total Results		117	296	413
Sensitivity: >99.9% (97.5%~100%)*			Specificity: >99.9%(99.0%~100%)*	
Accuracy: >99.9 %(99.3%~100%) *			*95% confidence Intervals	

Sensitivity and Specificity

The hCG One Step Pregnancy Test Device (Urine) detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/uL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentilis Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

None of the substances at the concentration tested interfered in the assay.

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Number: RPS088301
Effective date: 2017-06-21

F/C
302

5 Add whole blood sample using the sample dropper/ micropipette onto the sample pad in the sample well 'S'. fig. (g)

NOTE :Press the tip of the dropper onto the sample pad in the sample well "S" to ensure that the complete volume of whole blood has been transferred to the strip.

6. Add 3 drops of the Assay Buffer in the buffer well 'B'. fig. (h) **Ensure FREE FALLING OF DROPS on the membrane, holding the vial/dropper vertically for proper volume. Screw cap the vial after use.**

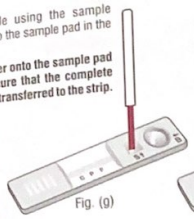
Fig. (g)

OR

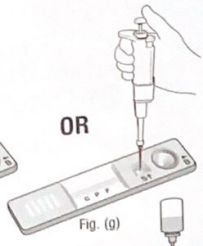
Fig. (g)

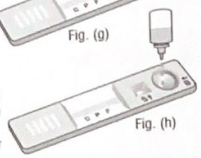
Fig. (h)

7. Allow the reaction to occur for 20 minutes.
8. Read the results at 20 minutes. **Do not read the result after 30 minutes. Reading beyond prescribed time may give false results.**
9. Discard the Advantage Malaria Pan + Pf Card immediately after reading results at 20 minutes as it is potentially infectious.

INTERPRETATION OF THE RESULTS

REACTIVE

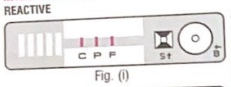
Fig. (i)

As shown in fig. (I), appearance of three purplish pink coloured lines one each in Pf. region (F), Pan region (P) & Control region (C) indicates that the sample is reactive for P. falciparum or mixed infection of Pf and Pv (or P. malarie, P.ovale).

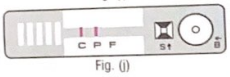
Fig. (j)

As shown in fig. (j) appearance of two purplish pink coloured line one each at P & C region only indicates that the sample is reactive for P. vivax / P. malariae / P. ovale only.

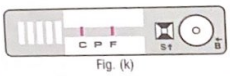
Fig. (k)

As shown in fig. (k) appearance of two purplish pink coloured line one each at F & C region only indicates that the sample is reactive for P. falciparum only. A difference of intensity in colour may occur between both the test lines ('P' & 'F') and between the test lines & control line depending on the concentration of pLDH & HRP-2 in the sample but this does not affect the interpretation of the results.

Depending on the concentration of pLDH & HRP-2 positive results may be observed within 60 seconds. However, to confirm a negative result the test result should be read only at 20 minutes. **Consider a faint test line also as a positive result.**

NON-REACTIVE

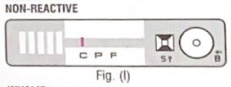
Fig. (l)

As shown in fig. (L), appearance of only one purplish pink coloured line at Control (C) region indicates that the sample is non-reactive for P. falciparum and other Plasmodium Species (P. vivax / P. malariae / P. ovale)

INVALID

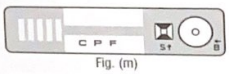
Fig. (m)

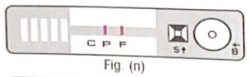
Fig. (n)

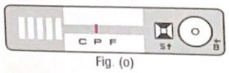
Fig. (o)

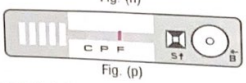
Fig. (p)

The test is invalid, if no control line appears after the completion of test, either with clear background or with complete pinkish/ purplish background fig. (m, n, o & p). **The test should be repeated using a new card.**

LIMITATIONS AND INTERFERENCES

1. The test procedure, precautions and interpretation of results for this test must be strictly followed.
2. This is only a screening test. All reactive samples must be confirmed with microscopy. As with all diagnostic tests, the test result must always be correlated with clinical finding. The results should be reported only after complying the mentioned procedure.
3. Though the test is accurate in detecting HRP-2 specific to P. falciparum or pLDH specific to Plasmodium species (P. falciparum/ P.vivax/ P. malarie/ P. Ovale), a low incidence of false results can occur. All reactive test results are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
4. Any modification to the test procedure and/ or use of reagents other than provided with the test kit will lead to invalid and/or false test result.
5. Since the HRP-2 persists for upto a fortnight even after successful anti-malarial treatment, a positive test result does not indicate a failed therapeutic response.
6. In P. falciparum malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in 'carriers', the HRP-2 test line (F) may be absent.
7. The possibility of resistant strain of malaria should always be considered if the reaction of the test remains positive with the same intensity after 5-10 days post treatment.
8. Patient with rheumatoid factors, anti-nuclear antibody or dengue may give false positive results.
9. The product performance will be hampered or degraded if test kit is stored at low temperature (<2°C) or high temperature (>30°C).
10. False negative results may be obtained in following conditions:
    i) Parasite density/ antigen concentration is below the detection limit of the test or analyte detected are not present during the stage of disease in which specimen is collected.
    ii) No production of HRP-2 antigen in the specimen due to deletion of HRP-2 gene.
11. In case of very faint or doubt for test band (F and/or P), the test should be repeated using fresh device.
12. Repeat the test in case of strong clinical evidence of malaria using fresh device.

PERFORMANCE CHARACTERISTICS OF ADVANTAGE MALARIA PAN + Pf CARD

(i) WHO Evaluation:

The ADVANTAGE MALARIA PAN + Pf CARD test kit has been evaluated by WHO, Geneva using a panel of wild & cultured malaria positive sample and the results obtained are as follows :

	Panel Detection Score*		Specificity*
	Pf	Pv	
200 Parasites	84%	100%	—
2000 Parasites	100%	100%	—
Negative Samples	—	—	100%

*Reference: Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 5 (2013), Page:38.

Note : The above information is provided for the scientific community, It is not for commercial or promotional purpose.

(ii) In-house Evaluation:

Analytical Sensitivity: The test can detect parasitemia levels of ≥50 parasites per µl of blood for P.falciparum (pLDH) & P. vivax (HRP-2), ≥ 100 parasites per µl of blood for P. falciparum.

The ADVANTAGE MALARIA PAN + Pf CARD has been evaluated in-house with malaria positive and negative clinical whole blood samples and compared with microscopic examination. The evaluation also included cross-reacting samples; Dengue, Rheumatoid factor, Leptospira, HIV, HCV, HBV, M. tuberculosis, Syphilis, Brucella, Scrub typhus positive samples. The results obtained are as follows:

Sample	Total no. of samples tested	ADV. MALARIA PAN + Pf CARD		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Malaria Negative	2100	1	2099	-	99.95
Cross-reacting sample	64	0	64	-	100
P. falciparum Positive	58	58	0	100	-
P. vivax Positive	105	105	0	-	100

Precision: Within-run and between-run precisions have been determined by testing 10 replicates of six specimens : two negative, two weak positive and two moderate positive. The C.V (%) of negative, weak positive and moderate positive samples were within 10% of the time.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an in vitro diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BIBLIOGRAPHY OF SUGGESTED READING

1. Jamshaid Iqbal; etal. Journal of Clinical Microbiology, 37(1), 1999, 3644-3646.
2. World Health Organization 2000. New perspectives malaria diagnosis. World Health Organization, Geneva, Switzerland.
3. Piper R, etal. Am J. Trop. Med. Hyg., 60(1), 1999, 109-118.
4. Moody A, Clinical Microbiological Review, 15(1), 2002, 66-78.
5. Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 5 (2013)

in vitro diagnostic reagent, not for medicinal use

J. MITRA & CO. PVT. LTD.
A 180-181, Okhla Indl. Area, Phase-1, New Delhi-110 020, INDIA
Ph.: +91-11-47130300, 47130500
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MALAPF302 VER-02 R-06
Revision Date: Feb.-24

SPS
MUMBAI

SPRING CLIP F

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care - 98925 64815
Email : omkarplastic8@gmail.com
Web : www.omkarplasticindustries.com
Made in India

TRUSTline HCV Ab Rapid Test - Cassette REF AR0024C IVD

for the Detection of Antibodies to HCV in Human Serum / Plasma / Whole Blood

3. **INVALID**: If no C line is developed, the assay is invalid regardless of development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

A total of 1089 samples including serum, plasma and whole blood from susceptible subjects were tested with the TRUSTline HCV Ab Rapid Test and with a commercial HCV ELISA Kit. Comparison for all subjects is shown in the following table.

	TRUSTline HCV Ab Rapid Test		
HCV ELISA	**Positive**	**Negative**	**Total**
Positive	130	0	130
Negative	2	957	959
Total	132	957	1089

Relative Sensitivity: 100%, Relative Specificity: 99.79%, Overall Agreement: 99.82%

2. **Cross-Reactivity**

No cross reactivity was observed when tested the TRUSTline HCV Ab Rapid test with the following infectious diseases samples with the standard test procedure

Cross reactivity Specimen		Sample Size	HCV Ab Reactivity
Dengue Positive	Serum	5	Negative
	Plasma	3	Negative
	Whole Blood	2	Negative
HAV Positive	Serum	5	Negative
	Plasma	2	Negative
	Whole Blood	3	Negative
HBsAg Positive	Serum	5	Negative
	Plasma	2	Negative
	Whole Blood	3	Negative
HIV Positive	Serum	5	Negative
	Plasma	3	Negative
	Whole Blood	2	Negative
Syphilis Positive	Serum	5	Negative
	Plasma	3	Negative
	Whole Blood	2	Negative
ANA Positive	Serum	3	Negative
	Plasma	1	Negative
	Whole Blood	1	Negative
RF Pos (≤2,500 IU/ml)	Serum	3	Negative
	Plasma	1	Negative
	Whole Blood	1	Negative

3. **Precision**

Within run and between run precisions have been determined by testing 20 replicates with four categories of Serum, Plasma and whole Blood specimens: negative, weak, medium and strong positive specimens. The negative, weak, medium and strong positive specimens were correctly identified in all of the tests performed in each run.

4. **Interference**

Common substances (such as pain and fever medication, blood components) may affect the performance of the TRUSTline HCV Ab Rapid Test. This was studied by spiking of these substances into three levels of HCV standard Serum, Plasma and whole Blood control. The results are presented in the following table and demonstrate that at the concentrations tested, the substances studied did not affect the performance of the TRUSTline HCV Ab Rapid Test.

Potential interfering substances spiked		HCV Reactivity		
		Negative	Weak Positive	Strong Positive
Control		-	+	+++
Bilirubin	1 mg/dL	-	+	+++
	15 mg/dL	-	+	+++
Creatinine	1.5 mg/dL	-	+	+++
	5 mg/dL	-	+	+++
Glucose	80 mg/dL	-	+	+++
	120 mg/dL	-	+	+++
Albumin	3.5 g/dL	-	+	+++
	5 g/dL	-	+	+++
CRP	1 mg/dL	-	+	+++
	4 mg/dL	-	+	+++
Urea	9 mg/dL	-	+	+++
	40 mg/dL	-	+	+++
Bicarbonate 0.23 g/dL		-	+	+++
EDTA 3.48 µmol/L		-	+	+++
Sodium citrate 3.8%		-	+	+++

EXTERNAL EVALUATION RESULTS

The TRUSTline HCV Ab Rapid test was externally evaluated by The National Institute of Biologicals and it complies with the CDSCO's specifications. The TRUSTline HCV Ab rapid test qualified the evaluation with a sensitivity of 99% and a specificity of 100%.

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HCV in serum plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The TRUSTline HCV Ab Rapid Test is limited to the qualitative detection of antibodies to HCV in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
4. A non-reactive result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. False negative results may arise because of hook effect due to very high titer of antibodies in sample. Repeat the test by using different dilution of same sample.
6. Hemolytic samples may give reddish background even after end of the reading time.
7. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
8. Infection may progress rapidly. If the symptoms persist and the result from the TRUSTline HCV Ab Rapid Test is non-reactive, it is recommended to test with an alternative device or to re-sample the patient a few days later.
9. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Kuo,G, Choo Q-L, Alter, HJ, et al. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. Science 1989. 244:362-4.
2. Esteban JI, Gonzalez A, Hernandez JM, et al. Evaluation of antibodies to hepatitis C virus in a study of transfusion-associated hepatitis. N Engl J Med 1990. 323:1107-12.
3. Miyamura T, Saito I, Katayama T, et al. Detection of antibody against antigen expressed by molecularly cloned hepatitis C virus cDNA: application to diagnosis and blood screening for posttransfusion hepatitis. Proc Natl Acad Sci USA 1990. 87:983-7
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5. Houghton M, Weiner A, Han J, Kuo G, Choo Q-L. Molecular Biology of the Hepatitis C viruses: Implications for diagnosis, Development, and Control of Viral Disease. Hepatology 1991. 14:381-8.
6. Alter HJ, Purcell RH, Shih JW, Melpolder JC, Houghton M, Choo Q-L, Kuo G. Detection of antibody to hepatitis C virus in prospectivity followed transfusion recipients with acute and chronic non-A,non-B hepatitis. N Engl J Med 1989. 321:1494-1500.
7. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
Temperature limit 1-30 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight
Do not use if package is damaged	Contains sufficient for <n> tests	

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road,
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

PI-AR0024C Rev. B
Effective date: 21.11.2022
English version

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc.
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98925 94815
Email : omkarplastic89spi@gmail.com
Web : www.omkarplasticindustries.com
Made in India

Literature files

F/C

TRUSTline HCV Ab Rapid Test - Cassette REF AR0024C IVD

for the Detection of Antibodies to HCV in Human Serum / Plasma / Whole Blood

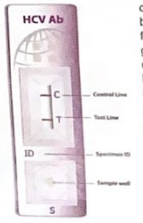
INTENDED USE

The TRUSTline HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as a screening test and as an aid in the diagnosis of infection with HCV. The test kit is not automated and does not require any additional instrument. Any reactive specimen with the TRUSTline HCV Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV), which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH)[1], causes chronic disease in 50% of cases[2]. HCV can also be transmitted through intravenous drug abuse and sexual contact[3].
Hepatitis C virus is a single-stranded RNA virus with structural similarities to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provide the basis for the construction of recombinant peptides representing putative hepatitis C virus proteins[4,5]. Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins helped to identify apparently healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus[6]. Therefore, the TRUSTline HCV Ab Rapid Test is a useful tool for blood bank screening safety.
The TRUSTline HCV Ab Rapid Test was developed to detect anti-HCV antibodies (IgG,IgM, IgA) in human serum, plasma or whole blood The test can be performed by minimally trained personnel and without cumbersome laboratory equipment.

TEST PRINCIPLE



The TRUSTline HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Antibodies to HCV, if present in the specimen, will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line, indicating a HCV Ab positive or reactive test result. Absence of the T line suggests a negative result.
The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of control antibodies regardless of the color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device b. One desiccant
2. Specimen transfer device
3. Sample diluent (5 mL/bottle)
4. One package insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Disposable gloves
3. Lancing device for whole blood test
4. Alcohol swab

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use the test device if pouch is not intact.
4. Do not use expired devices or components.
5. Bring all reagents to room temperature (15-30°C) before use.
6. Do not use the components of different lots and of any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Handle the negative and positive controls in the same manner as the patient specimens.
13. The test result should be read 15 minutes after a specimen is applied to the sample well of the device. Reading the test result after 20 minutes may give erroneous results.
14. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air conditioning.
15. Clean up spills thoroughly using appropriate disinfectant.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store test kit at 1-30°C. If stored at 2-8°C, ensure that all reagents are brought to room temperature before opening. The sample Diluent (Opened and unopened) and unopened test device is stable through the expiration date printed on the label, when stored at recommended temperature. Do not freeze the kit or expose the kit to temperatures above 30°C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into a new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test serum and plasma specimens as soon as possible after collecting. Store serum and plasma specimens at 2-8°C if not tested immediately. serum and plasma specimens can be stored at 2-8 °C for up to 5 days. The serum and plasma specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, Citrate or heparin, respectively, in vacutainer®). Do not use hemolysed blood for testing. Capillary blood (fingertip puncture) can be used directly without anti-coagulant. Collect blood with specimen transfer device and transfer it to sample well of device.
Whole blood specimen should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

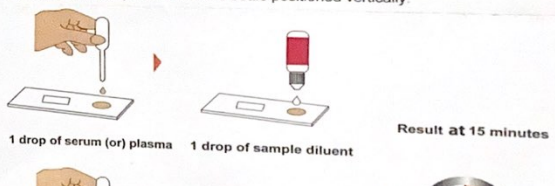
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

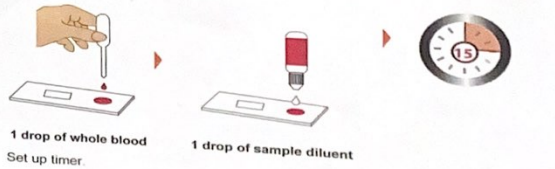
Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat and dry surface.

Step 3: Label the device with the specimen's ID number.

Step 4: Fill the specimen transfer device with the specimen.

Holding the specimen transfer device vertically, dispense 1 drop (about 30µL) of serum/plasma or 1 drop of whole blood (about 40µL) into the sample well making sure that there are no air bubbles. Immediately add 1 drop (about 35-50 µL) of Sample Diluent to the sample well with the bottle positioned vertically.





Step 5: Set up timer.

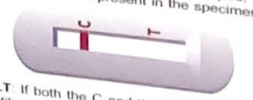
Step 6: Read the result at 15 minutes. Positive results may be visible as soon as 1 minute.
Do not read the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

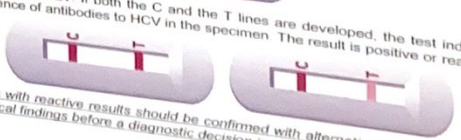
Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**. If only the C line is developed, the test indicates that no detectable antibodies to HCV are present in the specimen. The result is negative or non-reactive.



2. **POSITIVE RESULT**. If both the C and the T lines are developed, the test indicates the presence of antibodies to HCV in the specimen. The result is positive or reactive



Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic decision is made.

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc.
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98905 64815
Email : omkarplastic89pps@gmail.com
Web : www.omkarplasticindustries.com
Made in India

F/C
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Literature File

OSCAR

Syphilis Rapid Test

For qualitative detection of antibody of Syphilis / *Treponema pallidum (TP)* in human serum / plasma / whole blood

INTENDED USE:

Syphilis Rapid Test is an in vitro diagnostic rapid test based on the principle of immunochromatography on a membrane, for qualitative determination of antibodies (IgG/ IgM/ IgA) to *Treponema pallidum* (TP) a marker for diagnosis of Syphilis. For professional use only.

SUMMARY:

Treponema pallidum (TP) is the causative agent of venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. After infection, host forms non –treponemal anti lipodial antibodies to the lipodial material released from the damaged host cells as well as treponema specific antibodies. Diagnosis of syphilis depends on the correlation of clinical data with the non-treponemal and treponemal assays. Non-treponemal tests (VDRL, RPR, etc) are generally used for screening and treponemal tests (TPHA, FTA-ABS) are used as confirmatory tests. Rapid treponema antibody tests are gaining importance as screening and conformity tests, as they detect the presence of antibodies specific to *Treponema pallidum*.

PRINCIPLE:

Syphilis Rapid Test is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. As the test sample flows through the membrane assembly of the device, the colored recombinant antigen of TP-colloidal gold conjugate complexes with the anti TP in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant antigen of TP coated on the membrane leading to formation of a colored band 'T' which confirms a positive test result. Absence of this colored band in the test region 'T' indicates a negative test result. The unreacted conjugate and unbound complex moves further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region 'C' forming a colored band 'C'. This control band serves as an internal control to validate the test results.

PRESENTATION:

Catalogue Number	Number of Tests
HSR1050	50 Tests

REAGENTS AND MATERIALS SUPPLIED:

Each kit has

A. 50 individually sealed pouches containing:
   1. Test Device, comprising of a nitro cellulose membrane assembly predispensed with TP antigen at test line region "T" and anti mouse IgG at control line region "C". Conjugate pad containing TP antigen conjugated to colloidal gold.
   2. Disposable plastic dropper.
   3. Desiccant pouch.
   4. Sample Running Buffer.

B. Product insert.

MATERIAL REQUIRED BUT NOT PROVIDED:

Blood collection tubes, syringes, lancet, swab, gloves and timer etc.

STORAGE AND STABILITY:

The sealed pouches in the test kit may be stored between 2-30°C till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

PRECAUTIONS:

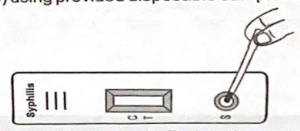
1. For professional use only, not to be used by the general public.
2. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
3. Bring all reagents and specimen to room temperature before use.
4. Do not pipette any material by mouth.
5. Do not eat, drink or smoke in the area where testing is done.
6. Use protective clothing and wear gloves when handling samples.
7. Use absorbent sheet to cover the working area.
8. Immediately clean up any spills with sodium hypochlorite.
9. Dispose off all the reagents and material used as if they contain infectious agent.
10. Neutralize acid containing waste before adding hypochlorite.
11. Do not use kit after the expiry date.
12. Do not mix components of one kit with another.

SPECIMEN COLLECTION AND STORAGE:

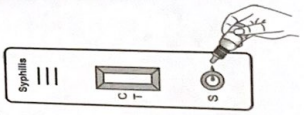
1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for 24 hours. For long storage, freeze at -20°C or below. Do not freeze whole blood. Specimen should not be frozen and thawed repeatedly. Maximum of two freeze/thaw cycles are allowed.
5. Do not heat inactivate before use.
6. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
7. Do not use turbid, lipaemic, haemolysed, clotted or contaminated specimens.

TEST PROCEDURE:

1. Bring the sealed pouch to room temperature, if the pouch of the test card is damaged discard the card and take a new one for the test. Open the pouch and remove the test card.
2. Label the card appropriately with patient identity. Once opened, the card must be used immediately. Refrigerated specimen must be bought to room temperature prior to use.
3. Add **one drop** (approx 20µl) of serum / plasma / whole blood into the sample well (S) using provided disposable sample dropper.



4. Add **one drop** of sample running buffer into the same well "S"



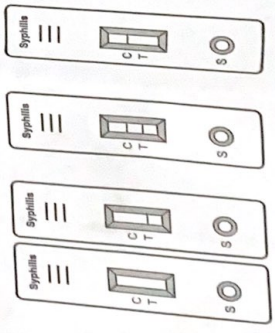
5. Read result between 15-20 minutes. Do not interpret result after 20 minutes.
6. Discard used card in a biomedical waste container after interpreting the results.

INTERPRETATION OF RESULTS:

Negative:
Appearance of only one colored band at control line region 'C'. The result should be considered negative.

Positive:
Appearance of two colored bands, one at test region 'T' and other at control line region 'C'. The result should be considered positive.

Invalid:
Appearance of no colored band at the control region C, the result should be considered as invalid. Repeat the test with a new test card.



QUALITY CONTROL:

The control line serves as an internal control for integrity of reagents. It is recommended to use known positive and negative samples to check performance.

SPS®
MUMBAI

SPRING CLIP FILE

302 : SPRING COBRA
Product Size : FC
Net Qty. : 1 Fc
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all Taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98920 84815
Email : omkarplasticinfo@gmail.com
Web : www.omkarplasticindustries.com
Made in India

Literature Cit

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SPS®
MUMBAI

SPRING CLIP FILE

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP ₹ : 70.00
(Incl. of all Taxes)
Mfg. and Mkt. By :
OMKAR PLASTIC INDUSTRIES
Customer Care : 98935 64615
Email : omkarplastic89spsl@gmail.com
Web : www.omkarplasticindustries.com
Made in India

DIAGNOS DENGUE CARD

Rapid Visual test for the qualitative & differential detection of IgM & IgG Antibodies to Dengue virus in Human Serum / Plasma

INTENDED USE

DIAGNOS DENGUE CARD is a rapid solid phase immuno-chromatographic assay for the qualitative and differential detection of IgM and IgG antibodies to dengue virus in human serum / plasma. This test is for *in vitro* diagnostic use only and is intended as an aid in the presumptive diagnosis between primary and secondary dengue infection. The kit detects all four subtypes; DEN1, DEN2, DEN3 & DEN4 of Dengue Virus.

PRINCIPLE

Dengue IgM/IgG test device contains three lines; "C" (Control line), "M" (IgM test line) & "G" (IgG test line). IgM test line is coated with anti-human IgM and IgG test line is coated with anti-human IgG. When a sample is added to the device, IgG and IgM antibodies in the sample react with anti-human IgM or IgG antibodies coated on the membrane respectively. Colloidal gold complexes containing dengue 1-4 antigens is captured by the bound anti-dengue IgM or IgG on respective test bands located in the test window causing a pale to dark red band to form at the IgG or IgM region of the test device window. The intensity of the test bands in the respective device will vary depending upon the amount of antigen/ antibody present in the sample. The appearance of any pink/red colour in a specific test region should be considered as positive for that particular antigen and/or antibody type (IgG or IgM). A red procedural control line should always develop in the test device window to indicate that the test has been performed properly.

KIT CONTENTS

a) Diagnos Dengue Card
b) Sample Dropper
c) Assay Buffer
d) Instruction Manual

KIT PRESENTATION

25 Test Pack

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical devices and their packing. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

- Manufactured By
- No. of tests
- LOT — Lot Number / Batch Number
- Manufacturing Date
- Expiry Date
- Do not use if package is damaged
- Single use only
- Keep Dry
- IVD — *In vitro* diagnostic medical device
- See Instruction for use
- Temperature Limitation
- Caution, see instruction for use
- REF — Catalogue Number
- Contains biological Material of Animal Origin
- Keep away from sunlight
- Country of Manufacture

WARNING FOR USERS

CAUTION: ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION. NO TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT HUMAN BLOOD PRODUCTS WILL NOT TRANSMIT INFECTION.

1. The use of disposable gloves and proper biohazardous clothing is STRONGLY RECOMMENDED while running the test.
2. In case there is a cut or wound in hand, DO NOT PERFORM THE TEST.
3. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
4. Tests are for in vitro diagnostic use only and should be run by competent person only.
5. Mark the test specimen with patient's name or identification number. Improper identification may lead to wrong result reporting.
6. Do not pipette by mouth.
7. All materials used in the assay and samples should be decontaminated in suitable disinfectant solution for 30-60 min. before disposal or by autoclaving at 121°C at 15psi for 60 min. Do not autoclave materials or solution containing sodium hypochlorite. They should be disposed off in accordance with established safety procedures and guidelines.
8. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. Consult a physician immediately in case of accident or contact with eyes, in the event that contaminated material are ingested or come in contact with skin puncture or wounds.
9. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
10. Assay Buffer contains Sodium Azide as a preservative. If these material are to be disposed off through a sink or other common plumbing systems, flush with generous amounts of water to prevent accumulation of potentially explosive compounds. In addition, consult the manual guideline "Safety Management No. CDC-22", Decontamination of Laboratory Sink Drains to remove Azide salts" (Centre for Disease Control, Atlanta, Georgia, April 30, 1976).
11. Follow standard biosafety guidelines for handling & disposal of potentially infective material.

PRECAUTION

1. Do not open or remove test card from their individually sealed pouches until immediately before their use.
2. Do not reuse test cards.
3. All test device, buffer and specimens must be at room temperature before running the test.
4. Do not use kit beyond the stated expiry date mentioned on the kit.
5. Do not mix components from different lot numbers.
6. Interpret the results at the end of 20 minutes only.

KIT STORAGE & STABILITY

The kit should be stored at 2-30°C in the coolest and driest area available. Expiry date on the kit indicates the date beyond which kit and its components should not be used. Diagnos Dengue Card should not be frozen and must be protected from exposure to humidity.

SPECIMEN COLLECTION AND PREPARATION

1. Serum / plasma samples may be used with this test.
2. If serum / plasma specimens cannot be tested immediately, they should be refrigerated at 2-8°C. For storage for more than 3 days, freeze the specimen at -20°C or below.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Specimens containing precipitate or particulate matter may yield inconsistent test results. Such specimens must be centrifuged and the clear supernatant should only be used for testing.
5. The use of hemolytic, lipaemic, icteric or bacterially contaminated specimens should be avoided as it may lead to erroneous results.

BEFORE YOU START

The Assay Buffer Solution provided in the kit has closed nozzle and screw cap with pin (outside). Before using Assay Buffer, keep the vial vertically straight and tap down gently on the working platform, so that Assay Buffer comes down at the bottom of the vial. To orifice/puncture the closed nozzle, follow the instruction as illustrated below:

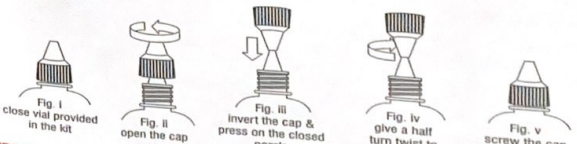

Fig. i close vial provided in the kit — Fig. ii open the cap — Fig. iii invert the cap & press on the closed nozzle — Fig. iv give a half turn twist to puncture the nozzle — Fig. v screw the cap tightly after use

TEST PROCEDURE

1. Bring the required number of Diagnos Dengue Card foil pouches and specimen to room temperature prior to testing.
2. Remove the test card from the foil pouch prior to use.
3. Label the test card with patient's name or identification number.
4. Fill the Dengue Antibody lower circular part of the sample dropper with the specimen upto the mark provided on the dropper as shown in fig. (a). Then add the specimen to the sample well "S" of antibody device as shown in fig. (b). This will add 10 µl of specimen to the device. Dispose off the dropper considering it to be biohazardous.

   Alternatively, add 10 µl of sample using micropipette to the sample well of the antibody device.

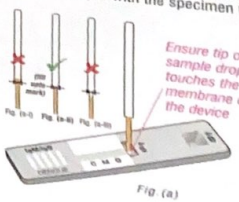

Fig. (a)

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Important Note

(i). During addition of sample to sample window "S", gently press the sample dropper onto the membrane of the device for 1 to 2 seconds. Ensure that the sample has been dispensed on the membrane and sample starts to flow on the membrane. This can be seen by observing the flow of the sample in device window. If the sample does not flow, again press the dropper tip gently and touch the membrane pad to remove entrapped air so that the sample starts to move and flow. Even if, still the sample does not flow, it could be that it contains particulate matter or is turbid. If so, rerun the test, after centrifuging at 10,000 rpm. for 10 minutes or more (in case clear sample is not obtained after centrifugation).

(ii) Do not add Assay Buffer until sample starts flow as it may lead to false positive results.

(iii) Never add assay buffer in the sample well "S" as it will stop the flow of conjugate. If in case the device does not show conjugate flow, it could be that the assay buffer has been added accidentally in the sample well. Repeat the test with fresh card.

(iv) The devices should not be opened / tampered as it will result in changes in the alignment of the membrane.

5. Add 2 drops (70 µl)of dengue antibody assay buffer to the Buffer well "B" of the device as shown in fig. (b).


Fig. (b)

NOTE: Please ensure, no air is entrapped and full drop falls down from the nozzle tip.

6. Allow reaction to occur during the next 20 minutes.
7. Read results at 20 minutes. Positive results may appear as early as 5-10 minutes. However, negative results must be confirmed after 20 minutes only.
8. Discard the Diagnos Dengue Card Test immediately after reading result at 20 minutes, considering it to be potentially infectious.

INTERPRETATION OF THE TEST

IgM & IgG REACTIVE

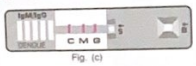

Fig. (c)

As shown in Fig. (c), appearance of red coloured line in the control region 'C' and Test region; IgM region 'M' and IgG region 'G' indicates that the sample is reactive for both IgM & IgG antibodies. This is indicative of a secondary dengue infection.

IgM REACTIVE

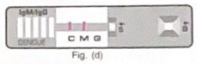

Fig. (d)

As shown in Fig. (d), appearance of red coloured line in the control region 'C' and Test region; IgM region 'M' indicates that the sample is reactive for IgM antibodies. This is indicative of a primary dengue infection.

IgG REACTIVE

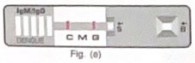

Fig. (e)

As shown in Fig. (e), appearance of red coloured line in the control region 'C' and Test region; IgG region 'G' indicates that the sample is reactive for IgG antibodies. This is indicative of a secondary dengue infection.

NON-REACTIVE

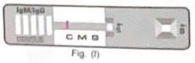

Fig. (f)

As shown in Fig. (f), appearance of one distinct red coloured line in the control region 'C' only (with no line in the IgM region 'M' & IgG region 'G') indicates that the sample is non-reactive for dengue antibodies.

INVALID

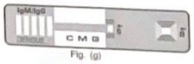

Fig. (g)

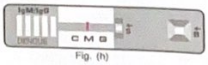

Fig. (h)

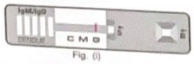

Fig. (i)

If no control line appears after the completion of test as shown in Fig. (g), (h) & (i), the test should be treated as Invalid which may be because of following reasons:

(a) Improper storage at temperature other than the recommended temperature.
(b) Wrong test procedure
(c) Long atmospheric exprosure of the test device after opening the pouch.
(d) Use of turbid/ lipemic/ haemolyzed sample.

In case of invalid result, the test sample should be centrifuged at 10,000 rpm for 15 minutes and retest using new Card.

LIMITATIONS OF THE TEST

1. The test is for *in vitro* diagnostic use only.
2. This test detects the presence of antibodies to dengue virus in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first seven to ten days after infection. Where symptoms persist, patients should be re-tested 3-5 days after the first testing date.
4. Serological cross-reactivity across the Flavivirus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.
5. As with all diagnostic tests, all results must be corelated with other clinical findings. 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 an early infection of Dengue virus.
6. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and serological test like haemagglutination inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

PERFORMANCE CHARACTERISTICS

An elaborated study has been done on Diagnos Dengue Card to determine its performance as a screening test. The performance of the test was evaluated and compared with a licensed commercially available ELISA test kit in-house by using a known panel of Serum/ Plasma dengue negative & positive samples. The samples included cross-reacting samples; Epstein-Barr virus, Malaria, Rheumatoid factor, Leptospirosis, Japanese encephalitis, yellow fever and West Nile viruses. The results obtained are as follows:

Sample Type	No. of Samples tested	Result of licensed test	Diagnos Dengue Card results
Negative for Ab to Dengue	4030	4030	3910
Dengue IgM Positive	120	120	114
Dengue IgG Positive	79	79	75

Sensitivity : 95% **Specificity : 97%**

Precision: Within run (Intra assay) & between run (Interassay) precision have been determined by testing 10 replicates of 9 samples - 2 negative, 7 Dengue positive (3 weak, 3 medium and 1 strong). The C.V. (%) of all the five samples were within 10% of the time.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an *in vitro* diagnostic assay within the limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BIBLIOGRAPHY

1. Guzman M.G. & Kourig Clinical & Diagnostic Laboratory Immunology (1996) Vol. 3, No. 6, 621-627.
2. Young PR., Hilditch PA., etal J. Clinical Microbiology (2000) Vol. 38, No.3, 1053-1057.

in vitro diagnostic Reagent, not for medicinal use

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302 - SPRING COBRA
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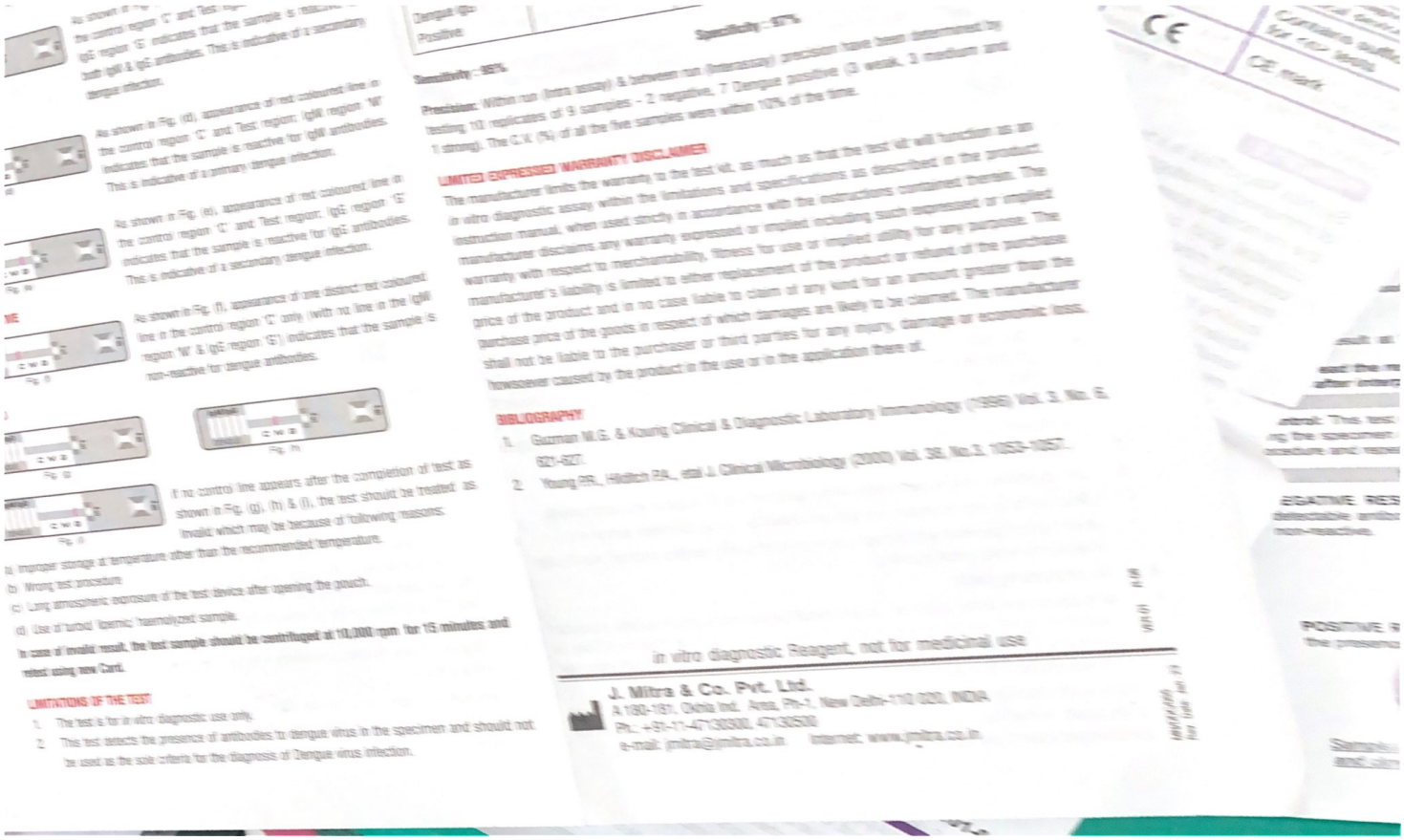

Sensitivity : 95%

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LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, so much as that the test kit will function as an in vitro diagnostic assay where the limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied ability for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind, for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BIBLOGRAPHY

1. Gubler M.G. & Kourig Clinical & Diagnostic Laboratory Immunology (1998) Vol. 5, No. 6, 821-827.
2. Young PR., Hilditch PA., etal J. Clinical Microbiology (2000) Vol. 38, No.3, 1053-1057.

in vitro diagnostic Reagent, not for medicinal use

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LIMITATIONS OF THE TEST

1. The test is for in vitro diagnostic use only.
2. This test detects the presence of antibodies to dengue virus in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.

If no control line appears after the completion of test as shown in Fig. (g), (h) & (i), the test should be treated as invalid which may be because of following reasons:

a) Improper storage at temperature other than the recommended temperature.
b) Wrong test procedure.
c) Long atmospheric exposure of the test device after opening the pouch.
d) Use of turbid /plasmic/ haemolyzed sample.

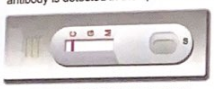
In case of invalid result, the test sample should be centrifuged at 10,000 rpm for 15 minutes and retest using new Card.

CE

CE Mark

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE OR NON-REACTIVE RESULT:** If only the C line is present, the absence of any color in the both test lines (M and G) indicates that no anti-*S. typhi* or *paratyphi* antibody is detected in the specimen. The result is negative or non-reactive.

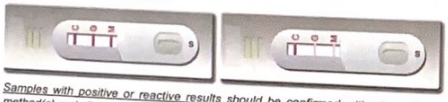


2. **POSITIVE OR REACTIVE RESULT:**

2.1 In addition to the presence of C line, if only M line develops, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgM in the specimen. The result is IgM positive or reactive.

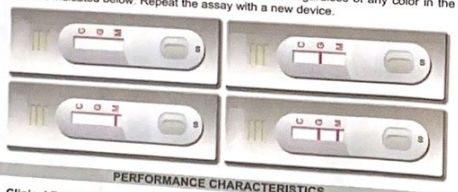
2.2 In addition to the presence of C line, if only G line develops, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgG in the specimen. The result is IgG positive or reactive.

2.3 In addition to the presence of C line, both M and G lines develop, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgG and IgM in the specimen. The result is both IgG and IgM positive or reactive.



Samples with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis decision is made.

3. **INVALID:** If no C line develops, the assay is invalid regardless of any color in the test lines as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. **Clinical Performance for IgM Test**

A total of 334 specimens were collected from susceptible subjects and tested by the Typhoid IgG/IgM Rapid Test and by a commercial *S. typhi* IgM EIA. Comparison for all subjects is shown in the following table:

IgM EIA	Typhoid IgG/IgM Rapid Test		
	Positive	Negative	Total
Positive	31	3	34
Negative	2	298	300
Total	33	301	334

Relative Sensitivity: 91%, Relative Specificity: 99.3%, Overall Agreement: 98.5%

2. **Clinical Performance for IgG Test**

A total of 314 specimens were collected from susceptible subjects and tested by the Typhoid IgG/IgM Rapid Test and by a commercial *S. typhi* IgG EIA kit. Comparison for all subjects is shown in the following table.

IgG EIA	Typhoid IgG/IgM Rapid Test		
	Positive	Negative	Total
Positive	13	1	14
Negative	2	298	300
Total	15	299	314

Relative Sensitivity: 92.9%, Relative Specificity: 99.3%, Overall Agreement: 99.0%

3. **Performance Comparison with Blood Culture**

Nine (9) *S. paratyphi* A positive and eleven (11) *S. typhi* positive specimens confirmed with the blood culture were tested with the Typhoid IgG/IgM Rapid Test. The Typhoid IgG/IgM Rapid Test correctly indentified 9 *S. paratyphi* A and 10 *S. typhi* specimens. The agreement was 95%.

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to *S. typhi* or *paratyphi* in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Typhoid IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to *S. typhi* or *paratyphi* in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable anti-*S. typhi* or *paratyphi* antibodies. However, a negative test result does not preclude the possibility of exposure to *S. typhi* or *paratyphi*.
4. A negative or non-reactive result can occur if the quantity of anti-*S. typhi* or *paratyphi* antibodies present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Infection may progress rapidly. If the symptom persists, while the result from Typhoid IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to test with an alternative test method, such as bacterial culture method.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.
2. Gotuzzo E, Frisancho O, Sanchez J, Liendo G, Carillo C, Black RE, Morris JG. Association between the acquired immunodeficiency syndrome and infection with Salmonella typhi or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.
3. Clegg A, Passey M, Omena MK, et al. Re-evaluation of the Widal agglutination test in response to the changing pattern of typhoid fever in the highlands of Papua New Guinea. Acta Tropica 1994; 57:255-63.
4. Pang T. False positive Widal test in nontyphoid Salmonella infection. Southeast Asian Journal of Tropical Medicine and Public Health 1989; 20: 163-4.
5. Ismail A, Hai OK, Kader ZA. Demonstration of an antigenic protein specific for Salmonella typhi. Biochem Biophys Res Commun. 1991;181(1):301-5.

Index of CE Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
	Store between 2-30°C	EC REP	Authorized Representative	2	Do not reuse
	Manufacturer		Date of manufacture		

Mfd. by: M/s. CTK Biotech, Inc,
13855 Stowe Dr, Poway, California 92064,
United States having factory premises at M/s.
Beijing Genesee Biotech, Inc., 36, Yanqi Donger
Road, Huairou Yanqi Industrial Development
Zone 101407 Beijing, China

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

PI-R0160C-ATH Rev. HP1.0
Date released: 2019-09-05
English version

For Export Only, Not For Re-sale in the USA

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F/C
302

SPS
MUMBAI

SPRING CLIP FILE

302 - SPRING COBRA
Product Size : FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98205 64815
Email : omkarplasticsbpo@gmail.com
Web. : www.omkarplasticsindustries.com
Made in India

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Typhoid IgG/IgM Rapid Test-Cassette (Serum / Plasma)

OnSite CE

REF R0160C IVD In vitro Diagnostic

INTENDED USE

The Typhoid IgG/IgM Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of anti-*Salmonella typhi* (*S. typhi*) and *paratyphi* IgG and IgM in human serum or plasma. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with *S. typhi* and *paratyphi*.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

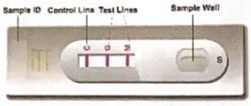
SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever and paratyphi fever are bacterial infections caused by *Salmonella typhi and paratyphi A, B, and C respectively*, which are transmitted through the ingestion of tainted food and water. Worldwide an estimated 17 million cases and 600,000 associated deaths occur annually[1]. Patients who are infected with HIV are at significantly increased risk of clinical infection. 1-5% of patients become chronic carriers harboring *S. typhi* in the gallbladder.

The clinical diagnosis of infections depends on isolation of *S. typhi and paratyphi* from blood, bone marrow or a specific anatomic lesion. In facilities that can not afford to perform this complicated and time-consuming procedure, Filix-Widal test is used to facilitate diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test[3,4].

In contrast, the Typhoid IgG/IgM Rapid Test is a simple, fast laboratory test that simultaneously detects and differentiates IgG and IgM antibodies to *S. typhi* and *paratyphi* antigen[5] thus aiding in the determination of current or previous exposure to *S. typhi* and *paratyphi*. IgM positive or IgM /IgG both positive suggest current infection, while IgG positive suggests late stage of infection, previous infection, or latent infection.

TEST PRINCIPLE



The Typhoid IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing recombinant H antigen and O antigen conjugated with colloidal gold (HO conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of anti-*S. typhi* and *paratyphi* IgM, G line is pre-coated with reagents for the detection of anti-*S. typhi* and *paratyphi* IgG, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the test specimen migrates by capillary action across the test cassette. IgM antibodies if present in the patient specimen will bind to the HO conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a colored M line, indicating an anti-*S. typhi* or *paratyphi* IgM positive test result.

IgG antibodies if present in the patient specimen will bind to the HO conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a colored G line, indicating an anti-*S. typhi* or *paratyphi* IgG positive test result.

Absence of any test lines (M and G) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of the color development on any of the test lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample diluent (REF SB-R0160, 5 mL/bottle)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test results should be read 15 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15 minutes window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma/Serum

Step 1: Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.

Step 2: To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.

Step 3: To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately. The specimens can be stored at 2-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature, if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

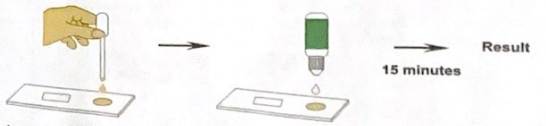
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: Fill the plastic dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of serum/plasma into the center of the sample well, making sure that there are no air bubbles.

Then immediately add 1 drop (about 35-50 µL) of sample diluent into the center of the sample well with the bottle positioned vertically.



1 drop of serum/plasma **1 drop of sample diluent**

Step 5: Set up timer.

Step 6: Results should be read at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only. ***Any results interpreted outside of the 15 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.***

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kit is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kit falls outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

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SPS MUMBA

MADE IN INDIA

SPRING CLIP

302 - SPRING COBR
Product Size : FC
Net Qty. : 1 Pc
Mfg. : June 2021
MRP : ₹ 70.00
(Incl. of all taxes)
Mfg. and Mkt. by
OMKAR PLASTIC INDUSTRIES
Customer Care : 98925 64815
Email : omkarplasticfittings@gmail.com
Web : www.omkarplasticindustries.com
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