Q-line® Rapid HCV

Reference / Pack Sizes
HCV-010PS 1 x 10 Test
HCV-025PS 1 x 25 Test

Kit Composition
Test Device, Buffer Vial
Sample dropper & IFU

INTENDED USE
Q-Line® *Rapid* HCV (Device) is an immunoassay for the rapid and visual detection of antibodies to HCV in human Serum/Plasma/Whole Blood for the diagnosis of Hepatitis C.

PRINCIPLE
After addition of the serum or plasma and assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HCV antigen and Mouse IgG. If the sample contains detectable levels of the antibodies against HCV antigen, it reacts with the gold conjugated HCV antigen to form a complex. This complex moves further and reacts with HCV antigen coated as a test line on the nitrocellulose membrane to form colored band. The unbound complex and the Mouse IgG conjugated colloidal gold particles move further to the goat anti-Mouse IgG coated control area to form a colored band (control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

KIT CONTENTS
- Q-Line® *Rapid* HCV antibody test devices, Individually pouched
- Buffer Vial
- Sample dropper
- Instructions for Use (IFU)

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer, Sample container, Disposable gloves

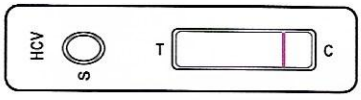
WARNINGS AND PRECAUTIONS
- For professional in vitro diagnostic use only. Do not reuse.
- Do not use after the expiration date printed on the foil pouch.
- Do not use if the pouch is torn or damaged.
- Please read all the information in this package insert before performing the test. Pay particular attention to the position of the control and test lines.
- Do not open the foil pouch until you are ready to start the test.
- Keep out of the reach of children.
- Use appropriate personal protective equipment
- Do not touch the membrane.
- Treat samples and used tests as potentially infectious. Avoid contact with skin.
- Do not mix the specimen sample or interchange the different specimen.
- Do not eat the desiccant provided in the package.
- Dispose off hygienically as per local regulatory requirements.

STORAGE & STABILITY
- Store in the sealed pouch in a dry place between temperature 4°C to 30°C. Do not freeze.
- Shelf life of the product is 24-months from the date of manufacture which is labelled on the box.

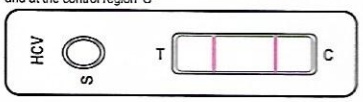
SPECIMEN COLLECTION
Serum/Plasma /Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted (for whole blood testing) or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

TEST PROCEDURE
- Before opening the foil, pouch allow the test device and sample to reach room temperature (20°C to 30°C).
- Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
- Remove the test device, sample dropper and desiccant from the pouch. Check the color of desiccant.
- It should be blue. If it has turned colorless or pink, discard the test device and use another test device.
- Label the test device with patient's identity
- Place the device on flat plane surface & add 2 drops (approx.60 µL) of serum / plasma or 1drop of whole blood (approx.30 µL) in well "S" using sample dropper.
- Immediately dispense one drop of assay buffer (approx.30 µL for serum/plasma samples) or 2 drops assay buffer (approx.60 µL for whole blood samples) into well "S", by holding the plastic dropper bottle vertically.
- Start the timer.
- Read the result at the end of 20 minutes. **Do not read the result after 30 minutes.**

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

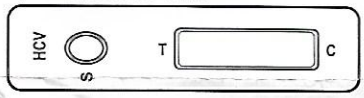


Positive: A distinct colored line appears at the test region "T" and at the control region 'C'

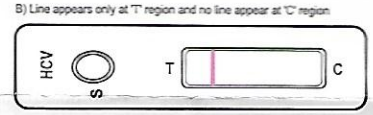


Invalid: The test should be considered invalid if,

A) If No line appearsat 'T' and 'C' region



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



NOTE: The intensity of color in the test line region (T) will vary depending on the levels of the antibody in the specimen. However, neither the quantitative value nor the rate of increase in level of antibody in the specimen can be determined by this qualitative test.

Positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 20 minutes.

QUALITY CONTROL
Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

PRODUCT PERFORMANCE
1) Sensitivity & Specificity

Q-Line® *Rapid* HCV antibody test device sensitivity & Specificity has been found as under

Parameter	(% age)
Sensitivity	100 %
Specificity	100 %

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

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

REFERENCES

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362
3. van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337:317
4. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204

SYMBOLS:-

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

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Q-line® *Rapid* HBsAg

Reference / Pack Sizes
HBS-025PS 1 x 25 Test

Kit Composition
Test Device, Buffer Vial
Sample droppers & IFU

INTENDED USE
Q-Line® *Rapid* HBsAg (Device) is an immunoassay for the rapid and visual detection of Hepatitis B Surface Antigen (HBsAg) in human Serum/Plasma/Whole Blood for the diagnosis of Hepatitis B.

PRINCIPLE
After addition of the serum/plasma/whole blood sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HBsAg specific antibody and rabbit IgG. If the sample contains detectable levels of the HBsAg Antigen, it reacts with the gold conjugated HBsAg specific antibody to form a complex. This complex moves further and reacts with HBsAg specific antibody coated as a test line on the nitrocellulose membrane to form colored band. The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat antirabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control
line should always appear if the test is performed as per the procedure and reagents are working properly.

KIT CONTENTS
- Q-Line® *Rapid* HBsAg Antigen test devices, Individually pouched
- Buffer Vial
- Sample droppers
- Instruction for use (IFU)

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer, Sample container, Disposable gloves

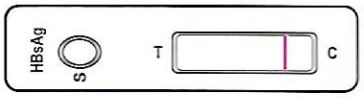
WARNINGS AND PRECAUTIONS
- For professional *in vitro* diagnostic use only. Do not reuse.
- Do not use after the expiration date printed on the foil pouch.
- Do not use if the pouch is torn or damaged.
- Please read all the information in this package insert before performing the test. Pay particular attention to the position of the control and test lines.
- Do not open the foil pouch until you are ready to start the test.
- Keep out of the reach of children.
- Use appropriate personal protective equipment
- Do not touch the membrane.
- Treat samples and used tests as potentially infectious. Avoid contact with skin.
- Do not mix the specimen sample or interchange the different specimen.
- Do not eat the desiccant provided in the package.
- Dispose off hygienically as per local regulatory requirements.

STORAGE & STABILITY
- Store in the sealed pouch in a dry place between temperature 4°C to 30°C. Do not freeze.

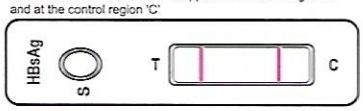
SPECIMEN COLLECTION
Serum/Plasma /Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted (for whole blood testing) or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

TEST PROCEDURE
- Before opening the foil, pouch allow the test device and sample to reach room temperature (20°C to 30°C).
- Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
- Remove the test device, sample dropper and desiccant from the pouch. Check the color of desiccant.
- It should be blue. If it has turned colorless or pink, discard the test device and use another test device.
- Label the test device with patient's identity
- Place the device on flat plane surface & add 2 drops (approx.60 µL) of serum / plasma or 1drop of whole blood (approx.30 µL) in well "S" using sample dropper.
- Immediately dispense one drop of assay buffer (approx.30 µL for serum/plasma samples) or 2 drops assay buffer (approx.60 µL for whole blood samples) into well "S", by holding the plastic dropper bottle vertically.
- Start the timer.
- Read the result at the end of 20 minutes. Do not read the result after 30 minutes.

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

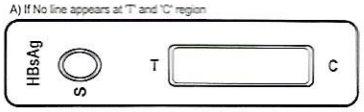


Positive A distinct colored line appears at the test region 'T' and at the control region 'C'

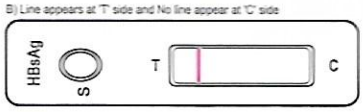


Invalid: The test should be considered invalid if,

A) If No line appears at 'T' and 'C' region



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



NOTE: The intensity of color in the test line region (T) will vary depending on the levels of the antibody in the specimen. However, neither the quantitative value nor the rate of increase in level of antibody in the specimen can be determined by this qualitative test.

Positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 20 minutes.

QUALITY CONTROL
Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

PRODUCT PERFORMANCE
1) Sensitivity & Specificity

Q-Line® *Rapid* HBsAg Antigen Test devices sensitivity & Specificity has been found as under

Parameter	(% age)
Sensitivity	100 %
Specificity	99.8 %

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

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

REFERENCES

1. Kim, C. Y., Tillis, J. G. 1973, Purification of Biophysical characterization of Hepatitis A antigen, J. Clin. Invest, 52, May 1973, Pgs. 1176-1186.
2. Kee Myung Lee et.al., Emergence of Vaccine- induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J.Korean. Med.Sci., 2001, 16, Pgs 356-361.
3. Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): Pgs1165-1169.

SYMBOLS:-

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

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CE

ENTEROSCREEN-WB™

Rapid test for detection of IgM and IgG antibodies to *S. typhi* in serum/plasma/whole blood

DEVICE

INTENDED USE

ENTEROSCREEN-WB ™ is a rapid, self performing, qualitative, sandwich immunoassay for the detection and differentiation of IgM and IgG antibodies to *S. typhi* in human serum/plasma or whole blood specimen.

SUMMARY

Typhoid fever is a systemic prolonged febrile illness caused by a bacteria *Salmonella typhi*. The disease is transmitted through ingestion of food or water contaminated with faeces or urine of infected persons.

Acute typhoid fever is characterized by prolonged fever, disturbances of bowel functions (constipation or diarrhoea), headache, malaise and anorexia. Cough is common in the early stage of illness. Chronic carrier is determined when excretion of *S.typhi* in stools or urine lasts for longer than one year after onset of acute typhoid fever. Accurate diagnosis of typhoid fever at an early stage is not only important for etiological diagnosis but to identify and treat the potential carriers and prevent acute typhoid fever outbreaks. Specific agglutinins appear during the course of most of the attacks during the second week of infection. Detectable levels of IgM antibodies against *S.typhi* appear and persists for four months, IgG antibodies are detected thereafter and remain in blood for two years. The detection of IgM reveals acute typhoid in the early phase of infection, while the detection of both IgG and IgM suggests acute typhoid in the middle phase of infection. In areas of high endemicity, where the rate of typhoid transmission is high, the detection of specific IgG increases.

In the conventional Widal test the interpretation of results is done against a baseline titre in the same geographical area since titres of diagnostic significance differ in endemic or non-endemic areas. A paired sera with a fourfold rise in titer is needed for a meaningful result.

The limitations of the traditional methods have prompted novel tests to be developed. **ENTEROSCREEN-WB** ™ qualitatively detects and differentiates between IgM and IgG class of antibodies specific to *S. typhi* in human serum/plasma or whole blood specimens.

PRINCIPLE

ENTEROSCREEN-WB ™ utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. **ENTEROSCREEN-WB** ™ is a dual test device assembly comprising of an IgM detection test assembly and an IgG detection test assembly. The conjugate pad of the IgM test assembly consists of two components, Agglutinating sera for Human IgM conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. Similarly the IgG test assembly consists of Agglutinating sera for Human IgG conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the respective membrane test assemblies, the Agglutinating sera for Human IgM or the Agglutinating sera for Human IgG -colloidal gold conjugate complexes with the *S. typhi* specific IgM or IgG antibodies in the specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further to the test regions of the respective test assembly where the specimen is immobilized by the *S. typhi* specific Lipopolysaccharide (LPS) O antigen coated at the test regions of the IgM/ IgG device assembly leading to formation of a pink to pink- purple colored band at the test regions of the respective test devices which indicates a positive IgM or IgG test result. The absence of this colored band in either of the test regions indicates a negative test result.

In both the test membrane assemblies the unreacted conjugate and unbound complex, if any move further on the membranes and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membranes at the control region (C), forming a pink to pink-purple colored band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

ENTEROSCREEN-WB ™ kit contains:

A. Individual pouches, each containing -

1. Dual test device :

   IgM Test Assembly: DEVICE Membrane assembly pre-dispensed with Agglutinating sera for Human IgM-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, *S. typhi* specific LPS O antigen and Agglutinating sera for rabbit globulin coated at the Test region 'T' and Control region 'C' respectively and

   IgG Test Assembly: DEVICE Membrane assembly pre-dispensed with Agglutinating sera for Human IgG-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, *S. typhi* specific LPS O antigen and Agglutinating sera for rabbit globulin coated at the Test region 'T' and Control region 'C' respectively.

2. Desiccant pouch.

B. PIPETTE Disposable Plastic Sample Applicator.

C. BUF Sample Running Buffer in a dropper bottle.

D. Package Insert.