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"DIAQUICK" HBsAg Cassette
(Hepatitis B surface antigen)
for serum and plasma samples

REF	Content
Z00350	- 30 tests individually packed, disposable pipette (30 x Ref. No: Z00350B). - 1 package insert
Z00350B	- 1 tests individually packed, disposable pipette - 1 package insert

For in vitro diagnostic use only

GENERAL INFORMATION

Method	sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	2 – 30°C
Sample	human serum or plasma
Results	within 15 minutes at room temperature
Sensitivity	1 ng/ml after 30 minutes incubation time

INTENDED USE

The "DIAQUICK" HBsAg Cassette is an immunochromatographic in vitro rapid test for the qualitative determination of Hepatitis B surface antigen (HbsAg) in human serum or plasma. It is a simple and sensitive test.

CLINICAL SIGNIFICANCE

The discovery of Australian antigen by Blumberg, et. al., and its subsequent identification as the surface antigen of hepatitis B virus (HBsAg) represents a significant break through in the understanding of the disease, serum hepatitis. It is known that the screening of blood donor for the presence of this antigen in serum has significantly reduced the incidence of hepatitis B in blood transfusion recipients.

TEST PRINCIPLE

The "DIAQUICK" HBsAg Cassette is a chromatographic immunoassay (CIA) for the rapid qualitative determination of human hepatitis B surface antigen (HBsAg) in serum. The membrane is pre-coated with anti-HBs antibody on the test band region and Rabbit anti-goat IgG on the control band region. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

WARNINGS AND PRECAUTIONS

- For in vitro use only.
- Do not smoke or eat or drink or pipet by mouth in the laboratory.
- Wear disposable gloves whenever handling patient specimens
- Treat serum samples as if they were infectious. All materials, also the cassette used for testing, should be sterilized before abandon.
- Do not use the test kit beyond expiration date.
- Humidity and temperature can adversely affect results.

STORAGE

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

SAMPLE COLLECTION AND PREPARATION

- The "DIAQUICK" HBsAg Cassette (serum/plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

ASSAY PROCEDURE

Allow test cassette, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75µl) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. It is important that the background is clear before the result is read.

Note: A low HBsAg concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

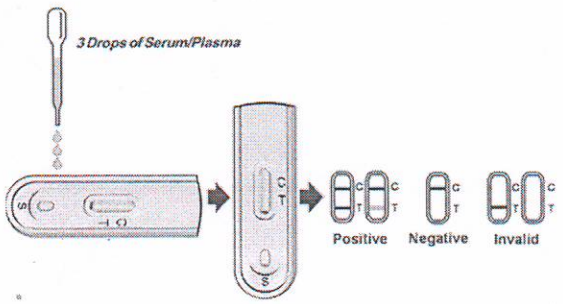
INTERPRETATION OF RESULTS

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

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

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

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

LIMITATION

- The "DIAQUICK" HBsAg Cassette (serum/plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.
- The "DIAQUICK" HBsAg Cassette (serum/plasma) will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- The "DIAQUICK" HBsAg Cassette (serum/plasma) cannot detect less than 1 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

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PERFORMANCE CHARACTERISTICS

Sensitivity
The "DIAQUICK" HBsAg Cassette (serum/plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg One Step Hepatitis B Surface Antigen Test Cassette (serum/plasma). The test can detect 5ng/mL of HBsAg in 15 minutes, and 1 ng/mL of HBsAg in 30 minutes.

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

HBsAg Reference Method

Method		EIA		Total Results
DIAQUICK HBsAg Cassette	Results	Positive	Negative	
	Positive	145	5	150
	Negative	0	150	150
Total Results		145	155	300

Relative Sensitivity: > 99.0%
Relative Specificity: 96.7%
Accuracy: 98.3%

Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens containing 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg. The negative and positive values were correctly identified 98% of the time.

Inter-Assay
Between-run precision has been determined by using the same three specimens of 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg in 15 independent assays. Three different lots of the "DIAQUICK" HBsAg Cassette (serum/plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

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