HBeAg Rapid Test Cassette (Serum/Plasma) Package Insert

REF IHBEG-302	English

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

【INTENDED USE】
The HBeAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of HBeAg in serum or plasma.

【SUMMARY】
Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. Hepatitis B e antigen is a viral protein secreted by HBV-infected cells. Its presence indicates high levels of virus in the blood, and it is an indicator of the infectiousness of the carrier. If this test is negative, but a person is known to be HBsAg positive, then it indicates low levels of virus in the blood or an "integrated phase" of HBV in which the virus is integrated into the host's DNA.[1] This test is often used to monitor the effectiveness of some HBV therapies, whose goal is to convert an actively replicating state to "e-antigen negative" state.[2]
The HBeAg One Step Hepatitis B e Antigen Rapied Test cassette (Serum/Plasma)is a rapid test to qualitatively detect the presence of HBeAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBeAg in serum or plasma.
This one step test is very sensitive and only takes about 15-20minutes. Test results are read visually without any instrument.

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

【REAGENTS】
The test cassette contains anti-HBeAg particles and anti-HBeAg coated on the membrane respectively.

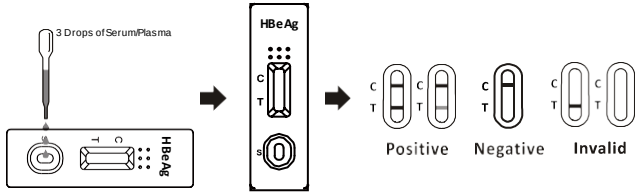
【PRECAUTIONS】
Please read all the information in this package insert before performing the test.
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Hand all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】
Store as packaged at room temperature or refrigerated (2-30°C). The test cassette 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】
- The HBeAg Rapid Test Cassette can be performed using either serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- 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 regulations covering the transportation of etiologic agents.

【MATERIALS】
Materials provided
• Test Cassettes • Droppers • Package Insert
Materials required but not provided
• Specimen Collection Containers • Centrifuge • Timer

【DIRECTIONS FOR USE】
1. Remove the test cassette from the sealed foil 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 clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx.75μL) to sample well of the test cassette respectively, then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the red line to appear. The result should be read at 15 minutes. Do not interpret the results after 20 minutes.



【INTERPRETATION OF RESULTS】
(Please refer to the illustration above)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBeAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored 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 colored line appearing in the control line 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 positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】
1. The HBeAg Rapid Test Cassette is for professional in vitro diagnostic use only. The test should be used for the detection of HBeAg in serum or plasma specimen. Neither the quantitative value nor the rate of HBeAg concentration can be determined by this qualitative test.
2. The HBeAg Rapid Test Cassette will only indicate the presence of HBeAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

【PERFORMANCE CHARACTERISTICS】
Sensitivity and Specificity
The HBeAg Rapid Test Cassette (Serum/Plasma) was compared with leading commercial RIA HBeAg tests; the results show that the HBeAg Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

Method		RIA		Total Results
HBeAg Rapid Test Cassette(Serum/Plasma)	Results	Positive	Negative	
	Positive	154	9	163
	Negative	6	429	435
Total Results		160	438	598

Relative Sensitivity: 96.3% (95%CI*: 92.1%-98.6%)
Relative Specificity: 97.9% (95%CI*: 96.1%-99.1%)
Accuracy: 97.5% (95%CI*: 95.9%-98.6%) *Confidence Intervals

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive, high positive of HBeAg. The negative and positive values were correctly identified 99% of the time.
Inter-Assay
Between-run precision has been determined by using the same three specimens of negative, low positive, high positive of HBeAg in 15 independent assays. Three different lots of the HBeAg Rapid Test Cassette (Serum/Plasma) has been tested over a 10 days period using negative, lowpositive and high positive specimens. The specimens were correctly identified 99% of the time.

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

Interfering Substances
The HBeAgRapid Test Cassette (Serum/Plasma)has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

【BIBLIOGRAPHY】

1. Tassopoulos NC, Volpes R, Pastore G, et al. Post lamivudine treatment follow up of patients with HBeAg negative chronic hepatitis B. J Hepatol1999;30 (Suppl 1) :117.
2. Fu X, Wu F, Chen G, et al. Feasibility analysis of quantitative detection on serum HBeAg/HBeAb by time-resolved immunofluorescence assay. Zhong Nan Da Xue Xue Bao Yi Xue Ban. 2016;41(8):852-5.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

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