HBeAg DEVICE (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHEG1	20 Tests

Intended Use:
The HBeAg Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Envelope antigen in serum and 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 infectivity of the carrier. If this test is negative, but a person is known to be HBV 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. 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.
The test uses a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBeAg in serum and plasma. This test is very sensitive and takes less than 20 minutes. Test results are read visually without any instrument.

Test Principle:
The HBeAg test is a qualitative, solid phase, two-site sandwich immunoassay. The membrane is pre-coated with anti-HBeAg antibody on the test region of the device. During testing the serum or plasma sample reacts with particles coated with anti-HBeAg antibody. The mixture migrates upward on the membrane by capillary action to react with the anti-HBeAg at the test region to generate a coloured line. The presence of a coloured line in the test region indicates a positive result, while absence indicates a negative result.
To serve as a procedural control, a coloured line should always appear in the control region indicating that proper volume of sample has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Disposable sample droppers
Instructions For Use sheet

Materials not provided: Timer, sample collection tubes, centrifuge

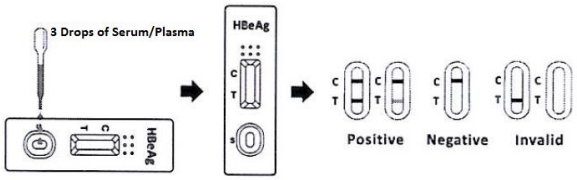
Precautions:
For professional *in vitro* diagnostic use only.
Do not eat, drink or smoke in the area where the samples or kits are handled.
Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of samples.
Wear protective clothing including laboratory coats, disposable gloves and safety glasses when samples are being tested.
Humidity and temperature can adversely affect results.

Reagent Preparation and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2 - 30°C).
The test is stable up to the expiry date printed on the sealed pouch.
The test must remain in the sealed pouch until use.
Do not freeze.
Do not use beyond the expiry date.

Sample Collection and Storage:
The HBeAg Rapid Test Device (Serum/Plasma) can be performed using either serum or plasma.
Collect serum and plasma by standard venepuncture technique. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolyzed samples can be used.
Testing should ideally be performed immediately after the samples have been collected. Do not leave the samples at room temperature for prolonged periods. Samples may be stored at 2 - 8°C for up to 3 days. For long term storage, samples should be kept below -20°C.
Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
If samples are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

Assay Procedure:
Allow test device, sample, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device 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 device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µL) to the sample well of the device, and then start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the coloured line(s) to appear. The result should be read at 15 minutes. Do not interpret any result after 20 minutes.



Interpretation of Results:

POSITIVE: Two coloured lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T).

NEGATIVE: Only one coloured line appears in the control region (C). No coloured line develops in the test region (T).

INVALID: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Controls:
A procedural control is included in the test. A coloured line appearing in the control region is the internal procedural control. It confirms sufficient sample volume and correct procedural technique.
Quality Controls are not supplied with this kit; however, it is recommended that positive and negative control be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The HBeAg Rapid Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. Neither the quantitative concentration nor the rate of HBeAg generation can be determined by this qualitative test.
2. The result from this test should not be used as the sole criteria for the diagnosis of Hepatitis B infection, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics:
Sensitivity and Specificity:
Comparison of the HBeAg Rapid Test Device (Serum/Plasma) with a leading commercial HBeAg EIA test showed that the HBeAg Rapid Test Device has a high sensitivity and specificity.

Method		EIA		Total Results
HBeAg Rapid Test Device (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
Intra Assay precision was determined using 15 replicates of three samples negative, low positive and high positive for HBeAg. The negative and positive values were correctly identified 99% of the time.

Inter-Assay
Inter Assay precision was determined using the same three samples of negative, low positive and high positive for HBeAg in 15 independent assays. Three different lots of the HBeAg Rapid Test Device (Serum/Plasma) were tested over a 10 days. The samples were correctly identified 99% of the time.

Cross-reactivity
The HBeAg Rapid Test Device (Serum/Plasma) was tested using HAMA Rheumatoid factor, HAV, Syphilis, HIV, H. pylori, MONO, CMV, Rubella and TOXO positive samples. There was no cross-reactivity using these samples.

Interfering Substances
The HBeAg Rapid Test Device (Serum/Plasma) has been tested for possible interference from visibly haemolyzed and lipemic samples. No interference was observed in samples containing up to 2,000 mg/dl haemoglobin, 1,000 mg/dl bilirubin and 2,000 mg/dl human serum albumin.

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References:

1.Tassopoulos NC, Volpes R, Pastore G, et al. Post Iamivudine treatment follow up of patients with HBeAg negative chronic hepatitis B. J Hepatol 1999;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.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Do not reuse

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