Japanese Encephalitis IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

The Japanese Encephalitis IgM Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgM Antibodies for Japanese Encephalitis virus in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PJEV 01
05 Tests	PJEV 05
10 Tests	PJEV 10
25 Tests	PJEV 25
50 Tests	PJEV 50

CLINICAL SIGNIFICANCE

Japanese encephalitis (JE) is an infection of the brain caused by the Japanese encephalitis virus (JEV). While most infections result in little or no symptoms, occasional inflammation of the brain occurs. In these cases, symptoms may include headache, vomiting, fever, confusion and seizures. This occurs about 5 to 15 days after infection. This disease is the leading cause of viral encephalitis in Asia, with 30,000 to 50,000 cases reported annually[1]. Case-fatality rates range from 0.3% to 60% and depends on the population and on age. JEV is generally spread by mosquitoes, specifically those of the *Culex* type. Pigs and wild birds serve as a reservoir for the virus. The disease occurs mostly outside of cities. Diagnosis is based on blood or cerebrospinal fluid testing[3].JE virus IgM antibodies are usually detectable 3 to 8 days after onset of illness and persist for 30 to 90 days, but longer persistence has been documented[2]. Therefore, positive IgM antibodies occasionally may reflect a past infection or vaccination. Serum collected within 10 days of illness onset may not have detectable IgM. For patients with JE virus IgM antibodies, confirmatory neutralizing antibody testing should be performed

Japanese encephalitis (JE) IgM Ab Rapid Test is the latest generation of chromatographic immunoassays which utilizes recombinant antigens to detect antibodies to IgM of JEV in human serum, plasma or whole blood. The test is user friendly, highly sensitive and specific.

PRINCIPLE

The kit employs a combination of colloidal gold immune-chromatography, the T line is pre-coated with mouse anti human IgM monoclonal antibody and the C line is pre-coated with goat anti-mouse IgG antibody, the recombinant encephalitis b virus antigen conjugated with on colloidal gold. The kit is used to qualitatively detect encephalitis b virus immunoglobulin M (JEV-IgM) antibody in human serum, plasma or whole blood. During testing with positive samples, JEV-IgM antibody in the sample can be captured on recombinant encephalitis b virus antigen of colloidal gold and will bind to the formation of immune complexes, by the chromatography effect complexes and sample in internal flow on nitrocellulose membrane. When the complexes move through the T line region with the mouse anti human IgM monoclonal antibody, it will bind to form colored test line indicating the presence of JEV IgM". The rest of the complexes through the C line with goat anti-mouse IgG antibody will bind to form a colored line on C region.
The test contains an internal control (C line), which should exhibit a 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.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only)
• Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The Japanese encephalitis IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the sample well of the test cassette by using a sample dropper. Avoid air bubbles.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- 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.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 20µL) and add 2

drop of buffer (approximately 80 µL) into the specimen well, and start the timer. See illustration below.

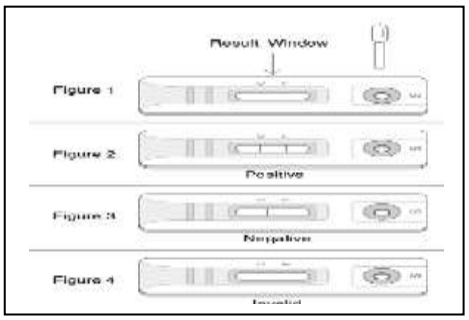
For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 20 µl) to the specimen well, then add 2 drops of buffer (approximately 80 µL), and start the timer. See illustration below.

For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 20 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.

4. Wait for the colored line(s) to appear. Read results at 15 minutes.

Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



1) Positive

The control line (C) and test line (T) lines are visible on the test device. This is positive for Japanese encephalitis IgM Ab. This is indicative of presence of JEV infection

2) Negative

The control line is the only visible line on the test device. No Japanese encephalitis IgM Ab Ab were detected, this marks non-infection of JEV

3) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The Japanese encephalitis IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of Japanese encephalitis IgM Ab in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Japanese encephalitis IgM Ab can be determined by this qualitative test.
2. A negative result can occur if the level of Japanese encephalitis IgM Ab present in the specimen is below the detection limits of the assay Japanese encephalitis IgM Ab that is detected is not present during the stage of JEV infection in which a sample is collected. However, a negative test result does not preclude the possibility of JEV infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

Sensitivity and Specificity

A total of 275 specimens were collected (including susceptible subjects) and tested by Japanese encephalitis IgM Ab Rapid Test and a commercial JEV IgM Rapid test as reference. Comparison for all subjects is showed in the following table.

Method		Other Rapid Test		Total Test
Japanese encephalitis IgM Ab Rapid Card Test	Result	Positive	Negative	
	Positive	73	2	75
	Negative	2	198	200
Total Results		75	200	275

Relative Sensitivity: 97.3% (95% CI: 97.8-98.9%) Relative Specificity: 99% (95% CI: 98.8-99.9%) Overall Agreement: 98.54% (95% CI: 98.8-99.9%)

Cross-reactivity

The Japanese encephalitis IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Japanese encephalitis IgM Ab Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/d.l

BIBLIOGRAPHY

1. Simon, LV; Kruse, B (January 2018). "Japanese Encephalitis". *Encephalitis,Japanese*.StatPearls. PMID 29262148.
2. *Solomon, T. (2006). "Control of Japanese encephalitis – within our grasp?". New England Journal of Medicine. 355 (9): 869–71*
3. Gambel JM, DeFraites R, Hoke C, et al. (1995). "Japanese encephalitis vaccine: persistence of antibody up to 3 years after a three-dose primary series (letter)". *J Infect Dis*. 171 (4): 1074. doi:10.1093/infdis/171.4.1074. PMID 7706798
4. Japanese encephalitis virus". Australian Government Department of Health and Aged Care. Retrieved 20 October 2022 and microbiological results. J. Clin. Microbiol.1994.32:46-50

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
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