Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IMON-C41	English

A rapid test for the diagnosis of infectious mononucleosis (IM) to detect heterophile antibodies (IgM) qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of heterophile antibodies (IgM) in whole blood, serum or plasma as an aid in the diagnosis of infectious mononucleosis (IM).

【SUMMARY】

Infectious mononucleosis[1,2] (IM; also known as mono, glandular fever, Pfeiffer's disease, Filatov's disease, and sometimes colloquially as the kissing disease from its transmission by saliva) is an infectious, widespread viral disease most commonly caused by the Epstein–Barr virus (EBV), a member of the herpes virus family[3], against which over 90% of adults are likely to have acquired immunity by the age of 40.[4] Occasionally, the symptoms can reoccur at a later period. Most people are exposed to the virus as children, when the disease produces no noticeable or only flu-like symptoms. In developing countries, people are exposed to the virus in early childhood more often than in developed countries. As a result, the disease in its observable form is more common in developed countries. It is most common among adolescents and young adults. Especially in adolescents and young adults, the disease is characterized by fever, sore throat and fatigue, along with several other possible signs and symptoms. It is primarily diagnosed by observation of symptoms[5], but suspicion can be confirmed by several diagnostic tests. It is generally a self-limiting disease, and little treatment is normally required.

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of recombinant antigen coated particles and capture reagent to detect heterophile IgM antibodies in whole blood, serum or plasma.

【PRINCIPLE】

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of heterophile antibodies in whole blood, serum or plasma. In this test procedure, anti-human IgM antibody is immobilized in the test line region of the test. After specimen is added to the specimen area of the cassette, it reacts with recombinant antigen coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgM. The test format can detect IgM antibody against IM in specimens. If the specimen contains IgM antibodies against IM, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain IgM antibodies against IM, a colored line will not appear in this region, indicating 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 contains recombinant antigen coated colloid gold particles and anti-human IgM coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). The test 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 after the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Mononucleosis Rapid test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- 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.
- 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 the specimens have been collected. 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

- Test Cassettes
- Buffer
- Droppers
- Package Insert

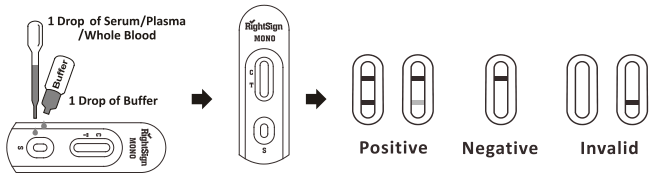
Materials required but not provided

- Specimen collection contain
- Centrifuge
- Timer

【DIRECTIONS FOR USE】

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

- 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.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of whole blood, serum or plasma (Approx.40μl) and add 1 drop of buffer (Approx.40μl) to the specimen well of the test cassette. Avoid trapping air bubbles in the specimen well. See the illustration below.
- Wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret results after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

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

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line 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. 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 considered an internal procedural control. It confirms adequate membrane wicking.

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】

1. Although the Mononucleosis Rapid Test is very accurate in detecting anti-IM IgM antibodies, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

【EXPECTED VALUES】

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Mononucleosis EIA test, demonstrating an overall accuracy of 99.5%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Mononucleosis Rapid Test using clinical specimens. The results show that the sensitivity of the Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is greater than 99.9% and the specificity is 99.5% relative to the leading EIA test.

Method		EIA		Total Result
Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	15	1	16
	Negative	0	197	197
Total Result		15	198	213

Relative sensitivity: 15/15>=99.9% (95%CI*: 81.9%~100.0%);
Relative specificity: 197/198=99.5% (95%CI*: 97.2%~100.0%);
Accuracy: (15+197)/(15+0+1+197)=99.5%(95%CI*: 97.4%~100.0%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of five specimens: a negative, low titer positive, middle titer positive and high titer positive. The negative, low titer positive, middle titer positive and high titer positive were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same five specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-day period using negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Mononucleosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis antibody, anti-HIV, anti-H.pylori, anti-CMV, anti-Rubella, anti-HSV, anti-TB and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Mononucleosis negative and positive specimens.

Albumin: 20mg/mL Bilirubin: 10mg/dL Triglycerides: 2mg/mL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Cozad J (March 1996). "Infectious mononucleosis". The Nurse Practitioner 21 (3): 14–6, 23, 27–8.
2. Hoagland RJ (June 1975). "Infectious mononucleosis". Primary care 2 (2): 295–307.
3. Bravender, T (August 2010). "Epstein-Barr virus, cytomegalovirus, and infectious mononucleosis". Adolescent medicine: state of the art reviews 21 (2): 251–64.
4. Schonbeck, John and Frey, Rebecca. The Gale Encyclopedia of Medicine. Vol. 2. 4th ed. Detroit: Gale, 2011. Online.
5. Odumade, OA; Hogquist, KA; Balfour HH, Jr (January 2011). "Progress and problems in understanding and managing primary Epstein-Barr virus infections". Clinical Microbiology Reviews 24 (1): 193–209.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Number: RP5307800
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