MONONUCLEOSI CARD IgM

For *in Vitro* **diagnostic use**

Immunochromatographic test for the Qualitative Detection of Infectious Mononucleosis Heterophile Antibody.

INTENDED USE AND SUMMARY

The Mascia Brunelli Mononucleosi card IgM Kit is a manual, rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

IM is an acute, self-limiting disease caused by the Epstein-Barr virus (EBV). Infection with EBV in early life usually is asymptomatic. However, up to 50% of infection occurring in young adulthood and adolescence will develop clinical manifestations associated with IM.

Diagnosis of IM is based on the evaluation of characteristic clinical symptoms and serological changes. Serological diagnosis of IM has been demonstrated by the detection of heterophile and EBV specific antibodies. The heterophile antibody is detectable at some point during IM in most adults. It is a widely accepted practical among physicians to most adults. It is a widely accepted practice among physicians to use the detection of heterophile antibodies as an aid in the diagnosis of IM. The Mononucleosi card IgM kit utilizes bovine erythrocyte extract which has a higher sensitivity and specificity than extracts from other species.

PRINCIPLES OF THE PROCEDURE

The Mononucleosi card IgM Kit has been designed to detect IM through visual interpretation of colour development in the test device, which is a sandwich solid phase gold conjugate immunoassay. *In this test, bovine erythrocyte extracted antigen is immobilized in the test line region of the test. During testing, the specimen reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test and interacts with the immobilized bovine erythrocyte extracted antigen. If the specimen contains IM heterophile antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain IM heterophile antibodies, 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 propre volume of specimen has been added and membrane wicking has occurred.*

MATERIALS PROVIDED

The Mascia Brunelli Mononucleosi card IgM Kit contains the following items to perform the assay:

Test Card (cassette) with	25 items
Disposable sample dropper.	25 items
Buffer	5.0 mL
Instruction for use	1 item

MATERIALS REQUIRED BUT NOT PROVIDED

Vacutainer tubes: Plan for serum procedure, EDTA, heparin or citrate for plasma or whole blood procedure; finger lancet for finger stick blood procedure; timer.

STORAGE AND STABILITY

The Mononucleosi card IgM Kit should be stored at room temperature 2-30ºC. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

WARNINGS

- For professional use and in vitro diagnostic use only
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND PREPARATION

Fingerstick:

- Clean the area to be lanced with an alcohol swab. Allow to dry.
- Squeeze the end of the fingertip and pierce with a sterile lancet.
- Wipe away the first drop of blood with sterile gauze or cotton. Allow the second drop to flow directly into the sample well of the test device or use the transfer pipette provided to obtain fresh blood, Add 2 drops (about 50 µL) into the sample well.

Whole Blood

- A certified phlebotomist should collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.
- The whole blood may be used for testing immediately or may be stored at 2-8 °C up to two days.

Plasma

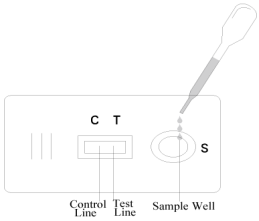
- A certified phlebotomist should collect whole blood into a top collection tube (containing EDTA, citrate or heparin. respectively) by venipuncture.
- Separate the plasma by centrifugation as soon as possible to avoid hemolysis.
- Carefully withdraw the plasma for testing or label and store at 2-8°C for up to three days. Plasma may be frozen at –20°C for up to one year.

Serum

- A certified phlebotomist should collect whole blood into a red top collection tube (containing no anticoagulants) by venipuncture.
- Allow the blood to clot and separate serum by centrifugation.
- Carefully withdraw the serum for testing, or label and store at 2-8°C for up to three days. Serum may be frozen at –20°C for up to one year.

TEST PROCEDURE

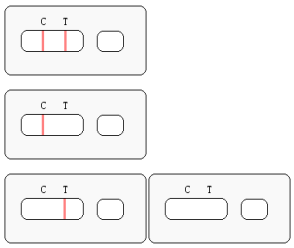
- Review specimen collection instructions.
- Test device, Test Buffer, patient's samples should be brought to room temperature prior to testing. Do not open pouches until ready to perform the assay.
- Remove the test device from its protective pouch. (Bring the device to room temperature before opening to avoid condensation of moisture on the membrane). Label the device with patient identification.
- Add specimen to sample well:
  1) For fingertip blood: Allow the second drop to flow directly into the sample well of the test device or use the pipet provided to obtain fresh blood, Add 2 drops (50 µL) into sample well.
  2) For whole blood samples in collection tubes: add two drops (50 µL) into the sample well, holding the provided transfer pipet in a vertical position.
  3) For plasma or serum samples: add 1 drop of serum or plasma (25 µL) into the sample well, holding the provided transfer pipette in a vertical position.
- Immediately add 1 drop (55 µL) of Buffer.



After adding the Test Buffer wait for the red coloured lines to appear. Depending on the concentration of heterophile antibodies present, positive results may be observed within 3 minutes. However, to confirm a negative result, the complete reaction time of 5 minutes is required. **Do not read test results after 10 minutes.**

INTERPRETATION OF THE TEST

1. As the test kit begins to work, a colour band will appear at the left section of the Result Window to show that the test is working properly. This band is the "Control Line." C *(Internal Quality Control)*
2. The right section of the Result Window indicates the test results. If another colour band appears at the right section of the result window, this band is the "Test Line." T



Positive: two red lines appear. One red line in the control region **(C)** and one in the test region **(T)**. When testing with strong positive samples, the intensity of the control line may be lighter than expected. Comparison of the line intensity is not recommended.

Negative: only one red line appears in the control region. No apparent faint red line on the test line region (T).

Invalid: The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.

LIMITATIONS OF THE PROCEDURE

Although the IM 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. 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 VALUE

- During the acute phase of IM, heterophile antibodies are detectable in 80-85% of patients. Heterophile antibodies are detectable during the first month of illness and decrease rapidly after four weeks.
- Positive results may be persistent for months or even years
- Some segment of the population who contract IM do not produce measurable levels of heterophile antibodies. Approximately 50% of children under 4 years old who have IM may test negative.

SENSITIVITY

The MONONUCLEOSI CARD IgM has been evaluated with specimens confirmed positive or negative by a leading commercial slide agglutination test. The slide agglutination test served as the reference method for the MONONUCLEOSI CARD IgM test. The result shows that the sensitivity of the MONONUCLEOSI CARD IgM test is *97.6%* relative to the slide agglutination test.

PRECISION

Intra-Assay: Within-run precision has been determined by using 3 replicates of three specimens: a negative, a low positive and a middle positive. The negative, low positive and middle positive values were correctly identified >99% of the time.

Inter-Assay: Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive and a middle positive. Three different lots of the MONONUCLEOSI CARD IgM test have been tested using negative, low positive and middle positive specimens. The specimens were correctly identified >99% of the time.

SPECIFICITY

The MONONUCLEOSI CARD IgM test uses an antigen that is highly specific for IM antibodies in whole blood, serum or plasma. The results show that the specificity of the MONONUCLEOSI CARD IgM test is *97.8%* relative to the slide agglutination test.

Method		Slide Agglutination		**Total Results**
MONONUCLEOSI CARD IgM	**Results**	Positive	Negative	
	Positive	*122*	*4*	*126*
	Negative	*3*	*176*	*179*
Total Results		*125*	*180*	*305*

Relative Sensitivity: *97.6% (93.1%-99.5%)** Relative Specificity: *97.8% (94.4%-99.4%)**
Relative Accuracy: *97.7% (95.3%-99.1%)** * 95% Confidence Intervals

CROSS-REACTIVITY

RF, HBsAg, HBeAg, HBcAb, HBeAb, HCV, TB, HIV and Syphilis positive specimens were tested with the MONONUCLEOSI CARD IgM test. No cross-reactivity was observed, indicating that the MONONUCLEOSI CARD IgM has a high degree of specificity for human antibodies to IM.

REFERENCES

1. Hickey SM, Strasburger VC. What Every Pediatrician Should Know About Infectious Mononucleosis in Adolescents. Pediatr Clin North Am. 1997; 44(6):1541-56
2. Omori M. Mononucleosis. 2002. http://www.emedicine.com/EMERG/topic309.htm
3. Linde A. Diagnosis of Epstein-Barr virus-related diseases. Scand J Infect Dis Suppl. 1996 ; 100 :83-8
4. Papesch M, Watkins R. Epstein-Barr virus infectious mononucleosis. Clin Otolaryngol. 2001; 26(1): 3-8
5. CDC National Center for Infectious Diseases. EBV & IM: http://www.cdc.gov/ncidod/diseases/ebv.htm

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Keep away from heat

CONTENT **Ref. VQ82705 (25 test)**

Test Card (cassette)	25 items
Disposable sample dropper	25 items
Buffer	1 x 5.0 mL
Instruction for use	1 item

EDMA Code 17 70 90 03 00 CE IVD

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