MONO-K20

for Whole Blood, Plasma or Serum

DIAGNOSTIK NORD
IHR PARTNER FÜR IN VITRO DIAGNOSTIKA

EXPLANATION OF THE TEST

An infectious mononucleosis (IM) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, whole blood. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

The Diagnostik Nord infectious mononucleosis (IM) test cassette has a letter "T" and "C" as "Test Line" and "Control Line" on the surface of the cassette. Both the "Test Line" and "Control Line" in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. The "Control Line" should always appear if the test procedure is performed properly and the test reagents of the control line are working properly. A purple "Test Line" will be visible in the Result Window if there are enough antibodies against IM in the sample. If antibodies against IM are not detected in the sample, there is no color appears in "Test Line".
This test is intended for professional use as an aid in the diagnosis of IM. The One Step IM Test is a chromatographic immunoassay for the qualitative detection of antibodies against IM in serum, plasma or whole blood.

MATERIALS PROVIDED

The Diagnostik Nord IM test kit contains the following items to perform the assay;
1. Diagnostik Nord IM test cassette.
2. Disposable sample dropper.
3. Instructions.
4. Developing buffer.

PRECAUTIONS

The Diagnostik Nord IM test cassette should be stored at room temperature 4-30 °C (40-86 °F). 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.

SPECIMEN COLLECTION STUDY

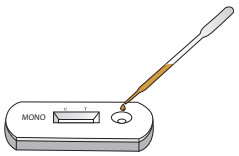
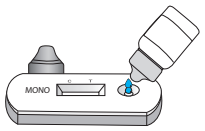
Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

Plasma/Serum specimen collection:
1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 °C. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

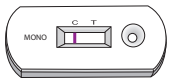
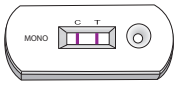
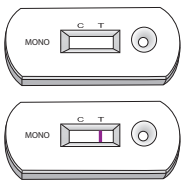
PROCEDURE OF THE TEST

1	Remove the test disk from the foil pouch, and place it on a flat, dry surface.	
2	Holding the sample dropper above the test disk, **squeeze 1 drop of specimen into the sample well.**	
3	Then **add 2 drops of the buffer.** As the test begins to work, you will see purple color move across the Result Window in the center of the Test Disk.	
4	**Interpret test results at 5 minutes.** Do not interpret test result after 10 minutes.	

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

negative	The presence of **only one purple color band** within the result window indicates a negative result.	
positive result	The **presence of two color bands** ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result. **Note**: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.	
invalid result	After performing the test and **no purple color band** is visible within the result window, this result is considered invalid. The direction may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.	

LIMITATIONS OF THE TEST

Although the One Step 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.

» SPECIFICITY AND INTERFERENCE STUDY

Determine the Specificity of the Diagnostik Nord IM test cassette.
An in-house study is conducted with 3 separate lots of the Diagnostik Nord IM test cassette. Compounds tested include: Serum with triglyceride concentrations up to 500 mg/mL, Serum with Bilirubin concentrations up to 10 mg/100mL, Prostatic acid phosphatase with concentrations up to 1000 mIU/mL and Albumin with concentrations up to 20 mg/mL. All of the above were analyzed and did not show interference or cross reactivity with the test.

» REFERENCES

1. *Evans AS and Niederman JC, "EBV-IgA and New Heterophil Antibody Tests in Diagnosis of Infectious Mononucleosis," Am J Clin Pathol, 1982, 77:555-60.*
2. *Fleisher GR, Collins M, and Fager S, "Limitations of Available Tests for Diagnosis of Infectious Mononucleosis," J Clin Microbiol, 1983, 17:619-24.*
3. *Horwitz CA, Henle W, Henle G, et al, "Persistent Falsely Positive Rapid Tests for Infectious Mononucleosis. Report of Five Cases with 4-6 Year Follow-Up Data," Am J Clin Pathol, 1979, 72:807-11.*
4. *Lee CL, Davidsohn I, and Slaby R, "Horse Agglutinins in Infectious Mononucleosis," Am J Clin Pathol, 1968, 49:3-11.*
5. *Vahlne A, Uertborn M, and Iwarson S, "Mumps Occuring as a Mononucleosis-Like Syndrome With Positive Monospot Test," JAMA, 1979, 242:711, (letter).*

» SYMBOLS

CE		Σ_n	Content
IVD	For in-vitro diagnostic use only	LOT	Lot number
	For single use only		Expiry date
	Carefully read package insert		Store at room temperature

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» PRODUCER

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