CENOGENICS

MONODEX - I.M. SCREENING TEST

SUMMARY AND TEST PRINCIPLE

Paul and Bunnel reported that sera from patients with infectious mononucleosis (IM) contain heterophile antibodies which agglutinated sheep and horse erythrocytes[1].

Forssman discovered a second group of heterophile antibodies, unrelated to IM, which were also found to agglutinate sheep and horse erythrocytes[2].

The Forssman type of heterophile antibodies were found in sera of patients with various disease conditions and also in individuals who had been exposed to horse serum[3,4].

While the Forssman heterophile are also absorbed from serum by horse or guinea pig kidney, the IM or heterophile antibodies are not. By contrast, only IM heterophile antibodies are absorbed by beef erythrocytes. This is the basis of the differential serological test introduced by Davidsohn[5, 6, 7].

MONODEX test incorporates both Paul and Bunnel screening procedures and the Davidsohn differential absorption techniques, thus providing a screening or differential test. Furthermore, the MONODEX uses horse erythrocyte stroma as indicator reagents for enhanced stability.[11]

In the MONODEX IM screening test, the serum is allowed to react with the indicator Horse Stroma reagent. In this case, agglutination of the stroma is indicative of a positive reaction.

REAGENT PREPARATION

The reagents in the MONODEX KIT are all ready to use. Prior to use bring all reagents and specimens to room temperature.

Shake Horse Stroma Reagent before use.

Use new dispenstir for each test sample.

Use new mixing stick for each sample.

Do not interchange kit reagents with those from other kits.

After use, wash glass slide with distilled water. Do not use detergent.

SPECIMEN PREPARATION

Serum or plasma can be used in this test. Inactivation of the serum is not necessary. However, inactived serum may be used. If the serum or plasma cannot be used within 24 hours after collection, it should be frozen. After thawing, specimen should be mixed thoroughly and clarified by centrifugation if particulate matter is present.

STORAGE

Store at 2° - 8°C. Do not freeze.

WARNING

The reagents in this kit contain sodium azide. Sodium azide may react with copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volume of water to prevent azide buildup.

TEST PROCEDURE

Materials provided:

Dyed Horse Erythrocyte Stroma, 50 tests
I.M. Positive Control Serum, 0.5ml
I.M. Negative Control Serum, 0.5ml
Disposable dispenstirs, 50
6-ring glass slide
Disposable mixing sticks, 50
Product instructions

Material required but not provided:

Isotonic saline (0.85% sodium chloride)

SCREENING TEST

1. Use new dispenstir for each sample. Squeeze dispenstir between the thumb and the forefinger and insert into the sample. Release pressure. This will allow serum to fill the tip.
2. Hold the dispenstir perpendicularly over the circle of the glass slide and squeeze to release one free-falling drop.
3. Shake the container of Horse Stroma, then squeeze a drop onto the sample.
4. Using the mixing stick, thoroughly mix the samples and reagent and spread over the entire circle.
5. Rock slide gently for one minute with a slight left and right rotation.
6. At the end of one minute, observe for agglutination while holding the slide under a high intensity lamp or fluorescent light.

Agglutination is indicative of a positive test. A blue homogeneous suspension or finely granular pattern is indicative of a negative reaction. (Note: In most cases, agglutination will occur in less than a minute).

PERFORMANCE AND LIMITATIONS OF THE TEST

The result of MONODEX test, as with other serological procedures, should not be used as a sole diagnostic criterion for the presence or absence of the disease state, but as an aid to diagnosis when other criteria are applied. In some cases, false positive results have been shown to be due to residual IM antibody present after clinical symptoms have subsided. Likewise, it has been shown that false negative results may be due to delayed heterophile antibody response[9].

PERFORMANCE CHARACTERISTICS

With over 500 tests performed MONODEX showed 99% correlation with other commercial tests, which utilize fresh stabilized horse erythrocytes.[10]

QUALITY CONTROL

For positive control, use I.M. Positive Control Serum in lieu of patient's serum. Positive reaction should occur within one minute.

For negative control, use I.M. Negative Control Serum. The negative control will produce no agglutination after one minute. The relative degree of smoothness of the reagents should be considered and incorporated in reading the results.

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CENOGENICS CORPORATION
Morganville, NJ
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