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Procedure No. _____

Procedure	Monogen - NCCLS
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Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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PRINCIPLE:

The **Monogen** reagent is a suspension of polystyrene latex particles of uniform size coated with highly purified Paul-Bunnell antigen from bovine red cell membranes. The degree of purity of the antigen is such that the **Monogen** reagent reacts only with infectious mononucleosis heterophile antibodies. For this reason, "differential" absorptions are not necessary.

Latex particles allow visual observation of the antigen-antibody reaction. If infectious mononucleosis heterophile antibodies are present in the serum or plasma, the latex suspension changes its' uniform appearance and a clear agglutination becomes evident.

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SPECIMEN COLLECTION

Type: Use fresh serum or plasma.

Handling Conditions: If the test cannot be performed on the day of sample collection, the serum may be stored between 2-8°C for no longer than 8 days. Plasma must be tested within 24 hours of blood collection. For longer periods, the serum sample must be frozen. Hemolytic or contaminated serum or plasma must not be used.

EQUIPMENT AND MATERIALS

Materials Required:

- Normal saline (0.9% NaCl) (for semi-quantitative technique)
- Serological or automatic pipettes
- Timer

Materials Provided:

- Monogen latex reagent
- Positive control - undiluted
- Negative Control - pre-diluted
- Disposable Slides

Storage Requirements: Reagents and controls should be stored at 2-8° C.
DO NOT FREEZE

QUALITY CONTROL

1. Prior to each set of determinations, the latex reagents should be tested with each run using the positive and negative controls provided in the kit.
2. Both controls should be used following steps 4 through 7 of the Qualitative procedure. Do not dilute the controls prior to use.

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3. The reaction between the positive control and the reagent should show a clear agglutination, different from the uniform appearance of the negative control.
4. If no agglutination takes place, the test should be repeated, and the kit discarded if there is no positive reaction.

PROCEDURE - QUALITATIVE (Stepwise)

1. Allow reagents and controls to reach room temperature (20-30° C).
2. Gently shake the reagent vial to disperse and suspend the latex particles. Vigorous shaking should be avoided.
- 3 Place 0.05 ml of serum or plasma in one section of the disposable slide.
4. Place one drop of reagent next to the drop of serum or plasma.
5. Mix both drops together using a stirrer covering the entire surface of the slide section.
6. Gently rotate the slide manually for 3-minutes or on a rotary shaker set at 80-100 rpm.
7. Look for the presence or absence of agglutination after the 3-minute time period.

PROCEDURE - SEMI-QUANTITATIVE (Stepwise)

1. Allow reagents and controls to reach room temperature (20-30° C).
2. Place 0.05 mL of normal saline on slide sections 2 through 6.
3. Using an automatic pipet, place 0.05 mL of serum or plasma on slide sections 1 and 2.
4. Using the same pipette, take in and release the serum or plasma and the normal saline in section 2 several times until well mixed.
5. Take 0.05 mL of the mixture made on section 2 and transfer to section 3. Repeat steps 4 and 5 to obtain a through mixing of reagents, transferring 0.05 mL from section 3 to section 4 and so on in succession through section 6, discarding the last 0.05 mL.

Section	1	2	3	4	5	6
Saline uL	-	50	50	50	50	50
Sample uL	50	50	-	-	-	-
Mix and Transfer			50→	50→	50→	50→
Dilution	1:1	1:2	1:4	1:8	1:16	1:32

50→ Discard

6. Gently shake the vial of latex reagent; place 1 drop of the latex reagent on sections 1 through 6 of the slide containing the different serum or plasma dilutions.
7. Mix both drops together with a stirrer covering the entire surface of the slide.
8. Gently rotate the slide manually for 3-minutes or on a rotary shaker set at 80-100 rpm.
9. Look for the presence or absence of agglutination after 3-minutes.

REPORTING RESULTS

Qualitative: The presence of agglutination indicates a clinically significant concentration of infectious mononucleosis heterophile antibody in the serum or plasma.

Semi-quantitative: The approximate titer corresponds to the highest serum or plasma dilution that still presents a clearly visible agglutination.

Limitations: Results should be read 3-minutes after the mixing of the reagents on the slide. A reading obtained after this period of time may be incorrect.

As with all diagnostic assays, the results of the Monogen assay should be interpreted in light of the clinical symptoms shown by the patient. Occasionally, detectable levels of heterophile antibodies are late in developing in patients symptomatic for infectious mononucleosis. If symptoms persist, it is recommended to repeat the assay in several days.

Reference Ranges: Although most patients will have a detectable heterophile level within three weeks of infection, occasionally a patient with strong clinical signs of infectious mononucleosis may take as long as three months to develop a detectable titer. Positive results may occur with or without any clinical symptoms or hematological evidence of IM.