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Color Slide II Mononucleosis Test

REF R2468936 ..... Σ 24
REF R2468944 ..... Σ 50
REF R2471088 ..... Σ 150

1. INTENDED USE

Remel Color Slide® II Mononucleosis Test is a one minute, color-enhanced slide test for detection of heterophile antibodies associated with infectious mononucleosis in serum, plasma, or finger-tip (whole) blood. The test is both qualitative and semiquantitative.

2. SUMMARY AND EXPLANATION

In 1932, Paul and Bunnell described a hemagglutination method using sheep erythrocytes for detection of heterophile antibodies associated with infectious mononucleosis (IM).[1] They demonstrated, such antibodies as well as other heterophile antibodies (i.e., non-IM) could be detected by agglutination with sheep erythrocytes. In 1936, Beer demonstrated horse erythrocytes were also agglutinated by heterophile antibodies but with greater sensitivity than sheep erythrocytes.[2] In 1965, a slide test using formalin-treated horse erythrocytes was described for detection of heterophile antibodies.[3-4] Davidsohn et al. reported that IM heterophile antibodies could be differentiated from non-IM heterophile antibodies by absorption with guinea pig kidney antigen.[5] Non-IM heterophile antibodies are absorbed (i.e., removed) by guinea pig kidney antigen while IM heterophile antibodies remain reactive to agglutinate the horse erythrocytes.

IM heterophile antibodies may be present as early as the fourth day of illness, almost always are present by the twenty-first day of illness, and may persist for several months thereafter.[6] Infectious mononucleosis has been reported to be associated with the Epstein-Barr Virus.[7]

3. PRINCIPLE

Color Slide II Mononucleosis Test is a rapid test for detection of heterophile antibodies associated with infectious mononucleosis. This test utilizes a disposable card, guinea pig kidney antigen, and specially treated horse erythrocytes (color-enhanced) to increase specificity and sensitivity, and to enhance readability of the test. In the presence of IM heterophile antibodies, horse erythrocytes agglutinate to form visible clumps.

4. PRECAUTIONS

This product is for *in vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and test materials after use. Directions should be read and followed carefully.

1. Potential Biohazardous Material: The human serum used to manufacture the Positive and Negative Controls has been shown to be nonreactive for the presence of hepatitis B surface antigen (HbsAg) and antibodies to HIV and HCV using FDA-licensed methods. Because no test can ensure the absence of every infectious agent, all human specimens should be considered potentially infectious and handled accordingly.[8]
2. Refer to the Safety Data Sheet for detailed information on reagent chemicals.
3. Reagents and controls are provided at the necessary working strength and are to be dispensed directly from the dropper bottles. Do not dilute reagents or controls.
4. Do not interchange reagents between kits of different lots.

5. STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not freeze or overheat. Prolonged storage at room temperature may compromise reagent stability. Reagents should be capped and returned to refrigerated storage when not in use.

6. PRODUCT DETERIORATION

This product should not be used if (1) the appearance of the reagents has changed, (2) the expiration date has passed, or (3) there are other signs of deterioration.

7. SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended laboratory guidelines.[6]

Serum or Plasma: Serum or plasma removed from whole blood should be clear and free of bacterial contamination. Avoid using grossly hemolytic serum or plasma. Store specimens at 2-8°C for up to 24 hours. For longer storage, freeze specimens at or below -20°C. It is not necessary to inactivate serum or plasma with heat prior to testing. If plasma is used, the blood should be collected with EDTA or Acid Citrate Dextrose (ACD) as an anticoagulant.

Whole Blood: Finger-tip blood may be used provided the blood is not "milked" from the finger after puncturing with a lancet.

8. REAGENTS AND MATERIALS SUPPLIED

1. Reagent A - Guinea Pig Kidney Antigen, preserved with 0.1% sodium azide
2. Reagent B - Preserved Horse Erythrocytes, preserved with 0.1% sodium azide
3. Positive Control – IM heterophile antibody-positive human serum, preserved with 0.1% sodium azide
4. Negative Control – IM heterophile antibody-negative human serum, preserved with 0.1% sodium azide
5. Test Cards
6. Pipettes
7. Bottle Droppers
8. Instructions For Use (IFU)
9. Result Interpretation Guide

9. KIT CONFIGURATIONS

R2468936 – 24 Tests
1 x 1.2 ml Guinea Pig Kidney Antigen
1 x 1.2 ml Preserved Horse Erythrocytes
1 x 0.5 ml Positive Control
1 x 0.5 ml Negative Control
2 each Bottle Droppers
1 bag 3-Well Test Cards (9 cards/bag)
25 each Pipette/Stirrers

R2468944 – 50 Tests
1 x 2.5 ml Guinea Pig Kidney Antigen
1 x 2.5 ml Preserved Horse Erythrocytes
1 x 1.0 ml Positive Control
1 x 1.0 ml Negative Control
2 each Bottle Droppers
2 bags 3-Well Test Cards (9 cards/bag)
50 each Pipette/Stirrers

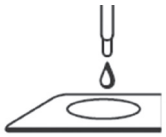
R2471088 – 150 Tests
3 x 2.5 ml Guinea Pig Kidney Antigen
3 x 2.5 ml Preserved Horse Erythrocytes
3 x 1.0 ml Positive Control
3 x 1.0 ml Negative Control
6 each Bottle Droppers
6 bags 3-Well Test Cards (9 cards/bag)
150 each Pipette/Stirrers

10. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Light Source (glare-free), (2) Timer, (3) 12 x 75 mm test tubes, for semiquantitative procedure, (4) 0.85% Saline solution for diluting specimens, (5) Pipettes for dilutions.

11. PROCEDURE

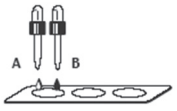
- Allow reagents and specimens to equilibrate to room temperature prior to use.
- Replace the caps on Reagent A and Reagent B with the bottle droppers provided.
- Determine the number of test circles required (one circle for each patient specimen or control to be tested). Tear the test card along perforations to remove the test circles needed. Save extra test circles for future testing.
- Pipettes and reagent droppers should always be held vertically when delivering drops. To ensure accuracy of test results, dispense free-falling drops of reagents and specimens to each test circle; otherwise, test accuracy may be compromised due to imprecise volume.


Free-falling drop

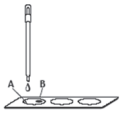
- Use of pipettes: Squeeze the bulb of the pipette and insert into the specimen. Release the pressure on the bulb to draw serum or plasma into the pipette channel. To dispense one drop of specimen, gently squeeze the pipette while holding it vertically over the test card. Use a separate pipette for each specimen. When handling pipettes, avoid touching the pipette tip.
- Before aspirating the Reagents (A and B) with the dropper, clear the dropper channel by squeezing the dropper bulb. Gently mix the Reagents by inversion to THOROUGHLY resuspend the cells and antigen.

Qualitative Testing:

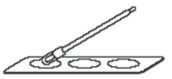
1. Gently mix Reagent A (Guinea Pig Kidney Antigen) and add one drop to the left side of the test circle on the test card. **Note**: When using whole blood, add one free-falling drop to the left side of the test circle; then, add Reagent A onto the drop of whole blood.



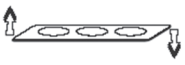
2. Invert Reagent B (Preserved Horse Erythrocytes) several times to mix well. Add one drop to the right side of the test circle.
3. Using a pipette add one drop of serum/plasma or control to Reagent A on the left side of the test circle.



4. Invert the pipette and use the "paddle" end to thoroughly mix (10 to 15 circular strokes) Reagent A (clear liquid) and the serum/plasma or control. Gradually blend this mixture into Reagent B (reddish-brown liquid) while covering the entire test circle.



5. Rock card slowly and gently for one minute (approximately 13-16 rocks per minute).



6. **Read results IMMEDIATELY.**

Semiquantitative Testing:

Note: To be used on serum and plasma specimens only.

1. Make serial dilutions of serum or plasma using 0.85% sodium chloride, starting at a dilution of 1:2 and continue forward (i.e., 1:4, 1:8, 1:16, etc.).
2. Test diluted samples following the procedure under Qualitative Testing.

12. INTERPRETATION

Qualitative:

Serum/Plasma: Interpretation does not require the use of a direct light source.

Positive Test - Agglutination, uniformly distributed dark clumps throughout the test circle against a blue-green background

Negative Test - No agglutination. Fine granularity against a brown/tan background may be observed. Peripheral color should be interpreted as negative, i.e., a faint blue-green color halo on the periphery of the test circle.

STRONG POSITIVE **WEAK POSITIVE** **NEGATIVE**

Whole Blood: The use of a direct light source is required to interpret the results when using whole blood.

Positive Test - Any agglutination observed when the reaction is viewed under a direct light source. Note: When using whole blood, the blue green colored background will not be evident.

Negative Test - No agglutination

POSITIVE **NEGATIVE**

Note: Interpret whole blood results cautiously. Any degree of agglutination observed using a whole blood sample indicates a positive result. If results are negative and infectious mononucleosis is suspected, repeat the test using serum or plasma.

Semiquantitative:

The highest dilution in which agglutination occurs is the end point.

13. QUALITY CONTROL

Positive and Negative Controls are included in each Color Slide II Mononucleosis Test kit. The Controls should be tested upon receipt of kit to verify reagent efficacy and provide visible representation of positive and negative test results. Follow the procedure under Qualitative Testing. Controls should be tested daily or following established laboratory guidelines. If aberrant quality control results are noted, patient results should not be reported.

14. LIMITATIONS

1. Positive heterophile tests have been reported with other diseases (e.g., hepatitis, rubella, leukemia, rheumatoid arthritis, etc.).[9-11] This test is only part of the overall scheme for the diagnosis of infectious mononucleosis. Diagnosis should be based on the results of all clinical and laboratory findings.[12-14]
2. Some segments of the population do not produce detectable heterophile antibodies (e.g., some children under the age of 4 and 10% of adolescents).[12,13]
3. Detectable levels of heterophile antibodies may persist for years in some individuals.[14]

15. EXPECTED VALUES

Color Slide II Mononucleosis Test has been adjusted to provide a positive test approximating the sensitivity of a guinea pig kidney absorbed Davidsohn sheep cell titer of 1:28 to 1:56. Therefore, a semiquantitative result can be approximated by multiplying the reciprocal of the highest dilution in which agglutination occurs (end point) by 28. While no correlation has been found between the severity of illness and the heterophile titer, it may be of interest to the clinician in following the course of the disease.[10]

16. PERFORMANCE CHARACTERISTICS

Serum/Plasma:

One hundred-ten serum and plasma specimens obtained from several laboratories as positive for infectious mononucleosis, and 89 specimens presumptively negative were tested using the Davidsohn differential tube test and Color Slide II Mononucleosis Test. One hundred-nine specimens were positive by the Davidsohn procedure. One specimen had an absorbed titer of 1:14. Using Color Slide Mononucleosis Test, 108 specimens were positive; of the two negative tests, one included the specimen with 1:14 absorbed titer with the Davidsohn procedure, and the other had a Davidsohn absorbed titer of 1:56.

Five of the 89 presumptively negative specimens were positive with the Davidsohn procedure and were excluded from the negative panel. With Color Slide II Mononucleosis Test, one negative specimen gave a weak but positive result. Thus, the overall agreement of Color Slide II Mononucleosis Test with the Davidsohn differential tube test was 98.9%.

Color Slide II Mononucleosis Test was positive with sera that had a Davidsohn guinea pig absorbed titer of 1:28 to 1:56 or higher and negative with titers of 1:14 or less.

Whole Blood:

In an independent study conducted at a major university hospital, three commercial infectious mononucleosis test kits were compared: Color Slide II Mononucleosis Test (whole blood), Organon Dri-Dot® (whole blood), and Ortho MonoSpot™ (serum). One hundred whole blood samples were collected from patients of random age and sex. The samples consisted of 50 positive specimens with random titers, and 50 negative specimens. Positive and negative samples were confirmed by testing serum from all specimens with a referee method, the Ortho MonoSpot™. All 100 whole blood samples were directly tested using both Color Slide II Mononucleosis Test and Organon Dri-Dot®.

When testing Color Slide II Mononucleosis Test, all 50 positive specimens were identified as positive; and all 50 negative specimens were identified as negative. Thus, the overall agreement of Color Slide II Mononucleosis Test with Ortho MonoSpot™ was 100%. Organon Dri-Dot® identified 49 of 50 positive specimens and all 50 of the negative specimens. The discrepant result was positive on both Color Slide II Mononucleosis Test and MonoSpot™.

17. BIBLIOGRAPHY

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18. PACKAGING

REF R2468936 ..... Σ 24
REF R2468944 ..... Σ 50
REF R2471088 ..... Σ 150

19. SYMBOL LEGEND

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
LAB	For Laboratory Use Only
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

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