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| **Infectious Mono Testing in Whole Blood or Serum** |
| **Purpose** | This procedure provides instructions for INFECTIOUS MONO TESTING IN WHOLE BLOOD or SERUM. |
| **Principle** | The Cardinal Health Mono II rapid test is an immunochromatographic assay for the qualitative detection of infectious mononucleosis (IM) heterophile antibodies in whole blood or serum. The serum or whole blood is mixed with diluent. Then the test stick is placed in the mixture and the mixture migrates along the membrane. If the specific IM heterophile antibody is present in the sample, it will form a complex with bovine erythrocyte extract conjugated color particles. The complex will then be bound by bovine erythrocyte extract immobilized on the membrane and a visible blue test line will appear to indicate a positive result. |
| **Policy Statements** | * This procedure applies to all laboratory technologists performing hematology, the section supervisor, and pathologist.
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| **Materials** | **Equipment** | **Reagents** | **Supplies** |
|  | N/A | Cardinal Health Mono II test – store at room temperature – DO NOT FREEZE1. Test strips:
* Test strips (25) contain bovine erythrocyte extracted antigen – coated particles and bovine erythrocyte extracted antigen – coated membrane.
1. Sample Buffer (3 mL)

• 0.20% sodium azide* Use as is.
1. Mono negative control (1mL)
* Goat albumin / tris buffer
* 0.20% sodium azide
* Use as is.
1. Mono positive control (1mL)
* Rabbit anti-beef stroma / tris buffer
* 0.20% sodium azide
* Use as is.

**NOTE: The reagents in this kit contain sodium azide and may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with a large amount of water to prevent azide buildup.**Warnings and Precautions* Do not use after expiration date.
* Do not mix components from different lots or different kits.
 | 1. Disposable sample tubes (25)
2. Disposable sample droppers (25)
3. Package insert (1)
4. Workstation and procedure card (1)
5. Hematology (H1 worksheet for MIN, H1S worksheet for STP)
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| **Sample** | 1. Serum collected in a red top tube may be used.
2. Minimum amount of serum is 0.2 cc.
3. Maximum amount of serum is 0.5 cc.
4. Refrigerate at 2-8°C for up to 48 hours or freeze at –20°C or below.
5. Samples should be at room temperature when tested.
6. Whole blood from heparinized or EDTA may be used:
* May be used immediately without centrifugation
* Or stored at room temperature for up to 24 hours
* Do not freeze specimen
1. Permit blood to clot for at least 30 minutes at room temperature (21°C to 30°C) before centrifuging.
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| **Quality Control** | A. External controls1. External positive and negative controls should be tested with each new lot number, new shipment of test materials or every 31 days.
2. Positive: A positive result is indicated by two distinct lines, one should be red in the control line region and another should be blue in the test line region.
3. Negative: A negative result is indicated by a red line appearing in the control region and no apparent blue line in the test region.
4. New Kit / Shipment
5. The controls of an unopened kit are run with the reagents of an open kit before it is put into use, as well as known positive and negative controls which are aliquoted and stored at -70°C.
6. The controls of the open kit are run with the reagents of the unopened kit.
7. The controls of the new kit are run with the reagents of the new kit.
8. Record information on "Documentation" sheet in Serology Procedure manual.
9. Mark boxes of new kit with date checked and initial.

B. Internal Quality Controls1. Internal positive procedural control* A red line appearing in the control region is an internal positive control.

2. Internal negative procedural control* A clear background in the result area is the internal negative control.

3. Record internal positive and negative controls on worksheet. |
| **Procedure** | Follow the activities in the table below for PERFORMING MONO TESTING IN WHOLE BLOOD OR SERUM. |
|  | **Step** | **Action** | **Related Document** |
|  | 1 | Remove the test stick from the canister and use it as soon as possible. |  |
|  | 2 | For serum or whole blood samples in tubes, use the sample pipette provided. **Add 1 drop of whole blood or 1 drop of serum to the bottom of the sample tube.** |  |
|  | 3 | Hold the Sample buffer bottle vertically. **Add 1 drop of buffer to the bottom of the sample tube, tap the bottom of the tube and mix.** |  |
|  | 4 | Place the test stick in the sample tube, set timer, read at five minutes. |  |
| **Procedural Notes** | 1. Use test strip as soon as possible after removal from canister.
2. To avoid cross-contamination, use a new disposable Sample Pipette for each sample.
3. To avoid contamination, do not touch the tip of the Sample buffer bottle to the sample tube.
4. Commercial controls other than those in the kit should not be used with the Cardinal Health Mono II Infectious Mononucleosis test because they may contain additives that may interfere with the test performance.
5. The Cardinal Health Mono II test is a qualitative test for the detection of IM heterophile antibodies.
6. A negative result may be obtained from patients at the onset of the disease due to antibody concentration below the sensitivity of this test kit. If symptoms persist or increase in intensity, the test should be repeated.
7. Some segments of the population who contract infectious Mononucleosis do not produce measurable levels of heterophile antibodies. Approximately 50% of children under 4 years of age who have IM may test IM heterophile antibody negative.
8. The appearance of a dry white line located near the test and / or control line positions has been observed on some test sticks. When present it can remain visible at the read time. This artifact is most often seen with plasma or serum specimens and has no impact on the performance of the assay.
9. A blue or red line that appears uneven in color density is considered a valid result.
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| **Interpretation/****Results/Alert Values** | 1. Reference value: Negative.
2. Negative result: One red line appears in the control region. No apparent line appears in the test region.

1. Positive result: **Any** shade of blue color in the test region should be considered positive along with a red line in the control region. The intensity of the blue line in the test region will vary based on the amount of IM heterophile antibodies in the sample.

1. Invalid Result: The red line in the control region fails to appear. **Note**: An invalid result indicates either the test was not performed correctly or the reagents are not working properly. Should an invalid result occur, review the procedure and repeat the test using a new test stick.

If the problem persists discontinue using the test kit and call for technical assistance at 1-800-332-1042. |
| **Result Reporting** | In Sunquest:Function: MEM <CR>Worksheet: H1 or H1S <CR>Test-1: <CR>Test-2: <CR>CAP Method: <CR>Accn. No.: Enter ###### <CR>INTERNAL QC RESULT: Enter IQC (Internal QC verified as acceptable) <CR>MONOS: Enter result (NEG or POS) <CR>Accept (A), Modify (M) or Reject (R): A <CR> |
| **References** | Cardinal Health Mono II, Test Package Insert 2019. |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Mpls: Unknown | 1984 | Initial Version |
| 1 | St. Paul: Mary Ellen Eckhoff | 1/1984 | Initial Version |
| 2 | Mpls: Deb Oman | 1990 | New test kit |
| 2 | St. Paul: Patrice Olsen | 12/1986 | Revised |
| 3 | Mpls: Jan Candilario | 7/1993 | Reformatted |
|  | 3 | St. Paul: Margaret Stacevich | 5/1991 | Changed test kit |
|  | 4 | Mpls: Laura Carmack | 6/1995 | Revised to system procedure |
|  | 4 | St. Paul: Laura Carmack | 11/1995 | Revised for testing change |
|  | 5 | Laura Rachford | 7/2003 | Merged and revised |
|  | 6 | Sandra Cassidy | 11/2005 |  |
|  | 7 | Al Quigley | 7/2007 | Changed test kit |
|  | 8 | Al Quigley | 9/2009 | Revised after CAP inspection |
|  | 9 | Al Quigley | 06/01/11 | Revised, reformatted, renamed |
|  | 10 | Al Quigley | 09/29/15 | Revised after CAP inspection to include the documentation in Suquest of internal QC results. |
|  | 11 | Al Quigley | 01/10/22 | New test kit (Cardinal Health Mono II) |