COLOR MONO LATEX TEST

I. PRINCIPLE

The Color MONO Latex Test is an agglutination test for the qualitative detection of heterophil antibodies, in human serum, associated with infectious mononucleosis (IM). The Color MONO Latex Test is based on the reaction between IM antibodies in the sample to be tested and dyed, color-enhanced horse erythrocytes. A visible agglutination takes place with horse erythrocytes when IM heterophil antibodies are present. Lack of agglutination indicates the absence of IM heterophil antibody in the test sample.

II. CLINICAL SIGNIFICANCE

UnityPoint Health Pekin Laboratory personnel will utilize this procedure to perform and interpret mono testing.

III. SPECIMEN

A. Use completely coagulated blood (30min).
B. Separate the serum as soon as possible after collection and store at 2 – 8 °C until testing can be performed.
C. If testing is not to be carried out within 72 hours, the serum should be stored at -20° C or below until testing.
D. It is not necessary to inactivate the serum by heat before testing.
E. Contaminated, lipemic, or grossly hemolyzed sera should not be used because of the possibility of nonspecific results.

IV. REAGENT

A. Color-Enhanced Latex Reagent: Contains a suspension of dyed horse erythrocytes in buffer with 0.1% sodium azide as preservative.
B. Controls (Reactive, Nonreactive) – Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as a preservative.
C. Warnings and Precautions:
    1. Color MONO Latex Reagent and Controls contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide buildup.

2. Color MONO Latex Test Controls contain human serum or plasma, which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the controls should be considered potentially infectious and universal precautions should be used.

E. Reagents must be well mixed before use.
F. Handling and Procedural Notes:
    1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
    2. Do not use past the expiration date indicated on the kit.
    3. Do not interchange components of one kit with those of another kit
G. Storage Instructions:
    1. Store all reagents at 2 – 8 °C in an upright position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration.
H. Indications of Deterioration:
    1. Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
    2. Bacterial contamination of reagents or specimens may cause false positive results.

V. QUALITY CONTROL

A. QC is ran with each patient/batch, on each new lot, new shipment and every 30 days. Log on Serology Monthly Log Sheet (UPPK SER-0551.01)
B. If controls do not react as expected, the test results are invalid and patient results cannot be turned out.
C. If controls remain out of range, contact the pathologist as previous patient test results need to be reevaluated.
D. REACTIVE and NONREACTIVE CONTROLS are to be included in each test run to confirm optimal reactivity of the ERYTHROCYTE REAGENT. In lieu of manufactured controls, specimens previously tested can be used.
E. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. Log action taken on Serology Action Log (UPPK 0551.02).
F. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the test and contact technical support at (800) 654-0146.

VI. PROCEDURE:

A. Allow all reagents and samples to warm to room temperature (20 – 30 °C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.

B. All reagents are ready for use as supplied. Gently mix the reagents before use to ensure homogeneity.
C. Gently shake the erythrocyte reagent before each use to ensure homogeneity.
D. Using the stirrer pipets, deliver one free-falling drop (0.05 ml) of each sample onto a separate circle on the test card. Use a fresh pipet for each sample. When using the stirrer pipet, keep it in a vertical position to ensure accurate delivery. Repeat by adding one free-falling drop of REACTIVE or NONREACTIVE CONTROL from the dropper vials supplied. Note the location of each sample by using the numbers located below and to the left of each circle.
E. Shake the vial of dyed, color-enhanced horse erythrocytes gently to uniformly mix the suspension. Add one free-falling drop of reagent to each control and patient sample.
F. Using the flat end of the stirrer pipets, mix each sample and reagent and spread over the entire circle.
G. Gently rotate the card for 2 minutes.
H. Observe for agglutination using Ott-Lite with attached magnification device. All test results should be compared to both REACTIVE and NONREACTIVE CONTROLS.

VII. REPORTING RESULTS

A. Interpretation of results – qualitative:
    1. REACTIVE (Positive): Any degree of agglutination or rimming within the test area as compared to the nonreactive control
    2. NONREACTIVE (Negative): Smooth or finely granular suspension with no visible agglutination.
B. Enter patients' and control results (positive or negative) on Serology Patient Worksheet (UPPK SER-0551.03) and result in computer.

VIII. METHOD LIMITATIONS:

A. In accordance with all diagnostic methods, a final diagnosis should not be made on the results of a single test, but should be based on a correlation of test results with other clinical findings.
B. Reaction times longer than specified might cause false positive results due to a drying effect.
C. Due to possible prozone effects, the strength of agglutination in the screening test is not indicative of the IM heterophil antibody titer.
D. False negative results have been reported. Some of these may represent cases of IM which persistently remain sero-negative for the IM heterophil antibody. However some false negative results have been shown to be due to a delayed IM heterophil antibody response.

E. IM heterophil antibody titers have been shown to persist in some cases for months and years after clinical symptoms have subsided. Conversely, IM heterophil antibodies have been detected prior to the onset of clinical symptoms. Thus, caution should be exercised in the interpretation of the test results.
F. Patients with exceptionally high levels of the serum sickness heterophil antibody may test falsely positive for the IM heterophil. These patients are generally found only in countries where "horse serum is used prophylactically.
G. The IM heterophil has been associated with several diseases other than IM. These include leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, cytomegalovirus infections and others. In these cases, it is difficult to disprove the possibility of concurrent disease states.

IX. EXPECTED RESULTS AND PERFORMANCE CHARACTERISTICS

A. Detectable levels of the IM heterophil antibody can usually be expected to occur between the sixth and tenth day following the onset of symptoms. The level usually increases through the second or third week of illness and thereafter, and can be expected to persist with gradual decline over a 12-month period. Positive results should be seen in approximately 98% of all IM cases. False negative and false positive rates of 2% and 6% to 13% respectively are to be expected.

X. REFERENCES

A. Color MONO Latex Test, Cardinal Health, Waukegan, IL 60085, Rev. C 1/13.

POLICY CREATION :		***Date***
Author:	***Sharrol Brisbin, MT (ASCP)***	***01/01/1987***
Medical Director:	***Sheikh, MA, MD***	***01/01/1987***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Reviewed by

Lead	**Date**	**Coordinator/ Manager**	**Date**	**Medical Director**	**Date**