PROGRAM Standard Operating Procedure – Laboratory Services	
Title: **URN40101 Pulse Scientific Monogen Latex Testing**	Policy Number: 15-144-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Effective Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Service Director, Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:

Infectious Mononucleosis (IM) is an acute infectious disease of viral etiology. The most frequent symptoms are fever, sore throat, tender lymphadenopathy, anorexia, malaise, headache, myalgia and splenomegaly. The complications of IM include secondary bacterial pharyngitis, rupture of the spleen, autoimmune hemolytic anemia, autoimmune thrombocytopenia, myocarditis, hepatitis and central nervous system involvement with meningoencephalitis or transverse myelitis. The diagnosis made on clinical history and symptomatology alone is difficult, and numerous cases in which IM has been misidentified with other non-related viral and bacterial diseases has been citied. For this reason, hematological and serological tests are very helpful in making a diagnosis.

PURPOSE/RATIONALE:

The Pulse IM Latex Test is intended to be used for the qualitative screening of heterophile antibodies in serum as an aid in the diagnosis of infectious mononucleosis. The Pulse IM Test provides a suspension of polystyrene latex particles which have been coated with partially purified glycoprotein from bovine red blood cells. The heterophile antibody associated with IM binds to the corresponding antigenic determinants on the glycoprotein coated latex. The binding is evident by rapid agglutination of the latex.

DEFINITIONS:

QC- Quality Control
IM-Infectious Mononucleosis
LIS- Lab Information System

SCOPE/APPLICABILITY:

This procedure applies to Medical Laboratory Technologists (MLT's) who will be performing this procedure.

SAMPLE INFORMATION:

Type	Serum sample
Source	Venipuncture
Collection Container	Gold SST tube
Volume	1 mL
Stability	Fresh samples (< 24 hours) should be used
Patient Preparation	No patient preparation required
Storage Requirements	Stored at 2-8°C for up to 8 days. For longer periods it must be frozen at -20°C.
Criteria for rejection and follow up action	• Incorrectly labelled specimens • Leaking specimens • Hemolyzed or contaminated specimens • Specimens not meeting stability requirements • Notify ordering ward or Community Health Center • Reject sample and document in LIS

REAGENTS and/or MEDIA:

- Pulse Scientific Inc. Monogen Kit
  - Latex reagent
  - Positive and Negative Controls

SUPPLIES:

- Pulse Scientific Inc. Monogen Kit
  - Disposable Pipettes
  - Testing Slides

EQUIPMENT

- Mechanical Rotator
- Magnified Light Source
- Timer

ENVIRONMENTAL CONTROLS:

Store reagents and controls at 2-8°C. Before use, allow reagents and controls to warm up to room temperature. **Do Not Freeze.**

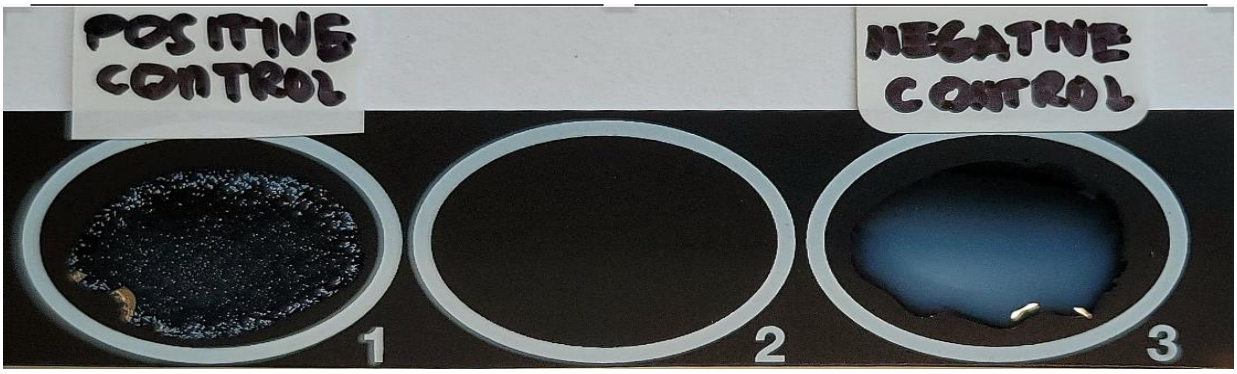
SPECIAL SAFETY PRECAUTIONS:

- Ensure proper PPE is used such as gloves, lab gowns and eye protection when possible exposure to splashes.
- Ensure all samples are treated following routine practices and assume all products as potentially infectious.
- The reagents contain sodium azide as a preservative. Azides may react with metal plumbing to form explosive metal oxides. After disposal, flush with large volumes of water to prevent metal azide build up.

QUALITY CONTROL:

- IM Positive Control
- IM Negative Control

Positive and negative controls should be run with each series of tests.

Step	Action
1	Bring all testing materials to room temperature.
2	Gently shake the IM Latex vial to disperse and suspend the latex particles. The IM Latex reagent must be agitated well for about 10 secs prior to use.
3	Place one drop of each control material into their own circle on the testing slides.
4	Place one drop of IM latex to each circle containing your QC material.
5	Using the end of the provided disposable pipettes, mix the control material and Latex reagent together. To prevent cross-contamination, use a separate pipette for each QC.
6	Gently tilt and rotate the slide by hand for 3 minutes. Observe for macroscopic agglutination under direct light. **Positive results**: Agglutination **Negative results**: Smooth milky suspension 
7	In TQC, enter QC results for SLAB-MONO.

PROCEDURE INSTRUCTIONS:

Follow the steps in the table below.

Step	Action
1	Bring all testing materials to room temperature.
2	Gently shake the IM Latex vial to disperse and suspend the latex particles. The IM Latex reagent must be agitated well for about 10 secs prior to use.
3	Using the disposable pipettes provided, place one drop of patient serum onto a circle on the testing slide.
4	Place one drop of IM latex to each circle containing patient serum.
5	Using the end of the provided disposable pipettes, mix the patient sample and Latex reagent together. To prevent cross-contamination, use a separate pipette for each patient.
6	Gently tilt and rotate the slide by hand for 3 minutes. Observe for macroscopic agglutination under direct light. **Positive results**: Agglutination **Negative results**: Smooth milky suspension
7	In LIS, open the Mono Resulting Worklist and enter results.

MEASUREMENT UNCERTAINTY/LIMITATIONS:

- The results of this test should not be used as a single diagnostic tool to make a clinical diagnosis.
- This test is designed to be performed using hand rotation, the use of a mechanical rotator could yield false positive/negative results.
- Reading the test results after the recommended time of 3 minutes can cause false positive reactions.
- If the Pulse IM test is negative in the presence of strong evidence of suggesting a diagnosis of IM, repeat testing is recommended after several days. However, some patients with hematological and clinical evidence of IM will persistently show negative results.

REPORTABLE RANGE:

The Pulse Scientific IM test Kit will provide qualitative results of Positive or Negative.

REFERENCE INTERVALS:

Negative

INTERFERENCES AND SOURCES OF VARIATION:

Apparent false positive results have been associated with patients with other conditions such as rheumatoid arthritis, certain respiratory infections, leukemia, Burkitt's lymphoma and serum sickness.

INTERPRETATION OF RESULTS:

Positive Result: Agglutination

Negative result: Smooth Milky Suspension

TROUBLESHOOTING:

If the expected results are not obtained when running QC, patient results should not be reported until rectified. Some steps to take are:

- Repeat testing, ensuring you are using correct materials
- Check expiration dates
- Report issues to supervisor

EXPECTED RESULTS:

Negative

REFERENCES:

Pulse Scientific Inc. IM Latex Test IFU, Form No. 1010 Rev. August 2011

Stanton Territory Health Authority SOP URN40100 Monogen Slide Test for Mononucleosis, Issue Date December 21, 2010

RELATED DOCUMENTS:

Not Applicable

APPROVAL:

March 13, 2024
Date

Director, Laboratory and Diagnostic Imaging Service

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	03Oct03	Initial Release	R.Greig
2.0	21Dec10	Update to New Format	C.Russell
3.0	27 Dec 13	Renumbered; Updated references; Purpose and principles information reduced to reflect only necessary information; Changes to resulting procedure in LIS.	JGD Bernier
4.0	14 Feb 24	Updated to new NTHSSA format and new manufacturer	L. Howlett