# Applicable Laboratory(s)):

[ ]  North Carolina Baptist Hospital (NCBH)

[ ]  Lexington Medical Center (LMC)

[ ]  Davie Medical Center (DMC)

[ ]  Wilkes Medical Center (WMC)

[ ]  High Point Medical Center (HPMC)

[x]  Westchester

[ ]  Clemmons

# Procedure Statement

The *LifeSign Status Mono* test is intended for qualitative detection of infectious mononucleosis antibodies in human blood. The purpose of this procedure is to provide procedural guidelines for staff and to ensure they are competent to perform the *Status* Mononucleosis (Mono) waived test according to manufacturer instructions.

# Principle

Infectious mononucleosis (IM) is an acute, self-limiting disease caused by the Epstein-Barr virus (EBV). Most individuals exposed to EBV develop a heterophile antibody response. Heterophile antibodies make up a broad class of antibodies which are characterized by the ability to react with surface antigens present on erythrocytes of different mammalian species. Common medical practice is to use the detection of IM heterophile antibodies to assist in the diagnosis of infectious mononucleosis.

*Status Mono* one-step antibody test for IM uses direct solid-phase immunoassay technology for the qualitative detection of IM heterophile antibodies in human whole blood. IM-specific heterophile antibody present in patient sample is captured by an antigen band (bovine erythrocytes extracts) impregnated in the test membrane. A developer solution is then added to the sample well. As specimen, followed by the developer, moves by capillary action to the antigen band, the solution mobilizes the dye conjugated to anti-human IgM antibodies. Visualization of the antigen band at the Test position (T) in the result window will occur only when the IM-specific heterophile antibody binds to the extracted antigen obtained from bovine erythrocytes. As the antibody-dye conjugate moves along the test membrane, it will bind to another band located at the Control position (C) to generate a colored band regardless of the presence of IM heterophile antibodies in the sample. Therefore, the presence of two (2) colored bands, one at (T)est and one at (C)ontrol position indicates a positive result, while the absence of a colored band at the (T)est position indicates a negative result.

# Scope

This procedure applies to all Westchester Lab staff after completion of Status Mono kit training. Once trained, all testing staff are required to maintain competency in order to perform this test.

# Definitions

1. Procedure: A process or method for accomplishing a specific task or objective.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Westchester Lab and Lab at Clemmons.
3. Waived Tests: Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.
4. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.
5. Quality Control (QC): A process to ensure the test system is performing as expected.
6. External QC - External liquid material or substance with known value(s) for the test(s) being performed.
7. Internal QC - An internal check within the test system to validate the test system is working properly.
8. Quality Assurance (QA): A system for ensuring a desired level of quality. Westchester Lab incorporates activities to monitor the quality of processes and the test system.
9. Technical Limits/Reportable Range: The range at which the analyzer has been verified to obtain accurate results. Each analyte has a specific reportable range.
10. Normal (Reference) Range: The range of values for the average patient population.

# Procedure Guidelines

1. Patient Prep

Patient must be properly identified by specimen collector.

1. Specimen Collection and Information
2. Venous whole blood using EDTA. Whole blood may be stored at 2-8°C for 24 hours.
3. Refrigerate all specimens at 2-8°C until time for testing.
4. Do not freeze and thaw whole blood; hemolyzed blood cannot be used in this test.
5. Storage and Stability – Store Status Mono test kit at 2-30°C (each test device stored in its sealed pouch). Do not freeze.
6. Materials and Supplies
7. Timer
8. PPE – lab coat, gloves, shield or protective eyewear, as needed
9. Each kit contains the following:
10. Twenty-five (25) individual test devices
11. Twenty-five (25) red transfer pipettes. The red (25 µL) transfer pipettes are for use with whole blood.
12. Developer Solution: Phosphate saline buffer containing 0.1% sodium azide
13. Positive and Negative Controls: Diluted in serum containing 0.1% sodium azide
14. Package insert and Procedure card

E. Quality Control - must be acceptable prior to reporting patient results

1. **Internal Quality Control**
2. There are two internal control features in Status Mono test.
3. A colored control band will always appear at the (C)ontrol position if the test has been performed correctly and if the device is working properly. This is considered an internal positive procedural control.
4. A clear background in the result window is considered an internal negative procedural control. If the test has been performed correctly and the device is working properly, the background in the result window will be clear, providing a distinct result.
5. Internal controls are included with each test device
6. **External Quality Control** – positive and negative controls are supplied with each box of Status Mono kits.
7. External QC should be run as follows:
8. Each new lot or shipment of kits
9. Each new lab tech (or lab assistant) trainee
10. Any time test performance is in question
11. Using external control in place of patient sample, dispense 1 drop of control solution into the upper end of the sample well (S). Add 2-3 drops of Developer Solution into the lower end of the sample well (S). Read the test result at 8 minutes (Do not read after 15 minutes).
12. Document external QC results on the ***Status Mono QC Logsheet***.
13. If the controls do not perform as expected, review procedure or ***Status Mono package insert*** and repeat QC testing with new test cartridge. No patient results may be released unless QC is acceptable.

e. **Invalid:** The test is invalid if no pink-purple colored horizontal band forms at the Control positon (C).

f. Document problems and any troubleshooting/corrective actions taken on the ***Corrective Action Log***.

1. Procedure
2. Remove the test device from pouch and label with patient identification (aliquot sticker from patient bar code label is sufficient).
3. Place an aliquot sticker with patient information on the ***Status Mono Patient Logsheet***.
4. Using the 25 µL (red line) sample transfer pipette for whole blood, dispense sample into the upper area of sample well (S).
5. Add 2-3 drops of Developer Solution into lower area of sample well (S).
6. Start timer after addition of Developer Solution.
7. Read results after 8 minutes - do **not** interpret test results after 15 minutes.
8. Record results on the ***Status Mono Patient Logsheet*** and enter results into the LIS using manual result entry process.
9. Interpretation of Results
10. Positive: Two pink-purple colored lines appear, one in (C)ontrol position and one in (T)est position - indicates that IM-specific heterophile antibodies have been detected.
11. Negative: Only one pink-purple colored line appears in the (C)ontrol position.
12. Invalid: Absence of a colored line in the (C)ontrol position. The test should be discarded and repeat testing performed.
13. Limitations of Procedure
14. The results obtained by this kit yield data which must be used only as adjunct to other information available to the physician.
15. Most patients will have detectable antibody levels within 3 weeks of infection. Occasionally patients with strong clinical symptoms will take more than 3 months to develop detectable antibody levels.
16. Some persons do not produce measurable levels of heterophile antibody, including about 50% of children less than 4 years old.
17. Some individuals maintain a low, detectable level of heterophile antibody long after primary illness. Heterophile antibodies have been detected in blood specimens taken more than one year after the onset of illness.
18. IM heterophile antibody has been associated with other disease states; including, leukemia, cytomegalovirus, Burkitt’s lymphoma, rheumatoid arthritis, adenovirus, viral hepatitis, and Toxoplasma gondii.
19. Status Mono for whole blood test is classified as waived under the CLIA’88 regulations.
20. Open or broken/damaged pouches may produce erroneous results due to kit instability from exposure to moisture and should be discarded – Do Not Use.
21. Reference Ranges

Negative

1. Critical Values

None

1. Patient Result Reporting

Report patient results in LIS

1. Downtime of Instrument/ Test System

This is a manual procedure and performance of the test is not affected by downtime. Record patient results in the LIS after computer system becomes operational.

# Attachments/Linked documents (title 21)

* Status Mono QC Logsheet
* Status Mono Patient Logsheet
* Corrective Action Log
* Status Mono Package Insert
* Status Mono Training Checklist
* Status Mono Written Exam

# Revision Dates: Review Change Summary as represented in Title 21.