## TITLE: Interpretation of Positive and Negative Results

## PURPOSE:

To define criteria for interpreting Detected and None Detected

PERSONNEL

Medical Technologists

### STEPWISE PROCEDURE:

1. Antistryptolysin O Screen and/or Titer - CMS Sure Vue ASO

 a. Detected- Visible Agglutination

 b. None Detected - No Agglutination should be visible

2. RA Test Screen and/or Titer-CMS Sure Vue

 a. Detected- visible agglutination with large aggregates and

 complete clumping

 b. None Detected - no visible agglutination

3. Heterophile Screen (MONO) and/or Titer -CMS Sure Vue

 a. Detected- visible agglutination

 b. None Detected- no agglutination should be visible

4. Pregnancy Test – Medline hCG Combo

 Positive Result: The sample contains a detectable amount of hCG when you see: A pink to red line in the result window next to the “T” Along with a pink to red line in the result window next to the “C”.

 NOTE: any shade of a pink vertical line in the Result Window should be

 Interpreted as a positive result.

 Negative Result:

 The sample does not contain detectable amounts of hCG

 When you see: No pink to red line in the result window next to the “T”, along with a pink to red line in the result window next to “C”.

 Invalid Result:

 The result is invalid if; no pink to red line appears in the result window next to the “C”.

 In the case of an invalid result, a new patient specimen should be tested using

 a new test cassette

If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested.

5. Rubella – SureVue

 Detected: Any agglutination

 None Detected: No agglutination

1. HIV-Alere

###  Non-Reactive

###  The presence of a vertical red Control Line next to the Control box and the absence of a red line next to the antigen and antibody boxes on the test membrane indicate that anti-HIV-1 antibodies and antigens were not detected. The test result is interpreted as NEGATIVE for HIV-1/2 antibodies and P24 antigen.

###  Reactive

 The presence of both a vertical red Control Line next to the Control boxand a red line next to the antigen box and/or the antigen box on the test membrane, regardless of intensity, indicate that anti-HIV-1/2 antibodies and/or P24 antigen **have been detected** in the specimen.

 **Invalid**

The absence of the vertical red Control Line next to the **Control** indicates that there has been a problem either with the test device or the specimen, during the **Testing Procedure. An invalid test result cannot be interpreted.**  If an invalid test result is obtained, the **Testing Procedure** should be repeated using a new test cartridge

and specimen.

1. HIPA Screen- Heparin Induced Platelet Antibody (HIT)

 **NEGATIVE/Non-Reactive:**

 TEST Window = BLUE-GREEN

NOTE: May contain various hues of BLUE-GREEN as the color is sample dependent.

 **POSITIVE/ Reactive:**

 TEST Window = YELLOW

 9. Interpretation of slide agglutination:

 a. 100% agglutination - 4+

 75% agglutination - 3+

 50% agglutination - 2 +

 25% agglutination - 1 +

 No agglutination = Negative

10. Procedure if any one of the controls does not show the proper reactivity:

 1. Recheck each control.

 2. Open new kit for test being run and test all controls.

 3. If new kit does not show proper reactivity of controls, advise supervisor

 of the problem and do not release test results.

### REFERENCE

College of American Pathologists: Commission on Laboratory Accreditation Checklist,

June 17, 2010

Manufacturer’s Current Package Insert

 RESULT CHART

1. ASO Qualitative CMS Sure Positive = Detected

 Vue: Order a titer on Negative = None Detected

 Positive screens through LIS (If requested by physician)

 ASO Quantitative Titer result in lu/ml according

to chart found in semi quantitative section of

ASO procedure.

2. Heterophile – Monogen Positive = Detected

 Negative = Not Detected

 Order titer through LIS on

 Positive screens (If requested by physician)

 Heterophile Titer Positives = Reported as titer

 See (1:4, 1:8 etc.)

3. HIPA Screen (HIT) Positive = Positive

 Negative = Negative

4. Pregnancy – Medline hCG combo Positive = Positive

 Serum and Urine Negative = Negative

5. RA Screen – CMS Sure Vue Positive = Detected

 Negative = None Detected

 A titer will reflex on all positive screens

 Through LIS

6. RA Titer: CMS Sure Vue Reported in lu/ml results in

 accordance with the results

7. Rubella Screen – Sure Vue Positive = Detected

 Negative = None Detected

8. HIV-Alere ½ HIV Antibody and Antigen Combo Positive – R

 Order Western Blot at Negative – NR

 Rush on all positive screens

 through LIS