## TITLE: Quality Control for Serology Kits and Reagents

## PRINCIPLE:

New reagents and old reagents in the kits are checked with the new and old controls. This is to verify that the reagents have the same reactivity and are suitable for use in patient testing. Controls are also run each day tests are performed and/or per manufacturer’s recommendation in the same manner and by the same personnel as the patient testing.

All serology kits and reagents are used in accordance with the manufacturer’s recommendation.

### PERSONNEL

Medical Technologists

### REAGENTS

Kits or reagents being evaluated.

### STEPWISE PROCEDURE

When opening new kits or reagents:

1. Run the previous controls, or external positive and negative controls, with the new kit or reagent.

2. Run the new controls, positive and negative, with the old reagents or kits, if controls are packaged in kit.

3. All controls should be showing the same reactivity with the old and new

 kits or reagents.

4. If the new kits or reagents do not show the proper reactivity with the controls,

 the kit or reagent should be quarantined.

5. Notify the supervisor of discrepancy.

Each day a test is performed:

1. Run controls per procedure.
2. Record in LIS using the Soft Total QC Module.

See Soft Procedure Manual for more information

 Controls out of range are documented with corrective action in LIS.

1. Verify control results for acceptability before reporting patient results.

 5. Patient results are not released unless controls are in range.

 6. QC is reviewed once a month by the senior technologist or designee.

Schedule of Quality Control Testing:

1. ASO (Qualitative) positive and negative controls provided with kit are run with each test

 series.

 ASO (Quantitative) – ASO Titer control is run each time semi quantitative ASO Tests are

 performed.

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

 PLUSS PF4 External Controls (Positive and negative) are run with

 each shipment of tests and once every 30 days thereafter.

Internal Controls – The PLUSS PF4 HIPA Screen (HIT) contains built-in control features for daily quality control. We will document these controls for each sample tested. No additional external or internal quality control is required.

1. HIV – External Controls (positive and negative) are run with each shipment of tests and

 once every 30 days thereafter.

Internal Controls – The Alere HIV Ag/Ab Combo contains built-in control features for daily quality control we will document these controls for each sample tested.

No additional external or internal quality control is required.

 4. Mono (Heterophile) - Positive and negative controls provided with the kit are run with each test series.

5. Pregnancy Test - External Controls (Positive and negative) are run with each shipment of tests and once every 30 days thereafter.

Internal Controls – The Medline hCG Serum/Urine contains built-in control features for daily quality control. We will document these controls for each sample tested. No additional external or internal quality control is required.

6. RF (RA) (Qualitative) - Positive and negative controls provided with the kit are run with each test series.

7. RF (RA) – (Quantitative) RF-Titer control is run each time semi quantitative RF tests are performed.

 RPR - Antigen is tested with reactive, weakly reactive and nonreactive control sera with each test run.

The RPR needles are calibrated when a new needle is put in use to deliver 60 free flowing drops/ml for the antigen. New needles are put in use with opening of a new kit.

 The rotator is checked for rotation between 95 to 110 rpm quarterly.

8. Rubella-positive, weak positive, and negative controls are provided with the

 kit and run with each test series.

9. CAP Analytes are run with routine testing per schedule for the following:

1. ASO

2. Mono

3. Pregnancy test

4. RF

5. RPR

6. Rubella

7. HIV

These analytes act as periodic “wet controls” to validate reagent quality and operator technique.

10. The Serology Department adheres to all Hospital and Laboratory Department Quality

 Assurance Policies as outlined in section 300 of the Department of Pathology and

 Laboratory Medicine General Policies and Procedures Book.

### REFERENCE

College of American Pathologists: Commission on Laboratory Accreditation Checklist,

Sept 25, 2012

Manufacturer’s Current Package Insert