## TITLE: Quality Control for Serology Kits and Reagents

## PRINCIPLE:

New reagents and old reagents in the kits that do not have an internal controls are checked with the new and old controls, this is a lot to lot comparison. 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 for lot to lot comparison:

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 Senior Technologist 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 new shipment of tests.

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 new shipment of tests 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 per package insert.

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.

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. Rubella

6. 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

Manufacturer’s Current Package Insert

Current CAP checklist