## TITLE: Reagent Handling and Validation

## PRINCIPLE:

The purpose of this procedure is to give detailed instructions for reagent handling and verification of performance. This procedure applies to all reagents, test kits and quality control materials.

**CLINICAL SIGNIFICANCE**:

To ensure accuracy and reproducibility of laboratory tests, all reagents must be handled and stored following manufacturer directions without modifications

To verify acceptable performance, new reagents are to be checked by an appropriate method before they are placed into service. The results of these checks must be documented.

**PERSONNEL:**

All Medical Technologists and Technicians

**SPECIMEN COLLECTION/TREATMENT:**

Not applicable

**REAGENT PREPARATION & EQUIPMENT:**

See individual procedures.

## STEPWISE PROCEDURE:

A. New Kit Validation

1. When a new kit is put in service, the adequacy of limiting daily QC to internal

controls must be validated. Validation studies must include daily comparisons of

external controls to built-in controls for at least 20 consecutive days when patient

samples are tested.

2. External controls are run with each new lot of kits.

3. External controls are run as frequently as recommended by the test manufacturer, or

every 30 days, whichever is more frequent.

B. Reagent Reception into Department.

1. When all reagents, test kits and quality control materials are received in the laboratory, before they are placed in storage, they must be labeled with the following:
2. content, quantity and concentration
3. storage requirements – All reagents, test kits, and quality control material must be stored as recommended by the manufacturer.
4. date prepared or reconstituted (where applicable)
5. date placed in use
6. expiration date and lot number
7. Place appropriate health hazard labels on any reagent in which they are required.

Refer to MSDS sheets.

1. When shelving, refrigerating or freezing packages, all of the same lot number of reagents, test kits, or quality control materials are to be grouped together with the oldest lot number or shortest expiration date in front so that it may be used first.
2. Store all reagents as recommended by the manufacturer
3. Under no circumstances should components of different kit lot numbers be

interchanged as reagent quality may be compromised.

1. A new expiration date must be recorded on each container if opening the

container changes the expiration date or storage requirement.

1. Quality reagent performance is verified by the assay, review, and documentation

of results of the routinely used control material specific for each reagent.

8. All new reagent lots are to be validated before or concurrent with use for patient

testing:

Reagent validation is performed by assaying the same patient specimens with both the

old and new reagent lots to ensure consistent results. One positive result and one

negative result will be run with both the old lot and new lot. In the absence of a

negative or positive patient, evaluated proficiency survey material may be used.

1. Method Performance Specifications (accuracy, precision, analytic sensitivity and

AMR (as applicable) verified by CAP survey material (2005) and manufacturer’s

Information.

1. Reagent Handling
   1. Never use expired reagent.
   2. Never pipette stock reagents directly from the bottle - - pour off a small amount, pipette the required volume, discard the rest – never pour reagent back into the bottle.
   3. Follow storage instructions closely for all reagents according to manufacturer directions.
   4. Follow all safety precautions and warnings. Clean up spills properly and as soon as possible.
   5. Handle large bottles with great care.
   6. Avoid inhaling fumes – use a hood and goggles.
   7. Never mouth pipette-pipette bulbs are available.
   8. Never mix the contents of old bottles or lots of reagent with new bottles or lots of reagent. Never mix reagents from different kits.
   9. Use reagent according to manufacturer directions.

**CALCULATIONS:**

Not applicable

**REPORTING RESULTS:**

Not applicable

**NOTES:**

1. Check appropriate manual or instrument procedure book for special reagent preparation instructions.

**REFERENCES:**

Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Clinical laboratory improvement amendments of 1988: final rule. Fed Register, 2003.

NCCLS. Evaluation of matrix effects; approved guideline EP 14-A. Wayne, PA: NCCLS 2001.

NEW LOT REAGENT VALIDATION WITH PATIENT SPECIMENS

### ANALYTE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Current Reagent Lot #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**New Reagent Lot #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Current Reagent Lot # PATIENT 1 Result Current Reagent Lot # PATIENT 2 Result**

**New Reagent Lot # PATIENT 1 Result New Reagent Lot # PATIENT 2 Result**

**Corrective Action (if required): External QC Done**

**Comments:**

**I have validated that the patient results from**

**the Current Lot # and the New Lot # of the**

**reagent for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_are**

**consistent**

**Technologist:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

S:Laboratory P&P/Serology/4840-IM-115/ch12/15/05