## 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 strips and quality control materials.

**CLINICAL SIGNIFICANCE**:

To ensure accuracy and reproducibility of laboratory tests, all reagents must be handled and stored following manufacturer directions

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

## STEPWISE PROCEDURE:

A. 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:

* content, quantity and concentration
* storage requirements – All reagents, test kits, and quality control material must be stored as recommended by the manufacturer.
* date prepared or reconstituted (where applicable)
* date placed in use
* expiration date and lot number
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. Under no circumstances should components of different kit lot numbers be interchanged as reagent quality may be compromised.
3. The date opened or the date prepared must be placed on all reagents, calibrators, tests kits and quality controls.
4. A new expiration date must be recorded on each container if opening the container changes the expiration date or storage requirement.
5. All reagents, calibrators, test kits and quality control materials must be used within their expiration dates.
6. 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 non-waived reagent lots are to be validated before use. Validation is not required for waived testing reagents.

9. Quality reagent performance for urine test strips (both Roche 10UA and Arkaray 9EB test strips) are validated by running a minimum of 2 patient samples (one positive and one negative) on both the new lot as well as the current lot. Patient specimens are best but if none are available QC or already graded PT samples are acceptable.

**REAGENT HANDLING:**

* 1. Never use expired reagents.
	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.

Note: 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.

**VALIDATION**

**NEW LOT OF URINE TEST STRIPS**

**Test Strips: (circle one) Arkray AUTION 9EB or Roche Cobas 10UA**

**Current Lot # of Test Strips\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp. Date\_\_\_\_\_\_\_\_\_\_\_**

**New Lot # of Test Strips\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp. Date\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sample ID | S.G. | pH | LEU | NIT | PRO | GLUC | KET | UROB | BIL | HGB | Acceptable?Yes or No |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
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**\*Tests strips must match within one semi-quantitative grade**

**Corrective Action (if required):**

**The new lot of test strips is acceptable for patient testing.**

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

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