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Applicability	Taylor + Trenton + Wayne

New Reagent Lot Verification for UN-Series Automated Urinalysis

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document is intended to guide the Urinalysis staff in the process of new reagent lot verification on the UN-Series UN2000 analyzer.

II. POLICY

A. Per College of American Pathologists' (CAP) Checklist item COM.30450 New Reagent Lot Verification, ***"New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service"***.

B. Quality Control (QC) materials are acceptable alternatives for validating new reagent lots. The laboratory is aware that QC materials may be affected by matrix interference between different reagent lot and patient specimens are the preferred sample for comparison studies. However, due to the low volume of Urinalysis testing being performed, the UF-CELLSHEATH onboard reservoir, and the limited stability of the urine samples, the manufacturer's recommended QC material is used for the UF5000 reagent verification process.

C. The use of QC material alone is adequate to check a new shipment of a reagent lot currently in use, as there should be no change in potential matrix interactions between QC material and different shipments of the same lot number of reagents.

III. SPECIMEN COLLECTION AND HANDLING:

A. Pull specimens from current day's run for comparison testing between current and new lots of

Clinitek NOVUS Urinalysis Cassettes. The most recent available specimens should be pulled and should include both "positive" and "negative" results when ever possible.

B. The current lot of UF-CONTROL is used for all UF-5000 reagent verification testing.

IV. REAGENTS:

A. Clinitek NOVUS Urinalysis Cassettes

B. UF-CellSheath-initial blending of the new lot and old lot occurs in the on board reservoir. Takes approximately 25 patients to be run to ensure that residual old lot of reagent has been replaced with the new lot of reagent.

C. UF-CellPack SF-dispensed directly from the reagent container.

D. UF-CellPack CR-dispensed directly from the reagent container.

E. UF-Flourocell SF-dispensed directly from the reagent container. Takes approximately 85 patients to be run to ensure that residual old lot of reagent has been replaced with the new lot of reagent.

F. UF-Flourocell CR-dispensed directly from the reagent container. Takes approximately 85 patients to be run to ensure that residual old lot of reagent has been replaced with the new lot of reagent.

V. PROCEDURE:

A. Clinitek NOVUS Urinalysis Cassettes

1. Follow the Urinalysis Strip Testing Verification procedure.
2. Patient testing will not be performed using Clinitek NOVUS Urinalysis Cassettes that fail the strip verification process.

B. UF5000

1. UF-CONTROL-H and UF-CONTROL-L are run each shift to consistently monitor the UF5000 reagents.
    a. In the event of a QC failure that is found to be caused by a new lot of reagent, all patient results since the last acceptable QC will be reviewed and retested when possible. The medical director will determine the clinical significance of the failure and the appropriate actions to be taken.

VI. REFERENCES:

1. College of American Pathologists' (CAP) Checklist item COM.30450 New Reagent Lot Verification
2. Product Notification: UN-Series Automated Urinalysis Solution, New Reagent Lot Verification. Document Number: 62-1704, 10/2021

Approval Signatures

Step Description	Approver	Date
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Applicability

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