PROCEDURE
Corewell Health East - New Reagent Lot Verification for UN-Series Automated Urinalysis

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to:	Within Corewell Health Grosse Pointe Hospital, Grosse Pointe only. Within Corewell Health Farmington Hills Hospital, Farmington Hills only. Within Corewell Health Wayne Hospital, Wanye only.
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Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Urinalysis

1. Purpose and Objective
A. This document is intended to guide laboratory personnel in the process of new reagent lot verification on the Sysmex UN-Series analyzers.

2. Principle
A. Per College of American Pathologists' (CAP) Checklist New Reagent Lot Verification, "**New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently before 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 lots and patient specimens are the preferred sample for comparison studies. However, due to the 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.

3. Responsibility
Personnel who have completed the competency requirements will perform these tasks.

4. Specimen Collection and Handling
A. Pull specimens from the 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 whenever possible.
B. The current lot of UF-CONTROL is used for all UF-5000 reagent verification testing.

5. 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.

6. Procedure

A. Clinitek NOVUS Urinalysis Cassettes
    1. Each new lot number and/or new shipment of test strips are tested in parallel with the current test strips in use.
    2. Two previously run patients (one "negative" and one "positive") are pulled and tested in parallel with each lot or shipment of testing strips.
    3. Results are recorded on a Lot to Lot worksheet. (See site specific worksheet).
    4. Results must agree within one grade and specific gravity must be within +/- 0.005.
    5. Results are given to the Lead Medical Technologist or designee for approval.
    6. Any new lot or shipments received that do not correlate with the previous lot or shipment should not be used for patient testing.
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 from 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.

7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

8. References

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

9. Procedure Development and Approval

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10. Keywords

Not Set