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Applicability Taylor + Trenton

+ Wayne

Urinalysis Strip Testing Verification

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document is intended to provide instructions for testing personnel to perform patient correlations for new lot or new shipments of Urinalysis testing strips for the Clinitek (Multistix), Clinitek NOVUS (Urinalysis Cassette) or iChem Velocity.

II. PRINCIPLE:

Clinical laboratory reagents and control materials are exposed to many variables due to conditions during transportation and storage environments in different laboratory settings. The validation of new shipments and/or new lot numbers of test kits with currently in use test kits is performed to ensure that, in spite of varying environmental conditions, there are no clinically significant differences in the results obtained when different shipments and/or new lot numbers of reagents are used. Patient comparisons are parallel tested to verify that the same results are achieved using reagents from each test kit.

III. PROCEDURE:

- A. Urinalysis Testing Strips
 - 1. Each new shipment and/or new lot number 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 the Urinalysis Testing Strip Verification 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.
- 7. New Lot number information should be updated on all Clinitek <u>or NOVUS</u> logs or in the iRICELL under consumables when put into use.

Attachments

Urinalysis Testing Strip Verification Worksheet

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	5/30/2024
Policy and Forms Steering Committee Approval (if needed)	Laura Bellon: Medical Technologist Lead	5/20/2024
	Christopher Ferguson: Dir, Lab Operations B	5/20/2024
	Kristen DiCicco: Mgr, Laboratory	5/20/2024
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Applicability

Taylor, Trenton, Wayne