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Document History:

Title: Procedure for New Reagent Lot or Shipment Verification for Urinalysis Testing

Site(s): All

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Section:	**Clinical Biochemistry**	**Subsection:**	**Urinalysis**

Approved by:	T Dembinski	**Date:**	26 Sept 2012

Approved by:	L Thorlacius	**Date:**	16 Feb 2021
Signature:	(Signature on File)		
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#	Details of Revisions:	Approval:	Date:
1	New document	T Dembinski	26 Sept 2012
2	Site applicability change from HSC, SBGH to DSM sites, minor edits & formatting, checked cross-references to other SOPs.	H Malvern	4 Mar 2015
3	Major revisions of previous document.	U Uddayasankar	28 Nov 2018
4	Added that procedure must be done for new shipment of same lot of strips as well as for new lots. Changed Site from HSC/SBH to “All”. Updated QC Material to quantify Plus (p.2). Attached the sign off document as Appendix 1.	H Vakili	16 Feb 2021

1.0 INTRODUCTION:

The following procedure describes the process for verification of new reagent lots or shipments of the same lot for urinalysis test strips or reagent cassettes. This is required to maintain consistency of test results for patient samples upon reagent lot change.

Urinalysis using test strips are qualitative tests. Testing QC samples that were tested on the previous lot/shipment may be used to verify performance of the new lot of reagent. New reagent lots/shipments are compared to the previous reagent lot/shipment using Bio-Rad quality control (QC) material before or concurrently with being placed in service. Records of verification of new reagent lots and shipments are maintained to show documentation for change-over to new reagent strips.

2.0 EQUIPMENT & REAGENTS:

- QC material:
  - BioRad qUAntify® Plus Control Levels 1 and 2
  - Do not change QC lots at the same time as reagent lots.
- Instrument specific materials for urinalysis are outlined in the respective SOPs (Clinitek Novus: 110-50-17; Clinitek Advantus: 110-50-18; Clinitek Status: 110-50-19)

3.0 SAFETY PRECAUTIONS:

Exercise normal precautions required for handling all laboratory reagents and QC material.
Disposal of all waste material should be in accordance with local guidelines.

4.0 PROCEDURE:

1. Upon receiving, inspect new reagent strips packaging for damage and expiry dates. Mark packages with the date of receipt. Check package inserts for any changes.

2. Enter product information into the Testing New Reagent Lots Signoff Document (Appendix 1), which includes Lot Number, Expiry Date, Date Received and Date Testing Initiated.

3. Make sure QC used to verify the new reagent lot or shipment is at room temperature, and inverted several times to ensure homogeneity. Make sure there are no bubbles present in the QC material

4. Calibrate according to the instrument SOP using appropriate calibration material. (Clinitek Advantus: 110-50-18; Clinitek Novus: 110-50-17; Clinitek Status: 110-50-19)

5. Analyze QC material on the new reagent strips in triplicate and assess acceptability of the new reagent. Acceptability criteria includes:

   - The results of the QC material (at least 2/3 measurements) should be within ±1 level of the predominant result obtained with the previous reagent lot for all analytes. Compare new reagent results to the QC values over the past 30 days and within acceptable range based on the QC package insert.

6. If acceptability criteria have been met, the new reagent has been validated and may be used for patient sample testing.

7. Once reagent strips have been validated, label the new reagents as ready to use and store the new reagent in its appropriate place and complete the rest of the signoff document (Appendix 1). Ensure the results of all analysis are placed in the “Outcome” section of the document along with a copy of the QC log sheet of the QC material that was used for validation.

8. If the product fails validation, it should not be used to test patient samples. The charge technologist or designate must be notified immediately.

9. The Charge or designate will then contact the supplier of the reagent to enquire if other institutions have noticed an issue with the lot of reagent strips, and request a replacement lot number for testing.

5.0 REFERENCES:

- Bio-Rad qUAntify Plus Control Package Insert. Printed 2018-11
- CAP Checklists: Urinalysis Checklist 2020 and All Common Checklist 2020
- SOP # 110-50-06 Quality Control of Urinalysis Test Strips

Appendix 1: Testing New Reagent Lots Signoff

	Current	New
Type of reagent		
Lot #		
Expiry Date		
Date Received		
Date testing Initiated		
Date testing Completed		

Acceptance criteria: Analyze QC material on the new reagent strips in triplicate. The results of the QC material (at least 2/3 measurements) should be within ±1 level of the predominant result obtained with the previous reagent lot for all analytes. Compare new reagent results to the QC values over the past 30 days.

Acceptable for use:

☐ YES – Meets acceptance criteria – Attach a copy of the QC log sheet of the QC material that was used for validation

☐ NO – (Provide explanation below and indicate actions taken)

Outcome:

Senior/Charge Technologist: **Date:**