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Urinalysis Quality Control Procedures - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. All quality control (QC) testing is to be performed daily, unless indicated otherwise, and all results are entered into BioRad Unity Realtime. If results are within the acceptable range indicated on the daily control sheet, record the test result for the appropriate date. If results are out of control, follow the identified procedure below.

II. PROCEDURE:

A. Troubleshoot to resolve the QC problem.

B. **Document the unacceptable QC result** in BioRad Unity Realtime and free-text the appropriate comment (e.g. QC repeated and OK on new vial, instrument was cleaned/recalibrated and QC within acceptable range, reagents were replaced, etc.)

C. **Document the repeat, acceptable QC result** which permits patient results to be reported.

D. Record any additional results obtained during trouble-shooting, together with details of instrument problems and corrective action on the log forms behind the maintenance sheets.

E. Quality Control testing is to be performed as described in the following sections:

1. **Specific Gravity**

   a. Check that the Refractometer chamber is clean and if necessary wipe clean with a Chemwipe moistened with deionized water. Dry the chamber.

   b. Measure the specific gravity (SG) of deionized water; this should be 1.000. If the result is greater than 1.000, verify that the Refractometer chamber is clean and repeat the testing. If the SG result remains abnormal, inform the Chemistry Supervisor.

   c. Measure the SG of Kova-Trol (urine controls by Hycor). If the result(s) is outside the acceptable range, check the SG of a freshly opened bottle of Kova-Trol. If the result (s) is still out of range, inform a Chemistry Supervisor.

   d. The SG of a standard solution of NaCl (2.9 g NaCl in 100 ml distilled water) is to be measured monthly. The acceptable range for SG is 1.014 – 1.016. If the result is out of range, verify that

the refractometer is clean and repeat the reading. If the result is still out of control, inform a Chemistry Supervisor.

2. **Reagent Strips**
    a. **Clinitek 500** – Bayer Multistix 10SG test both Normal and Abnormal Kova-Trol controls with Multistix reagent strips for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes (WBC esterase). If any of the reagent pads give a result which is out of the acceptable range, repeat testing with a newly thawed vial of Kova-Trol, or service the Clinitek 500 as appropriate. If result(s) remain out of range, repeat with a newly opened bottle (Clinitek 500) of reagent strips. If results continue out of range, inform a Chemistry Supervisor.
    b. **iChem Velocity** – iChem Velocity Test Strips test IRISpec CA, CB, and CC controls for Normal and Abnormal results for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobiliniogen, nitrite, and leukocyte esterase. If any reagent pad gives a result outside of the expected range, repeat testing with a fresh aliquot of control, or service the iChem Velocity as appropriate. If result(s) remain out of range, repeat with a newly opened bottle of reagent strips. If results continue out of range, inform a Chemistry Supervisor.
3. **Ictotest**
    Both Normal and Abnormal Kova-Trol control materials should be tested for bilirubin using the Bile-Ictotest Procedure. If either Kova-Trol result is out of range, a newly thawed vial of Kova-Trol should be tested. If either result remains out of range, a new kit of Ictotest reagents should be used. Additional problems should be brought to the attention of a Chemistry Supervisor.
4. **Positive and Negative controls for iQ200 Analyzers**
    a. Two levels of QC are included with each iQ200 control kit.
    b. Controls are ran at 12 hour intervals. QC is performed between 4:30am and 5:30am and then again between 4:30pm and 5:30pm
    c. Each iQ200 control kit contains a package insert with lot # specific expected assay ranges. We validate these ranges before routine use.
    d. When a new shipment of iQ200 controls arrives:
        i. Run new QC along with old QC (in the appropriate files) until 5 data points are obtained.
        ii. Evaluate the controls to determine if they are acceptable. If the run of the new controls is unacceptable a call must be placed to service to have the instrument calibrated.
        iii. Monthly, evaluate statistics to monitor standard deviation for all parameters.
5. **New Lots of Quality Control/Reagents**
    a. Any new lot or shipment of control or reagent should be flagged at receipt with an Item Lot # Slip that includes item name, lot #, date received, and date of expiration.
    b. Any new shipment of control or reagent should be tested with the appropriate quality control protocol prior to its introduction for routine patient testing. When applicable QC results are to be documented in BioRad Unity Realtime.
    c. Any new lot number of reagent should be tested with the appropriate quality control prior to its introduction. When applicable, QC results are to be documented in BioRad Unity Realtime.
    d. Additionally, where feasible, a known positive and negative patient specimen should be tested

on the new lot number against the old lot number.

e. The Urinalysis Tech who initiates the use of new lot/ new shipment of QC or reagents is responsible to log date received, date in use, tech initials, QC OK? And QC in BioRad Unity Realtime? Give these forms to the Lead in charge of Urinalysis.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	1/27/2022
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory [RC]	1/27/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	1/27/2022
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	1/27/2022
Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	1/20/2022
	Colette Kessler: Mgr Laboratory [RC]	12/6/2021

Applicability

Royal Oak