Document History:

Title:	Quality Control of Urinalysis Test Strips and Cassettes	Site(s):	Shared Health Diagnostic Services – All sites
Document #:	**110-50-06**	**Version #:**	**06**
Section:	**Clinical Biochemistry**	**Subsection:**	**Urinalysis**

Approved by:	T Dembinski	**Date:**	30 Mar 2010

Approved by: *(approval on file)*	L Thorlacius	**Date:**	26 May 2023
		Effective Date:	1 June 2023

#	Details of Revisions:	Approval:	Date:
1	Replaces 110-10-09 to go under Urinalysis section;	T Dembinski	30-Mar-10
2	Addition of Appendix 3: Urinalysis Control Log Sheet Rural Sites (F110-50-06C); addition of test strip lot no. & exp. date recording to QC charts # F110-50-06 A-C; removal of 'reviewed by' and 'date' at bottom of charts A-C, and replacement by daily review supervisor initials column, 'Supvr'; Correction to 'Control results must be retained for a minimum of two years' (from three years).	T Dembinski	May 11, 2010
3	Major revisions to previous version.	U Uddayasankar	28 Nov 2018
4	Removed Bio-Rad Liquichek QC from document. Updated QC Stability (p.4). Updated requirements for level 2 QC ranges (p.4).	H Klassen Vakili	31 May 2022
5	Updated responsibility for performing and validating daily QC. Updated qUAntify Advance QC, removed qUAntify Plus.	H Klassen Vakili	1 May 2023
6	Re-added qUAntify Plus QC handling and stability for sites that still have in stock.	L Thorlacius	26 May 2023

1.0 PURPOSE:

To describe the quality control (QC) procedures for urinalysis test strips and reagent cassettes.

2.0 QUALITY STANDARDS:

Quality control of urinalysis testing requires running QC specimens to verify validity of test strips or reagent cassettes and procedure. This must be done in compliance with the following standards.

1. The maximum analytical run length for urinalysis testing is 1 day (24 hours) in laboratories performing urinalysis daily. In situations where testing is performed at lower frequency than daily, the laboratory is to be directed by the note below[#]. *An analytical run length defines the interval between evaluations of control results.*

   [#]***N.B.*** *Controls should be tested at a frequency defined by the laboratory, related to workload. For example, a laboratory consuming one container of dipsticks over a month may choose to perform weekly QC, while a laboratory using several containers of dipsticks per day may perform one set of QC specimens per container (refer to page 31 of referenced CLSI document)*

2. All urinalysis test strips must be controlled with 2 levels (negative and positive) of urinalysis QC material. *This is a minimum acceptable standard.*

3. Quality control specimens must be analyzed on urinalysis analyzers on each new lot and/or shipment of reagent strips, prior to patient testing, after instrument calibration, maintenance or repair, and whenever an operational problem is suspected.

4. Quality control results must be dated, compiled, available for review, complied with and retained for a minimum of two years as per Shared Health document # 100-10-05 Laboratory Records and Material Retention Policy.

3.0 MATERIALS:

- Bio-Rad qUAntify® Advance Control Levels 1 and 2, Cat # 12007028 Bilevel pack, or
- Bio-Rad qUAntify® Plus Control Levels 1 and 2, Cat # 995 Bilevel pack
- QC log sheets (F110-50-06C for non-Unity rural sites) or Bio-Rad Unity Software
- 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)

4.0 RESPONSIBILITY

Refer to Shared Health SOP # 110-10-21 (Quality control monitoring, review and troubleshooting) for details.

- QC must be performed daily and reviewed prior to patient testing.
- Weekly and monthly review of the QC results must be performed by the senior or charge technologist, or designate.
- Any failures or atypical trends must be noted, and the clinical biochemist in charge of urinalysis testing notified.
- Oversight of QC practice is the responsibility of the clinical biochemist. They will provide direction on how QC is performed and monitored.

5.0 PROCEDURE:

Two levels of QC must be tested, and these should be analyzed:

- At least once every 24 hours when the instrument is used for daily patient testing.
- If patient testing is not performed every day, QC may be run right before testing patient samples. Once performed, QC results are valid for 24 hours.
- After instrument maintenance or repair
- After instrument calibration
- After instrument shutdown and restart
- Whenever a problem is suspected

5.1. Bio-Rad **qUAntify® Advance** Control Levels 1 and 2 Storage and handling

Unopened: Stable until expiration date when stored at 2 to 8 °C
Opened: Stable for 31 days at 2 to 8 °C when stored tightly capped

Clinitek Novus Sites: aliquot controls into conical tubes and label with lot number, date vials opened and open expiry date.

Clinitek Advantus and Status+ Sites: controls may be dropped directly on to each pad of the Siemens Multistix. Aliquoting is not necessary.

Blood and ketone values may decrease and pH may increase over the storage period

Do not freeze. Store protected from light.

Mix well prior to testing and minimize exposure to air by recapping vials immediately after analysis.

5.2. Bio-Rad **qUAntify® Plus** Control Levels 1 and 2 Storage and handling

Unopened: Stable until expiration date when stored at 2 to 8 °C
Opened: Stable for 14 days at 2 to 8 °C

HSC only: original 120 mL bottles are stable for 31 days at 2 to 8 °C when aliquots are used for analysis.

Blood and ketone values may decrease and pH may increase over the storage period

Do not freeze. Store protected from light.

Mix well prior to testing and minimize exposure to air by recapping vials immediately after strip immersion or automated analysis.

5.3. Acceptable ranges of QC material:

For every new lot of QC material, the allowable ranges should be established by running the QC material over at least 10 days as a test sample when the instrument is calibrated and in control. Ranges provided in the manufacturer product insert should only be used as a guide.

Level 1 QC material (negative): should give a negative result for most tests.

Level 2 QC material (positive): The most frequently occurring value obtained (the mode) when establishing acceptable range will serve as the mean and the acceptable range is set at ±1 colour block from the mean.

5.4. QC testing procedure

1. Before sampling, allow the control material to reach room temperature (18 to 25 °C) for 15-30 minutes.

2. Gently invert the vial several times to ensure homogeneity. Do not shake and avoid the formation of bubbles.

3. Remove cap from vials and perform testing as described in the appropriate instrument SOP. (Clinitek Novus: 110-50-17; Clinitek Advantus: 110-50-18; Clinitek Status: 110-50-19).

4. After each use, promptly recap the vials and return to refrigerated storage. If sampling directly from dropper bottles, wipe the tip before capping.

5. Record all quality control data on the QC data log sheet that has all the required details filled (i.e. analyzer name, control level, test strip and control lot numbers, test strip and control expiry dates and expected ranges of results). Alternatively, the QC may be recorded using the Bio-Rad Unity software.

   NOTE: QC log sheets must be stored for at least 2 years.

6. Verify that all results are within the assigned allowable range. In the “Comment” section of the QC log, indicate if QC has passed or failed and any follow-up action taken.

7. Do not proceed with testing patient samples if QC results are outside allowable ranges. Troubleshooting QC failures may involve:
   - Repeat QC using a fresh vial of QC material
   - Recalibrate instrument and repeat analysis of QC material
   - If not resolved, inform senior or charge technologist for additional troubleshooting.

6.0 REFERENCES:

1. CLSI document, GP16-A3: Urinalysis; Approved Guideline – 3rd Edition.
2. Bio-Rad qUAntify Advance Control Product Insert
3. CAP Urinalysis Checklist 2021
4. Burtis, Carl A., Edward R. Ashwood, and David E. Bruns. *Tietz textbook of clinical chemistry and molecular diagnostics-e-book*. Elsevier Health Sciences, 2012.