



Current Status: *Active*

PolicyStat ID: 4209224



Origination: 11/2017
Last Approved: 11/2017
Last Revised: 11/2017
Next Review: 11/2019
Owner: *Karen Lea: Manager-Lab compliance*
Policy Area: *Lab / Urinalysis*
References:
Applicability: *St. Joseph Medical Center
St. Anthony Hospital
St. Clare Hospital
St. Elizabeth Hospital
St. Francis Hospital*

POCT Urine Dipstick Quality Control Process

PURPOSE

To define the process for managing the inventory and performing quality control for ROCHE Chemstrip urine dipsticks used on the hospital floors for visual urine dipstick testing.

BACKGROUND

The ROCHE Chemstrip urine test system is a multi-parameter test strip that simultaneously measures specific gravity, pH, nitrite, protein, glucose, ketones, leukocytes, and blood in urine. Different reagent pads attached to inert plastic strips change color as they react with the various constituents to be measured. The color change provides semiquantitative measurements which are read visually against a standard color chart on the test strip container.

RELATED DOCUMENTS

[POCT Inventory Receipt, R-PR-POC0169](#)

[POCT Urine Dipstick Quality Control Check](#)

PROCESS

Hospital	Process
SJMC CLIA: 50D0897059	Pharmacy: <ul style="list-style-type: none"> Brings Chemstrips to the Laboratory Technical Assistant (LTA) to have quality controls (QC) completed Lab Technical Assistant: <ul style="list-style-type: none"> Brings Chemstrips to Urinalysis department to be Quality Control checked. Lab Tech: <ul style="list-style-type: none"> Run QC, document results on the QC form.

	<ul style="list-style-type: none"> • Enter received date, expiration date, and the package insert version date on the QC form • Return Chemstrips to LTA <p>LTA:</p> <ul style="list-style-type: none"> • If QC Controls acceptable, Tag Chemstrips with “Ready to Use” sticker • Return Chemstrips to pharmacy, to be placed in to use. • LTA send/take QC form(s) to Point of Care Coordinator <p>POCT Coordinator:</p> <ul style="list-style-type: none"> • Review QC form and result details and file.
<p>SFH CLIA: 50D0897230</p>	<p>Pharmacy/Materials Management:</p> <ul style="list-style-type: none"> • Brings Chemstrips to the Lab to have quality controls (QC) completed <p>Lab Tech:</p> <ul style="list-style-type: none"> • Run QC, document details on the QC form including the receive date, expiration date, and package insert version date. • QC controls acceptable, Tag Chemstrips with “Ready to Use” sticker • Document QC in SFH Point of Care Testing Manual • Tech delivers Quality Control checked strips to pharmacy <p>Med Tech Coordinator:</p> <ul style="list-style-type: none"> • Reviews QC monthly from POCT Testing Manual • Pharmacy is called to pick up Chemstrips, if needed.
<p>SCH CLIA: 50D0978628</p>	<p>Pharmacy:</p> <ul style="list-style-type: none"> • Brings Chemstrips to the Lab to have quality controls (QC) completed <p>Tech:</p> <ul style="list-style-type: none"> • Run QC, document details on the QC form including the receive date, expiration date, and package insert version date. • QC controls acceptable, Tag Chemstrips with “Ready to Use” sticker • Document QC in Point of Care Testing Manual • Tech delivers Quality Control checked Chemstrips to pharmacy <p>Med Tech Coordinator:</p> <ul style="list-style-type: none"> • Reviews QC monthly from POCT Testing Manual
<p>SAH CLIA: 50D1095584</p>	<p>Materials Management:</p> <ul style="list-style-type: none"> • Brings Chemstrips to the Lab to have quality controls (QC) completed. <p>Lab Tech:</p> <ul style="list-style-type: none"> • Run QC, document details on the QC form including the receive date, expiration date, and package insert version date. • QC controls acceptable, Tag Chemstrips with “Ready to Use” sticker • Document QC in Point of Care Testing book <p>Med Tech Coordinator:</p>

	<ul style="list-style-type: none"> • Reviews QC monthly from POCT Testing Manual <p>Lab Staff:</p> <ul style="list-style-type: none"> • Delivers the tagged Quality Control checked Chemstrips to pharmacy department
<p>SEH CLIA: 50D2002804</p>	<p>Materials Management:</p> <ul style="list-style-type: none"> • Brings Chemstrips to the Lab to have quality controls (QC) completed. <p>Lab Tech:</p> <ul style="list-style-type: none"> • Run QC, document details on the QC form including the receive date, expiration date, and package insert version date. • QC controls acceptable, Tag Chemstrips with “Ready to Use” sticker • Document QC in Point of Care QC clipboard <p>Med Tech Coordinator:</p> <ul style="list-style-type: none"> • Reviews QC monthly <p>Lab Staff:</p> <ul style="list-style-type: none"> • Delivers the tagged Quality Control checked Chemstrips to Materials Management department

SUPPLIES

- Quantimetrix, Dipper, 2 levels
- Chemstrips
 - Protect against exposure to light, heat and moisture
 - Store at room temperature 2-30°C
 - Do not freeze
 - Store unused strips in bottle. Do not remove strips from bottle until immediately before use.
 - Replace cap immediately after removing strips, keeping bottle closed tightly
 - Discoloring or darkening of reagent areas may indicate deterioration
- Timer
- Pipette
- POCT Urine Dipstick Quality Control Check Form

QUALITY CONTROL

Quality Control Process

1. Print QC form, from PolicySTAT (Lab/Urinalysis) *POCT Urine Dipstick Quality Control Check Form*
2. For each level of QC, remove one strip from bottle and pipette drops of the Quantimetrix QC on the Chemstrip covering all the test pads.
 - i. Be careful not to have the QC liquid run together while dropping the liquid on the Chemstrip. This can cause false reactions from the reagent in the pads reacting together.
3. Immediately start timing
4. Read the test pads visually comparing the results to the corresponding row of color blocks on the bottle label
5. Read each pad at the time shown on the label, starting with the shortest time. Hold the strip close to the

color blocks and match carefully. Read the pads in good light

- i. All test pads should be read at **1** minute
 - ii. If the leukocytes pad indicates a trace results, it should be read again in **2** minutes
6. Record lot number, expiration date, and results on QC form (POCT Urine Dipstick Quality Control Check Form)
7. Fill in the appropriate acceptable ranges on the QC form:
- i. Quality control ranges are listed under **ROCHE VISUAL TESTING (Visual Test Strips Only) (USA)** on the Quantimetrix, Dipper package insert
8. All results must fall into ranges established by the manufacturer. If any result is out of the established range, repeat testing, taking care to mix reagent thoroughly and time steps carefully. If any result is still out of range, remove the Chemstrip container from service and open a fresh container to perform Quality Controls. Document all corrective actions taken
9. Once the QC has been completed and passed, place a "Ready to Use" sticker on the Chemstrips bottle; along with the date and your Tech ID
- i. Document the QC according to your hospitals process
 - ii. Follow your hospitals protocol in dispensing the urine dipsticks to the pharmacy department

LIMITATIONS

- Reagent pad colors are stable up to 120 seconds after immersion. Color changes that occur after 2 minutes from immersion are irrelevant and should be ignored. Color changes that occur only along the edge of the test pads should be ignored as well (careful removal of excess urine should eliminate this effect).

Attachments:

No Attachments

Approval Signatures

Approver	Date
Arlene Brennan: Administrative Coordinator	11/2017
Adam Saenz: MD, Medical Director	11/2017
Shane Anderson: MD, Medical Director	11/2017
Linda Burkhardt: MD, Medical Director	11/2017
Brian Folz: Medical Director	11/2017
Joren Keylock: MD, Medical Director	11/2017
Arlene Brennan: Administrative Coordinator	11/2017
Karen Lea: Manager-Lab compliance	11/2017