ICHEM ™ 100 OPERATION

☒ St. Joseph Medical Center Tacoma, WA ☐ St. Clare Hospital Lakewood, WA ☐ St. Elizabeth Hospital Enumclaw, WA
☐ St. Francis Hospital Federal Way, WA ☐ St. Anthony Hospital Gig Harbor, WA ☐ PSC

PURPOSE

To provide instructions for performing Urinalysis testing and maintenance on the iChem™ 100 Urine Chemistry analyzer.

BACKGROUND

The iChem™ 100 Urine Chemistry Analyzer is a semi-automated urine chemistry analyzer for the in vitro measurement of the following analytes in urine: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocytes, ascorbic acid, color and user-defined clarity.

RELATED DOCUMENTS

Urinalysis Quality Assurance	R-PO-UA-2027
ICHEM™ 100 Maintenance	J-W-UA-2201
ICHEM™ 100 QC & Maintenance Log	J-F-UA-2202
Urinalysis Reagents	R-W-UA-0822

SUPPLIES

Reagent	Storage	Stability	Open-vial Expiration
Iris System Cleanser	Room Temp	Manufacturer's Dating, if unopened.	18 months
iChem™10 SG Urine Chemistry Strips	2°C - 30°C Protect from light and moisture. Store in a cool dry place. Do not freeze.	Manufacturer's dating, if stored in original capped container.	Remove only the number of strips required for testing and immediately reseal the container. Unused strips are stable to manufacturer's expiration date if stored in the original capped container.
Irispec CA/CB/CC Quality Control	Store at 2-8°C.	Manufacturer's dating, if unopened.	15 days
Thermal Paper	Room Temp	N/A	N/A

SPECIMEN REQUIREMENTS

Container Type	Leak proof plastic urine container, or Yellow Cap Urine Transport tube
Specimen Type	1st morning specimen recommended: Random, Clean Catch, or Catheter collection of Urine
Preferred Volume	Adult: 25 mL Pediatric: 10 mL
Minimum Volume	2 mL for orders including a Urine Dip, Microscopic, and Culture.
Specimen Handling	Refrigerate at 2-8°C. Protect from light. If testing is delayed, specimens in Urinalysis transport tube (YELLOW CAP) are acceptable. Specimens collected in Culture Transport tube (Grey Cap) for UA Testing are not recommended and require recollection or special handling. See Specimen Limitations and Special Handling below.
Stability	Specimens collected in grey tubes can be held for 24 hours at room temperature. Stabile for up to 72 hours when refrigerated. Specimens not collected in preservative are stable 72 hours when stored refrigerated.
Unacceptable Condition	Unpreserved urines should not be at room temperature for more than 2 hours.
Limitations	• For Reflex orders a microscopic exam and/or culture are performed only if indicated. Protect samples from light. • Specimens with suspected fecal contamination will be rejected. • Specimens collected in Culture Transport tube (Grey Cap) for UA Testing should be recollected if the patient is in-house. If unable to recollect, or specimen is from an out-patient location, follow instructions below in Special Handling.
Special Handling	**Urinalysis testing on specimens collected in Culture Transport tube (Grey Cap), when unable to recollect:** • Perform the Urine Chemistries, Manual Microscopic, and SSA confirmation testing for Protein. • The SSA result is reported instead of the urine strip Protein. • Leukocyte Esterase: If the urine strip is negative, AND WBC's are present on the manual microscopic, report LE as: "Interfering substance present, unable to report.

STEPS

Powering the Instrument On

1. Turn on the power to the instrument and wait for the completion of the system check. A calibration check will be performed.

2. Press [F1] for the Main Menu. A display will ask if you have emptied the waste container. Press [F1] if not emptied or [F2] if emptied.

- If the waste container is nearly full (> 125 strips), empty it prior to performing testing.

- If the instrument cover is removed while the instrument is on, you will be alerted that it is ajar. Replace the cover and indicate if the waste container was emptied. The incubation belt will clear any strips and then return to the Main Menu. This will take 1-2 minutes.

Running Patient Specimens and Quality Control Samples

1. Press the [F2] key from the main menu to display the *Run Patient* screen and activate the urine strip sensor. The green LED on the instrument indicates the sensor is active.

2. Scan the patient or QC barcode. If a barcode is unavailable enter the information using the keyboard. Press the [Enter] key or use the [↑] or [↓] arrow keys to move to the next field.

3. Assess the clarity of the sample and scan the appropriate barcode on the top of the instrument.

4. Dip the urine test strip into the urine, making sure all the test pads are wet.

5. Immediately remove the strip, dragging the edge against the side of the container as you remove it.

6. Blot the strip by touching the edge to a paper towel. Do not drag the strip across the towel. Touch the edge only.

7. Place the strip on the transport belt with the test pads facing up and slide forward until it touches the end stop. A red LED light will turn ON.

    - NOTE: If you move the strip away from the sensor prior to transport, you will be prompted to remove the strip and press the [F1] key to continue.

    - Approximately two minutes after the urine strip is transported, the results will be available.

8. To run another specimen: Wait for the Green light and then scan and load the next sample.

    - If no strips are loaded within 10 minutes, the screen will return to the Main Menu.

    - Return to the Main Menu screen any time by pressing the [F1] key.

    - If the testing is incomplete, a message will prompt you to wait for analysis to finish.

REPORTING RESULTS

- If the iChem™ 100 Urine Chemistry Analyzer is connected to the Iris IriCell Urine Analyzer, the results will transmit to the Iris IQ200 software for review and validation.

- If the instrument is not connected, results must be printed and manually entered into the LIS

QUALITY CONTROL

1. Perform quality control once daily and as needed for problem-solving.

2. Perform quality control with each new lot or shipment of strips

REFERENCE VALUES

Parameter	Normal Values
Glucose	Negative
Bilirubin	Negative
Ketones	Negative
Specific Gravity	1.003 – 1.030
pH	5 - 9
Protein	Negative or Trace
Urobilinogen	<2.0
Nitrite	Negative
Leukocyte Esterase	Negative
Ascorbic Acid	Negative

LIMITATIONS / INTERFERENCES

ANALYTE	LIMITATIONS / INTERFERENCE
Bilirubin	• Some urine medications may cause color interference with result interpretation. • Increased Ascorbic Acid and Nitrite may cause a false negative result. • Prolonged exposure to light may result in a false negative result. • Increased Urobilinogen may result in an elevated bilirubin result.
Urobilinogen	• Excreted pigments or medications with red coloration may cause a false positive result: i.e. Pyridium, red beets, azo dyes, p-aminobenzoic acid.
Ketones	• Beta-Hydroxybutyric Acid does not react with this test pad. • Phenyl pyruvic acid may interfere and color interference. • Phthaleins and anthraquinone derivatives exhibit a red color in alkaline specimens and may mask the response.
Ascorbic Acid	• No interferences known.
Glucose	• Ascorbic Acid may interfere with glucose results up to 10 hours after discontinuation of Vitamin C. • Color formation may be inhibited by high specific gravity, gentistic acid, or acidic pH (pH 4.0) in association with ketonuria. • False positive reactions may occur with exposure to hypochlorite or peroxidase.

Protein	• False positive results may occur with highly alkaline urines (pH 9.0) • False positive results may occur with high specific gravity, disinfectants, wetting agents, quartenary ammonium compounds, chlorhexidine. • Samples with highly alkaline pH >8.5 must have confirmation testing using 3% SSA for result confirmation. • Therapeutic dyes (methylene blue, pyridium) or red pigments may mask the test result.
Blood	• Uric Acid, glutathione, gentistic acid, and ascorbic acid may cause false negative results. • Formalin, hypochlorite, and peroxide may cause false positive results. • Very high levels of nitrite or a high specific gravity may delay the color response.
pH	• No interferences known
Nitrite	• False negative results may occur in the presence of bacteriuria due to non-nitrite producing microorganisms, antibiotic therapy, low-nitrite diets, strong diuresis, high levels of ascorbic acid, high specific gravity or insufficient urinary retention time in the bladder. • False positive results can be caused by dyes excreted in the urine (i.e. pyridium, or red beets)
Leukocyte Esterase	• False positive results may occur in the presence of formaldehyde. • Protein concentration >300mg/dl., cephalexin, gentamicin, very high concentrations of glucose, or high specific gravity, may diminish the color reaction. • The test may be positive in the absence of observable cells, if the granulocytes have been lysed. • The test may be negative in the presence of observable cells, if non-lysed leukocytes are present, or the cells are not granulocytes.
Specific Gravity	• pH <5 may slightly elevate the specific gravity, while a pH 8 or greater, may lower the results.

REFERENCES

iChem™ 100 Urine Chemistry Analyzer – Operations Manual, Iris Diagnostics, Rev C, 1/2007.

iChem™ 100 Urine Chemistry Analyzer – Quick Start Guide, Iris Diagnostics.

iChem™10 SG Urine Chemistry Strips, package insert, Iris Diagnostics Division, 1/30/2012.

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
New Document			
☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: 10/24/13 ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Linda D. Blumenthal, MD 10/24/13