ICHEM VELOCITY OPERATION

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PURPOSE

To provide instructions for the use of the IRIS iChem Velocity Urinalysis instrument.

BACKGROUND

The iChemVELOCITY is an automated urine chemistry system performing measurements of urine physical and chemical constituents utilizing test strips read by Wavelength Reflectance, and specific gravity using the Refractive Index. Since the iChemVELOCITY also determines color and clarity, a complete urinalysis is determined automatically. Visual measurements are no longer necessary.

The sample probe mixes the specimen, then aspirates an aliquot of urine from the tube and dispenses the sample onto each reagent pad. The test strip reagent pads and urine components react causing the color of the test strip to change, and the color change is measured by the instrument. The test strip is then transported to the waste container.

RELATED DOCUMENTS

J-W-UA-2206 IRIS iChem Velocity Reviewing Results
J-W-UA-2207 IRIS iChem Velocity Quality Control
J-W-UA-2208 IRIS iChem Velocity Calibration
J-W-UA-2209 IRIS iChem Velocity Maintenance

SUPPLIES

Reagent	Storage	Stability	Open-vial Expiration
iChem Wash Solution	Room Temp	Manufacturer's Dating, if unopened.	18 months
iChem™Velocity 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. 5 days on the instrument	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.

SPECIMEN COLLECTION

1. Collect urine in clean tube or container. Perform testing within 2 hours if specimen is at room temperature. If greater than 2 hours specimen must be refrigerated at 2-8˚C. Bring specimen to room temperature before testing. If the specimen is not warmed to room temperature prior to testing the specific gravity can be affected.

2. Do not centrifuge specimen prior to testing.

3. Mix specimen well before testing.

4. Volume needed for the iChem Velocity alone is at least 2 mls. 3 mls more of urine will be needed if a microscopic analysis is also indicated.

5. For yellow BD vacutainer tubes the maximum allowable volume without spillage is 8mls.

6. For KOVA tubes, the maximum allowable volume without spillage is 12mls.

STEPS

1. Make sure that sufficient supplies and consumables are available to complete the anticipated workload. Replenishment of consumables can be performed without stopping the measurements.

2. The On button is located on the left of the iChem Velocity. Pressing this button after applying power to the instrument places the system in Standby.

3. The Logon button is located on the top right side of the instrument screen. Until someone is logged on the Specimen, Worklist and Instrument buttons are inactive.

4. Click Logon on the computer screen. Type the user name (drop down box may be used) and password. Click OK to logon.

System Status Lights

1. The system status lights display “Stand By”(green),” Measure”(blue) and “Error”(Red).

2. Green LED only is On: The instrument is in Standby mode and ready for operation.

3. Blue LED only is On: The instrument is in the Measure mode. A rack has been placed on the right side of the sampler station. The heater is on and the front door cannot be opened. All operations are interrupted immediately if the door is opened.

4. Red LED only is On: The instrument has encountered an error. A message will display on the instrument screen.

5. Green and Red LED’s are on: The instrument has run out of iChem Wash solution.

6. Blue and Red LED’s are on: The instrument has run out of test strips or there is a strip jam. A message will display
   - If the strip container is empty, refill with strips
   - If a jam occurred, to clear the condition, turn the instrument main power switch Off then On.

7. Green, Blue and Red LED’s are blinking: The main power switch has been turned on and the On button (Front door) has not yet been pressed. The Red LED will blink when the system is waiting to connect to the user interface software. The heater will not be on and the door can be opened and closed.

Testing patient specimens

1. There are 4 racks for the iChem Velocity system.
   - Patient sample rack

- Control rack for CA/CB/CC controls (labeled rack)
- CalCheck rack to calibrate Specific gravity, color and clarity (blue rack)
- Dilution rack for performing dilution of samples for microscopic analysis on the iQ200. (orange rack)

2. Run the Quality Control specimens if needed. If a QC run fails, the system will not allow the operator to run specimens. The QC run should be repeated and must be successful before running patient specimens.

3. Apply barcode labels to sample tubes, placing the start of the barcode approximately ½ inch below the top of a yellow tube or just below the flare of a KOVA tube. Make sure the barcode is up and down, not sideways.

4. Compare the barcoded tube with the specimen making sure the correct specimen is used and transfer at least 2 mls or more of well mixed urine, but do not exceed the maximum volume for the tube used.

5. Make sure the barcode labels are properly oriented in the rack. The sample tubes must be placed straight and resting in the middle of the grommets located in the base of the rack. The barcode labels should be visible through the slots in the rack and face the instrument.

6. Place the barcoded tubes in the sample rack and place on the right side of the Velocity sampler. The instrument will move the rack automatically. The barcode reader on the instrument reads the tube barcode label and provides the patient identification data to the system.

7. If the Velocity is in Measure (blue light lit), block the sensor at the front of the sampler (nearest to the operator), and the rack will move to the sampling position automatically. If the system has been in standby for a while, press the Start button.

8. Six test tube racks (maximum of 60 test tubes) can be placed onto the load station for measurement. After sampling is complete, the test tube racks are transferred to the unload station for removal or moved on to the iQ for further testing.

9. The following tests will cause a microscopic exam to reflex and/or be required:
   - Blood, trace amount or greater
   - Protein, 1+ or greater
   - Leukocyte esterase, 1+ or greater
   - Clarity other than clear
   - Nitrite positive

10. Test results will print on the printer. All results that are negative and/or normal will autorelease to Cerner and autoverify. Any results that need microscopic or chemistry confirmation will appear on the worklist and prevent autorelease of the results.

11. Proceed with any confirmatory tests if indicated.

12. Any specimens that are cloudy (you can't see through the urine), you must run a tube of diluent before the next specimen to prevent carryover.

13. Remove the sample racks and pour finished urines down the sink after completion of testing. Discard tubes in red biohazard bags.

Manual Testing

1. If the LIS is not available, the user can manually enter a work list for the chemistries.

2. Access the Manual Orders Menu by clicking on Instrument on the top right side of the main screen.

3. Click on Manual Orders button located on the lower left side of the Instrument screen.

4. Select the rack to be used.
   - Enter the accession number of the patient sample.
   - Fluid type, select URN.
   - Dilution field, not available for the chemistry
   - Work order, defaults to No order

5. When the information has been entered, place the sample tube into the corresponding position of the selected sample rack.

6. Repeat for each specimen to run in the sample rack

7. If more than one rack is to be run, select a new rack number and then enter the specimen information.

8. Click OK to save the manual entries or click OK & Print to save the entries and print a report.

9. When analysis is complete, select the rack on the Manual Orders screen and click Clear Rack to clear specimens in that rack. To clear all specimen racks click Clear All.

LIMITATIONS

1. If a urine specimen contains high levels of ascorbic acid (Vitamin C), the results for glucose and blood may be lower than the actual results.

2. Do NOT test specimens that exhibit gross hematuria as this may cause incorrect results in subsequent samples. Spin the urine before testing and use the supernatant. Repour a fresh aliquot of urine before running a microscopic exam on the iQ200, do not centrifuge the urine before placing on the iQ200 instrument. Perform a dilution.

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. • Large amounts of Levodopa and medications containing sulfhydryl groups may produce atypical color reactions • MESNA (cancer agent) may produce false positive results
Ascorbic Acid	• Samples at a pH of 9.0 may interfere with this test. • MESNA (cancer agent) may produce false positive results.

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. • MESNA (cancer agent) may produce false positive results.
Protein	• 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. • Samples with a pH of 5 can interfere with this test • MESNA (cancer agent) can cause a false negative
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. • Boric acid concentrations of >=500 mg/dL may interfere with this test. • MESNA (cancer agent) may produce false positive results.
Specific Gravity	• pH <5 may slightly elevate the specific gravity, while a pH 8 or greater, may lower the results.

REFERENCES

iChem Velocity Operator's Manual, IRIS Diagnostics, 1/2011.

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
New Document, new instrument			
☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 12/6/13