

Operation of Iris iChem 100 Urine Analyzer

Purpose The iChem 100 urine chemistry analyzer is a semi-automated benchtop urine chemistry analyzer. This procedure describes how to perform and report macroscopic (dipstick) testing of urine specimens included on the following orders UANM, UMAC, UAC, UACMB and UAB.

- Policy**
- QC is assayed once every 24 hrs following QC of the iRICELL 3000 Analyzer (using CA & CB Controls).
 - QC is run when a new lot of Chemistry Test Strips are used.
-

Equipment Iris iChem100 Urine Analyzer

Reagents

Reagent	Storage & Stability
iChem 10 SG Test Strips (only)	<ul style="list-style-type: none">• Store at 2-30°C under dry conditions, tightly capped. Protect from light and moisture. Do not freeze.• Stable until manufacturer's expiration date.• Store strip container on its side
IRISpec CA & CB Controls	<ul style="list-style-type: none">• Store at 2-8°C, tightly capped. Protect from light.• Open stability: 15 days.• Unopen stability: to manufacturer's expiration.

iChem100 10 SG test strips include the following analytes:

- Specific gravity
- Leukocytes
- Nitrite
- pH
- Blood
- Protein
- Glucose
- Ascorbic acid
- Ketones
- Urobilinogen
- Bilirubin

Note: Ascorbic acid analyte will not be reported.

*Specific Gravity will require confirmation by refractometer
Color & Clarity to be determined visually by CLS or MLT*

Supplies 15 ml conical tubes

Specimen Requirements

- 10 ml or more (1 ml minimum) of fresh urine collected in sterile plastic container.
- Testing should be performed within 1-2 hours of collection if stored at room temperature. If testing cannot be performed within this timeframe, specimens should be stored refrigerated at 2-8°C. Specimens stored refrigerated are acceptable for testing up to 24 hours from collection.
- Specimens stored in BD preservative tubes are stable for 72 hrs refrigerated

Method Limitations

Commonly encountered limitations are listed below. Refer to product insert for more detailed listing.

- Grossly bloody urines may produce color interference of test pad reactions. Refer to *Procedure Notes* section for instructions.
- Highly colored urines, including those containing metabolite of Pyridium, may produce color interference with all test pad reactions. Refer to *Evaluating Results* section for instructions.

Analyte	Limitations
pH	No known interfering substances
Specific gravity	<ul style="list-style-type: none"> • Low pH (<5) slightly increases SG • High pH (≥8) decreases SG.
Leukocytes	<ul style="list-style-type: none"> • May be positive in absence of observable WBCs if the WBCs have lysed. • May be negative in the presence of visible WBCs if they have not lysed and/or are not granulocytes.
Nitrite	Negative result in the presence of bacteria can be caused by non-nitrite producing organisms, high ascorbic acid levels, high specific gravity, antibiotic therapy, insufficient urinary retention time in the bladder, etc.
Blood	False negative results can be caused by ascorbic acid, uric acid, glutathione, etc.
Protein	False positive results can be caused by highly alkaline urine (pH >9), high specific gravity, etc.
Glucose	Decreased results can be caused by high ascorbic acid levels, high specific gravity, low pH (≤4), etc.
Ketones	Beta-Hydroxybutyric acid does not react with this test pad. Interference of reaction may be caused by increased levels of phenylpyruvic acid, phthaleins, etc.
Bilirubin	Decreased results can be caused by high ascorbic acid levels, high nitrite concentration, prolonged exposure of specimen to light.

- Quality Control**
- Bring aliquots of control material to room temperature before testing.
 - Use aliquots from the IRICELL 300 within one hour of pouring.

Step	Action
1	From the analyzer Main Menu, press [F4] CONTROLS.
2	Select the desired control file to run.
3	Press [F3] RUN.
4	When green light is lit, dip test strip into control aliquot tube making sure all test pads are immersed.
5	Immediately remove the test strip dragging the edge of the strip against the side of the tube.
6	Place test strip onto the transport belt with the test pads facing up. Slide the strip forward until it touches the end stop. Red sensor light will come on when strip is detected.
7	At the end of analysis the results will display on the screen. Press one of the following: <ul style="list-style-type: none"> • [F1] ACCEPT to accept and print results. Instrument will return to Controls Menu. • [F2] REJECT to reject results and return to Run Controls screen to re-run the control material. • [F3] MAIN MENU to reject results and return to Main Menu.
8	Repeat steps 2-7 for each additional control to be run.

- Enter QC results Sunquest :
 - Function: MEM
 - Worksheet: RVUA
 - Control ID
 - IRISpec CA control = C-UAN
 - IRISpec CB control = C-UAA
 - Tests:
 - USG (Specific gravity)
 - UPH (pH)
 - ULEU (Leukocytes)
 - UNIT (Nitrite)
 - UPR (Protein)
 - UGL (Glucose)
 - UKET (Ketone)
 - UBIL (Bilirubin)
 - UBLD (Blood)
 - UBG (Urobilinogen)
- Retain QC printout in designated location.

Procedure Notes

- Refrigerated specimens must be allowed to warm to room temperature prior to testing.
- Specimens with <1 ml volume should be tested by manually introducing urine onto the test strip.
- Grossly bloody urines should be centrifuged and dipstick testing performed on the urine supernatant.


Procedure Options

- Procedure A: Iris iChem100 Testing (Single)
- Procedure B: Patient Specimens-Batch Mode Testing
- Procedure C: Manual Backup Testing

**Procedure A:
Iris iChem100
Testing (Single)**

Follow the steps below to perform single testing of specimens using the Iris iChem 100 analyzer.

Step	Action
1	<ul style="list-style-type: none"> • Label a tube for each patient specimen/control to be tested. Use patient accession label or write patient name (last, first) and accession #. • Label original urine container with aliquot label. <p>Note: Outpatient urine specimens submitted in aliquot tubes can be used directly.</p>
2	Pour aliquot of well-mixed patient specimen or control into appropriate tube: <ul style="list-style-type: none"> • Patient specimen: 10 ml ideal • Control: 2-3 ml needed (use tubes from iRICELL 3000)
3	From the Main Menu screen, press the [F2] key to display the <i>Run Patient</i> screen
4	The <i>Run Patient</i> screen assigns a sequence number and is automatically assigned each time a new patient sample is analyzed. NOTE: Sequence number can be used as a form of ID, but if used, it must be written on the specimen sample tube/cup.
5	Enter specimen ID manually or use the barcode scanner
6	Use the barcode scanner to: <ul style="list-style-type: none"> • Enter Clarity or use arrow keys to select other options from the keyboard • Enter Specimen Type or use arrow keys to select other options from the keyboard
7	Remove test strip from container.

8	When green LED is lit, dip test strip into the tube of urine, making sure all test pads are immersed or use pipette for small volume samples.						
9	Immediately remove the test strip from the urine, dragging the edge of the strip against the side of the container as you remove it.						
10	Blot the test strip by touching the <u>edge</u> of the strip to a paper towel. Do not drag the strip across the towel.						
	Place the test strip on the transport belt with the test pads facing up, sliding the strip forward until the strip touches the end stop. When correctly positioned, a red LED will light. Note: If the strip is moved away from the sensor prior to being transported. You will be prompted to remove the test strip from the transport belt. Press [F1] to continue.						
11	Repeat steps 4-9 for each specimen/control to be tested. 						
12	Recap test strip container when finished.						
13	<table border="1"> <thead> <tr> <th>If...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>No microscopic exam needed.</td> <td>Discard aliquot tube in appropriate biohazard container.</td> </tr> <tr> <td>Microscopic exam needed</td> <td> <ul style="list-style-type: none"> • Retain aliquot tube. • Proceed to the <i>Urinalysis: Microscopic Exam Procedure.</i> </td> </tr> </tbody> </table>	If...	Then...	No microscopic exam needed.	Discard aliquot tube in appropriate biohazard container.	Microscopic exam needed	<ul style="list-style-type: none"> • Retain aliquot tube. • Proceed to the <i>Urinalysis: Microscopic Exam Procedure.</i>
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14	When finished with testing, store original specimen container in designated refrigerator.						

**Procedure B:
Patient
Specimens –
Batch Mode**

Follow the steps below to operate the analyzer for patient testing using batch analysis mode.

Step	Action
1	At the analyzer Main Menu, press [F1] WORKLIST.
2	Press [F1] CREATE.
3	If a previous incomplete worklist exists, the prompt “Delete existing worklist?” will display. Select YES to delete previous worklist. (Very important to remove any unfinished samples) Then press [F1] CONTINUE
4	At the CREATE WORKLIST screen, enter 0001 in the Sequence Number (SEQ) field.

5	<p>At the SPEC / PAT ID field, enter the patient’s accession number by scanning the barcode label on the tube (or manually enter accession number).</p> <p>Optional: You can enter Clarity and /or Specimen Type at this screen if desired by scanning appropriate barcode on top on analyzer or toggle through field result options.</p>												
6	Press [F1] NEXT to proceed to entry of next specimen.												
7	Repeat steps 5-6 for each specimen to be added to the worklist. Note: Sequence number automatically advances for each specimen entered.												
8	<p>When all specimens have been entered, press [F3] WORKLIST to return to Worklist Menu.</p> <table border="1" data-bbox="581 709 1416 1740"> <thead> <tr> <th data-bbox="581 709 998 751">To...</th> <th data-bbox="998 709 1416 751">Do the following...</th> </tr> </thead> <tbody> <tr> <td data-bbox="581 751 998 793">Run worklist</td> <td data-bbox="998 751 1416 793">Proceed to step 9.</td> </tr> <tr> <td data-bbox="581 793 998 835">Print worklist</td> <td data-bbox="998 793 1416 835">Press [F5] PRINT.</td> </tr> <tr> <td data-bbox="581 835 998 1094">Edit worklist</td> <td data-bbox="998 835 1416 1094"> <ul style="list-style-type: none"> • Press [F3] VIEW /EDIT • Press [F1] NEXT or [F2] BACK to scroll to desired specimen. • Edit field entry • Press [F4] to return to Worklist Menu. </td> </tr> <tr> <td data-bbox="581 1094 998 1436">Delete specimen(s) from worklist.</td> <td data-bbox="998 1094 1416 1436"> <ul style="list-style-type: none"> • Press [F3] VIEW / EDIT • Press [F1] NEXT or [F2] BACK to scroll to desired specimen. • Press [F3] DELETE • Select YES to confirm deletion, then press [F1]. • Press [F4] to return to Worklist Menu. </td> </tr> <tr> <td data-bbox="581 1436 998 1740">Delete entire worklist</td> <td data-bbox="998 1436 1416 1740"> <p>At Worklist Menu screen:</p> <ul style="list-style-type: none"> • Press [F1] CREATE • Select YES at the “Delete existing worklist?” prompt. • Press [F1] CONTINUE. • Press [F3] WORKLIST to return to Worklist Menu. </td> </tr> </tbody> </table>	To...	Do the following...	Run worklist	Proceed to step 9.	Print worklist	Press [F5] PRINT.	Edit worklist	<ul style="list-style-type: none"> • Press [F3] VIEW /EDIT • Press [F1] NEXT or [F2] BACK to scroll to desired specimen. • Edit field entry • Press [F4] to return to Worklist Menu. 	Delete specimen(s) from worklist.	<ul style="list-style-type: none"> • Press [F3] VIEW / EDIT • Press [F1] NEXT or [F2] BACK to scroll to desired specimen. • Press [F3] DELETE • Select YES to confirm deletion, then press [F1]. • Press [F4] to return to Worklist Menu. 	Delete entire worklist	<p>At Worklist Menu screen:</p> <ul style="list-style-type: none"> • Press [F1] CREATE • Select YES at the “Delete existing worklist?” prompt. • Press [F1] CONTINUE. • Press [F3] WORKLIST to return to Worklist Menu.
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9	Press [F4] to run												
10	Print will include all samples from the worklist and will not print each sample individually												



Evaluating Results

If...	Then...
<ul style="list-style-type: none"> • Protein $\geq 1+$, • Nitrite positive, • Leukocyte positive, and/or • Blood positive 	UMAC and UAC orders will reflex to microscopic exam.
Test strip specific gravity is questionable <u>or</u> >1.035 .	Do refractometer specific gravity to verify. Refer to <i>Determining Urine or Fluid Specific Gravity Using a Refractometer</i> procedure.
Urine color is “orange”, “blue”, “green”, etc. due to dyes/drugs.	<ul style="list-style-type: none"> • Do the following: <ul style="list-style-type: none"> – Specific gravity by refractometer. – Microscopic exam • Report all other analytes with CINT (Color Interference). • Refer to specific procedures: <ul style="list-style-type: none"> – <i>Determining Urine or Fluid Specific Gravity Using a Refractometer</i> – <i>Urinalysis: Microscopic Exam Procedure</i>

Interpreting Results

Analyte	Interpretation / Report as...							
	1.000	1.005	1.010	1.015	1.020	1.025	1.030	1.035
SG								
pH	5	6	7	8	9			
Nitrite	Neg	Pos						
Uro mg/dl	Norm	2	4	8	12			

Analyte	Interpretation / Report as...				
	Neg	1+	2+	3+	4+
Leu WBC/ μ l	Neg	25	75	500	
Blood RBC/ μ l (mg/dl)	Neg	5-10 (0.03)	50 (0.2)	300 (≥ 1.0)	
Prot mg/dl	Neg	30	100	≥ 500	
Gluc mg/dl	Neg	50	150	500	≥ 1000
Ket mg/dl	Neg	25	100	300	
Bili mg/dl	Neg	1	2	4	


Reference Range

Analyte	Reference Range
Color/Clarity	No established reference range
Specific gravity	1.001 – 1.035
pH	5.0 – 7.0
Urobilinogen	0.1 – 1.0 mg/dl or Normal
All other analytes	Negative

Critical Limits N/A

Reporting Results

Follow steps below to report results using Sunquest Gateway.

Step	Action								
1	On Sunquest Gateway main menu, double click on Urinalysis Result Entry								
2	At Keyboard field, use drop down menu to select RVURIN (or manually type RVURIN), then click OK								
3	At Acc # prompt, scan specimen barcode or enter the patient's accession number, then press [Enter].								
4	<p>Enter results for the following:</p> <ul style="list-style-type: none"> ○ UCOL (Urine color) ○ UAPP (Urine appearance) ○ CTYP (Specimen Type)  <p>To enter a result:</p> <ul style="list-style-type: none"> ○ Click appropriate test key ○ Click appropriate result key ○ Click Enter ○ Repeat for each test to be resultd. 								
5	Enter comment(s) if needed by resulting UCOM test.								
6	If UAC ordered <u>and</u> no reflex microscopic exam is needed, result MCULT test with NOCULP (Urine culture not indicated, culture not performed).								
7	<p>Click Result Review tab and review results for accuracy by performing QA review.</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>If...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>Results accurate</td> <td>Click Save.</td> </tr> <tr> <td>Result(s) need editing</td> <td> <ul style="list-style-type: none"> ● Click Resulting tab ● Repeat steps 4-7. </td> </tr> <tr> <td>Results rejected</td> <td> <ul style="list-style-type: none"> ● Click Close. ● Click Do Not Save. </td> </tr> </tbody> </table>	If...	Then...	Results accurate	Click Save.	Result(s) need editing	<ul style="list-style-type: none"> ● Click Resulting tab ● Repeat steps 4-7. 	Results rejected	<ul style="list-style-type: none"> ● Click Close. ● Click Do Not Save.
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	Patient is < 3 years old	<ul style="list-style-type: none">• When the QA tab is selected, RSUB will be resultated with the English Text Code “CLIN”: “Unable to perform a Copper Sulfate test (Clinitest) for urine reducing substances since the manufacturer has discontinued making the reagent. Correlation with the patient’s clinical picture and newborn screen result is recommended.”
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Attachment Form A: Manual Urine Dipstick Testing

- References**
- Iris iChem 10 SG Urine Test Strips Product Insert, Iris Diagnostics/Iris International Inc., 1/30/2012
 - IRISpec CA/CB/CC Product Insert, Iris Diagnostics/Iris International Inc., 2011.
 - iChem 100 Urine Chemistry Operators Manual, Iris Diagnostics/Iris International, Inc. Rev C 01/2007
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