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	<b>Owner:</b> <i>Matthew Sawyer: Spvr, Laboratory</i>
	<b>Policy Area:</b> <i>Lab - Urinalysis</i>
<b>References:</b>	
<b>Applicability:</b> <i>Sutter Roseville Medical Center</i>	

## Maintenance and Quality Control on the iChem, AX-4030 and iQ200

### Purpose

This procedure describes how to perform maintenance, quality control, and other routine tasks on the iChem, AX-4030 & iQ200.

### On-board Help

The Operator's Manuals for the iChem, AX-4030 & iQ 200 can be found on-board. The Help (i.e. "?") button is located in the middle top of the screen and is visible virtually at all times.

Step	Action
1.	Select the Help (i.e. "?") button. An Open Help File window will be displayed.
2.	Select the "Desktop" icon from the left side of the Open Help File window.
3.	Select the appropriate Operator's Manual and click Open. The file will be displayed in a separate window.

### Equipment/Supplies

- iChem + iQ200 = IRICELL 3000
- AX-4030 + iQ200 = iQ Workcell
- 16x100 mm tubes
- Dilution Barcodes

Material	Function	Storage	Stability/Other Info.
<b>AX-4030</b>			
AX-4030 Arkray Strips	Chemistry Test strips for the AX-4030 Arkray only	Room Temp	<ul style="list-style-type: none"> <li>• Onboard stability of 4 days when in the Strip Feeder</li> <li>• Protect the strips against light and moisture</li> </ul>
Check Strip Set	Color and Clarity calibrator	Room Temp	<ul style="list-style-type: none"> <li>• Stable unopened until expiration date on bottle.</li> <li>• Open tube stability = 8 hours</li> </ul>

			<ul style="list-style-type: none"> <li>• Strips: use within 30 minutes, 1 time use only</li> </ul>
AX-4030 Wash Concentrate & Filter	Chemistry wash solution	Room Temp	<ul style="list-style-type: none"> <li>• Concentrate stable unopened until expiration date on bottle</li> <li>• Open bottle stability = 3 months</li> <li>• Made up Wash solution stability = 15 days</li> <li>• Replace the Wash Solution Filter monthly</li> </ul>
Aution Check Plus Controls	Chemistry Controls	2-8°C	<ul style="list-style-type: none"> <li>• Stable unopened until expiration date on bottle.</li> <li>• Open bottle stability = 30 days</li> <li>• Bring poured aliquot to room temperature before use.</li> </ul>
SG Calibrator	SG Calibrator	2-8°C	<ul style="list-style-type: none"> <li>• Use immediately after opening</li> </ul>
<b>iChem</b>			
iChem Velocity Strips	Chemistry Test strips for the iChem Velocity only	Room Temp	<ul style="list-style-type: none"> <li>• Onboard stability of 5 days when in the Strip Provider Module</li> <li>• Protect the strips against light and moisture</li> <li>• Unused strips that remain in the original capped container are stable until the expiration date.</li> </ul>
iChem Wash Solution & Wash Filter	Chemistry wash solution	Room Temp	<ul style="list-style-type: none"> <li>• Stable unopened until expiration date on bottle</li> <li>• Open bottle stability = 3 months</li> <li>• Replace the Wash Solution Filter with each bottle</li> </ul>
IRISpec CA/CB/CC	Chemistry controls	2-8°C	<ul style="list-style-type: none"> <li>• Stable unopened until expiration date on bottle.</li> <li>• Open bottle stability = 15 days</li> <li>• Bring poured aliquot to room temperature before use.</li> </ul>
iChem Velocity CalCheks	Color, Clarity, SG calibrator	Room Temp	<ul style="list-style-type: none"> <li>• Stable unopened until expiration date on box.</li> <li>• Open tube stability = 8 hours</li> <li>• Strips: use within 30 minutes, 1 time use only</li> </ul>
<b>iQ200</b>			
iQ Lamina	iQ 200 fluidic system	Room Temp	<ul style="list-style-type: none"> <li>• Stable unopened &amp; open until expiration date on bottle.</li> <li>• Replace Lamina filter every 1st bottle</li> </ul>

iQ Control/Focus Set	Microscopy controls	2-8°C	<ul style="list-style-type: none"> <li>Stable unopened until expiration date on bottle.</li> <li>Open bottle stability = 30 days</li> </ul>
iQ Calibrator	Microscopy calibrator	2-8°C	<ul style="list-style-type: none"> <li>Stable unopened until expiration date on bottle.</li> <li>Open bottle stability = 24 hours</li> </ul>
Iris System Cleanser	Cleans iQ system	Room Temp	<ul style="list-style-type: none"> <li>Stable unopened &amp; open until expiration date on bottle.</li> </ul>
Iris Diluent	Dilutions, Primes system	Room Temp	<ul style="list-style-type: none"> <li>Stable unopened &amp; open until expiration date on bottle.</li> </ul>

# Replacing Consumables

## iChem Strips

Load one strip vial at a time (100 strips). Remove and replace one desiccant pouch with each strip load or when the Strip Provider Module (SPM) is opened (i.e. strip jam or maintenance). Any existing strips must be replaced with new strips whenever the SPM is opened. The instrument will display a message when empty (*Alarm 43*).

- Note: It is recommended that this process should be completed within 5 minutes after removing the strips from the canister and locking the strip loader back into place.

Step	Action
1.	Rotate the strip loader to unlock position and pull out from analyzer.
2.	Remove and discard the old desiccant and replace with the new desiccant. (Remove and discard any old strips as well.)
3.	Fully extend the strip loader and tilt it at a 45-degree angle. Load the strips inside the Test Strip Loader as indicated on the loader (Iris logo facing the back of the instrument).
4.	Retract the strip loader, and then shake the loader lightly so that the strips are straight. Insert the strip loader inside the analyzer and rotate the strip loader counter clockwise to the lock position. The strips drop inside the strip provider module, and the strip provider module will tumble to place the strips in the flat position using a quick constant rotation.

### iChem Strips - New Lots/Shipments

- New Lots of Strips: New strip lots must be parallel tested before putting into use. IRISpec CA/CB/CC controls may be used to check new strip lots. QC results must be within acceptable limits and within +/- 1 grade of the current strip lot. Document on iChem Velocity Strip Lot Verification Log.
- New Shipments of an existing Lot of Strips: New shipments of existing lots must be QC'd before using for patient testing.
- Enter LOT information into Consumables prior to running.

# iChem Wash Solution

The instrument will display a message when empty (*Alarm 42*). Replace the Wash Solution Filter (WHITE FILTER) with each bottle.

Step	Action
1.	Ensure the system is in Standby.
2.	Wearing fresh gloves, remove the cap of the old Wash Solution bottle.
3.	Remove the old filter by grasping the tube above the filter and pulling the filter straight off and discard.
4.	Remove the new filter from its package and push straight onto the tubing of the Wash Solution cap. The filter only fits with the narrow section attaching into the tube.
5.	Insert the tubing with the new filter into the new Wash Solution container and tighten the cap. Do not mix the contents of the container.
6.	Write expiration date (3 months or future date, whichever comes first) and tech code on new Wash Solution container.
7.	Discard old container.

## AX-4030 Strips

Load one strip vial at a time (100 strips). Remove and replace one desiccant pouch with each vial loaded.

1.	Turn the locking lever to unlock the feeder cover, and open the cover.
2.	Tilt the side panel of the storage section in the direction of the arrow.
3.	Take out a desiccant bag from the test strip bottle and attach it to the feeder cover. For loading 100 test strips, attach a desiccant bag on the side panel of the storage section. If loading 200 test strips, attach one bag on the back of the cover, and another bag on the side panel of the storage section.
4.	Place the side panel as before.
5.	Take out as many test strips as you need from the bottle, and load them into the feeder.
6.	Close the feeder cover and turn the locking lever clockwise to lock it.

## AX-4030 Wash Solution

When the instrument is getting low on washing solution, discard the remaining solution and refill the bottle with newly prepared solution. A maximum of about 600 measurements can be made with 2 L of washing solution. If warning "W003" occurs due to low washing solution, replace the solution immediately.

1.	Make sure the standby screen is displayed.
2.	Uncap the washing solution bottle, and discard the remaining solution. Rinse the bottle with DI water to wash out old solution.
3.	Dilute concentrated washing solution 3 with DI water. Follow the indications on the wash bottle by adding DI water (1800mL) and then add washing solution 3 (200mL).
4.	Seal the bottle with a piece of sealing film. While holding the film in your hand, gently invert the

	bottle so as not to froth the solution.
5.	Insert the tubing for the wash solution and tighten lid.
6.	Write expiration date (15 days) on the wash Solution bottle.

## iQ200 Lamina

The instrument will display a message when empty (*Lamina Container is low*). Replace the Lamina Filter (GREEN FILTER) every 1st bottle.

Step	Action
1.	Ensure the system is in Standby.
2.	Wearing fresh gloves, remove the cap of the old Lamina bottle.
3.	Remove the old filter by grasping the tube above the filter and pulling the filter straight off and discard.
4.	Remove the new filter from its package and push straight onto the tubing of the cap. The filter only goes on one way, with the narrow section going into the tube.
5.	Insert the tubing with the new filter into the new Lamina container and tighten the cap. Do not mix the contents of the container.
6.	Write open date and tech code on new Wash Solution container.
7.	Discard old container.

## Maintenance

For the complete Maintenance schedule, refer to the attached Maintenance logs for the iQ200, iChem and AX-4030.

**Note:** there are 2 separate logs for the iQ200. One is for the Iricell 3000 and the other is for the iQ Workcell.

For detailed instructions on completing each Maintenance task, refer to the Operators Manuals for the iQ200, iChem and AX-4030.

**Note:** Electronic copies of the Operators Manuals are available on the Laboratory drive.

## Quality Control

Quality Control materials are to be assayed at least daily for both chemistry and microscopy modules. Controls should also be run following service events and software updates as indicated by technical support or field engineer.

### New Lots - iChem, AX-4030 & iQ200 Controls

- Target ranges must be verified for each new QC lot for the iChem, AX-4030 and iQ 200 quality control materials.
- Target range verification is done by first running the current in-use controls to verify the instrument is working correctly, then running the new lot of controls and verifying they are within range.
- Enter LOT information into Consumables prior to running.

# iChem

Step	Action						
1.	Obtain iChem Velocity control rack.						
2.	Remove controls from refrigerated storage and promptly pour 3 ml of the CA, CB, and CC control into 3 separate 16x100 mm test tubes. First black line on the control rack is approx. 3 ml. <ul style="list-style-type: none"> <li>• Do not mix control bottles prior to use</li> <li>• Do not use plastic pipettes to transfer controls</li> <li>• Return tightly capped control bottles to the refrigerator immediately after pouring</li> <li>• Place the controls in the corresponding color-coded control rack inserts:               <ul style="list-style-type: none"> <li>◦ CA control into position 8 (RED)</li> <li>◦ CB control into position 9 (BLUE)</li> <li>◦ CC control into position 10 (YELLOW)</li> </ul> </li> </ul>						
3.	Allow aliquots to warm up to room temperature (approx. 15 minutes). Protect from light.						
4.	Place the rack on the right side of the iChem Velocity to begin testing.						
5.	When complete, control results will automatically print. Review QC: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">If...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>QC Passed (CA, CB, &amp; CC)</td> <td>Record Tech Code on print-outs.</td> </tr> <tr> <td>QC Failed</td> <td>Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on QC Corrective Action Log. Troubleshooting tips:               <ul style="list-style-type: none"> <li>• Only rerun the level that failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run all controls</li> <li>• Check strips loaded in instrument for discoloration. If discolored, discard and add new strips and repeat.</li> <li>• If unable to resolve, contact technical support.</li> </ul> </td> </tr> </tbody> </table>	If...	Then...	QC Passed (CA, CB, & CC)	Record Tech Code on print-outs.	QC Failed	Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on QC Corrective Action Log. Troubleshooting tips: <ul style="list-style-type: none"> <li>• Only rerun the level that failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run all controls</li> <li>• Check strips loaded in instrument for discoloration. If discolored, discard and add new strips and repeat.</li> <li>• If unable to resolve, contact technical support.</li> </ul>
If...	Then...						
QC Passed (CA, CB, & CC)	Record Tech Code on print-outs.						
QC Failed	Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on QC Corrective Action Log. Troubleshooting tips: <ul style="list-style-type: none"> <li>• Only rerun the level that failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run all controls</li> <li>• Check strips loaded in instrument for discoloration. If discolored, discard and add new strips and repeat.</li> <li>• If unable to resolve, contact technical support.</li> </ul>						

## AX-4030

Step	Action
1.	Obtain AX-4030 control rack.
2.	Allow controls to warm up to room temperature (approx. 15 minutes).
3.	Add approx. 3 mL of the Level 1 and Level 2 controls into 2 separate 16x100 mm test tubes. Black line on the control rack is approx. 3 mL. <ul style="list-style-type: none"> <li>• Return tightly capped control bottles to the refrigerator immediately after pouring.</li> <li>• Place the controls in the corresponding number-coded control rack inserts:               <ul style="list-style-type: none"> <li>◦ Level 1 into position 8</li> <li>◦ Level 2 into position 9</li> </ul> </li> </ul>

4.	Place the rack on the right side of the AX-4030 to begin testing.	
5.	When complete, control results will automatically print. Review QC:	
	If...	Then...
	QC Passed	Record Tech Code on print-outs.
	QC Failed	<p>Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on QC Corrective Action Log.</p> <p>Troubleshooting tips:</p> <ul style="list-style-type: none"> <li>• Only rerun the level that failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run all controls</li> <li>• Check strips loaded in instrument for discoloration. If discolored, discard and add new strips and repeat.</li> <li>• If unable to resolve, contact technical support.</li> </ul>

## Enter QC results for iChem and AX-4030 into Sunquest

- **Function:** MEM
- **Worksheet:** RVUA
- **Method:** RVIR (iChem)=DEFAULT      RVIRB (AX-4030)=Modify tests
- **Tests:** UGL, UBIL, UKET, USG, UBLD, UPH, UPR, UBG, UNIT, ULEU
- **Control:** Level1 C-AUA1, Level2 C-AUA2

## iQ200 Quality Controls

Step	Action
1.	Remove controls from refrigerated storage and allow to warm up to room temperature.
2.	Obtain iQ 200 control rack.
3.	Label 16x100 mm tubes with each individual barcode label for the Focus, Positive and Negative control. The barcodes contain Lot specific information. DO NOT mix barcodes of different lot #'s.
4.	Mix the Focus and Positive controls by holding the bottle upside down and giving 5 hard shakes followed by 5 gentle inversions. Let bottle(s) sit one minute to allow air bubbles to disperse. Do not shake the negative control bottle.
5.	<p>Pour the controls into each respective labeled tube (following outline on Step 6). First black line on the control rack is approx. 3 ml, second line is approx. 6 ml</p> <ul style="list-style-type: none"> <li>• Do not use plastic pipettes to transfer controls</li> <li>• Return controls to refrigerated storage</li> <li>• Controls must be run immediately after pouring off</li> </ul>
6.	<p>Load the iQ 200 control rack in the following order:</p> <ul style="list-style-type: none"> <li>• Position 1: 3 ml of Iris Cleanser</li> <li>• Position 2: 3 ml of Iris Diluent</li> <li>• Position 3: 3 ml of Iris Diluent</li> <li>• Position 4: Leave Empty</li> </ul>

- Position 5: 6 ml of Focus
- Position 6: 3 ml of Positive Control
- Position 7: 3 ml of Negative Control

Note: If running a second lot of controls (i.e. Parallel testing for new lots), place the parallel lot Positive into Position 8 and the parallel lot Negative into Position 9. Be certain to use the barcode labels from the parallel lot.

Do not place in a tube in Position 10 – this will shut down the system.

7. Place the rack on the **iQ 200** sampler side. Press the Start button.

8. When complete, control results will automatically print. Review QC:

If...	Then...
QC Passed (Focus, Pos & Neg)	Record Tech Code on print-outs.
QC Failed	Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on QC Corrective Action Log. Troubleshooting tips: <ul style="list-style-type: none"> <li>• Look at message code to see why the control failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run</li> <li>• Open new bottles as needed</li> <li>• If unable to resolve, contact technical support.</li> </ul>

## iQ200 Calibration

iQ 200 Calibration is to be performed monthly. Additional calibrations may be required following service events or as otherwise recommended by technical support or field engineer. Note: iQ200 calibration is not routinely suggested for troubleshooting of unacceptable QC. See iQ 200 Quality Control section or contact technical support as needed.

Step	Action
1.	From refrigerated storage, obtain one Focus bottle, one bottle of the iQ 200 Calibrator, QC and corresponding labels. Allow to warm up to room temperature.
2.	Obtain iQ control rack and iQ calibration rack.
3.	Prepare/load the control rack in the following order: <ul style="list-style-type: none"> <li>• Position 1: 3 ml of Iris Cleanser</li> <li>• Position 2: 3 ml of Iris Diluent</li> <li>• Position 3: 3 ml of Iris Diluent</li> <li>• Position 4: Leave Empty</li> <li>• Position 5: 6 ml of Focus               <ul style="list-style-type: none"> <li>◦ Label 16x100 mm tube with Focus label</li> <li>◦ Hold the bottle upside down and give 5 hard shakes followed by 5 gentle inversions. Let bottle sit one minute to allow air bubbles to disperse.</li> <li>◦ Return Focus bottle to refrigerated storage</li> </ul> </li> </ul>
4.	Place the control rack on the iQ 200 sampler side. Press the Start button.



5.	Ensure the Focus passed before processing the calibrator. Monitor will update with the Focus run information.	
6.	Prepare/load the <u>calibration rack</u> as follows: <ul style="list-style-type: none"> <li>• Hold the Calibrator bottle upside down and give 5 hard shakes followed by 5 gentle inversions. Let bottle sit one minute to allow air bubbles to disperse.</li> <li>• Pour at least 4 ml of Calibrator into ten 16x100 mm glass tubes</li> <li>• Place one provided barcode label on the tube that will be placed in Position 1</li> </ul>	
7.	Place the calibration rack on the iQ 200 sampler side. Press the Start button as needed.	
8.	If...	Then...
	Calibration passed	The date/time and new REF value will be displayed in the Last Calibration field on the Instrument screen, print Calibration. Run QC, See section: iQ200 Quality Controls.
	Calibration failed	Troubleshoot, taking necessary corrective action before continuing with patient testing. Document on the Corrective Action Log. Troubleshooting tips: <ul style="list-style-type: none"> <li>• Look at message code to see why the calibration failed</li> <li>• Check tube positions</li> <li>• Re-pour and re-run</li> <li>• Open new bottles as needed</li> <li>• If unable to resolve, contact technical support.</li> </ul>

## Shutdown/Startup

- In the event the system needs to be Shutdown: 1<sup>st</sup> – Computer, 2<sup>nd</sup> – iQ 200, 3<sup>rd</sup> – iChem or AX-4030
- To bring the system back up: 1<sup>st</sup> – Computer, 2<sup>nd</sup> – iChem or AX-4030, 3<sup>rd</sup> – iQ 200

## Related Procedures

- Patient Testing on the iChem, AX-4030 and the iQ200 #8071002

## References

- AX-4030 Operating Manual, May 2019
- iChem Velocity Instructions for Use, July 2020
- iQ 200 Series Instructions for Use, January 2019

All revision dates:

1/14/2021

## Attachments

- [AX-4030 Maintenance Log](#)
- [iChem Maintenance Log](#)
- [iQ200 Maintenance Log iQ Workcell](#)
- [iQ200 Maintenance Log Iricell 3000](#)

## Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	1/14/2021
Laboratory Director	Lindsey Westerbeck: Dir, Lab	12/30/2020

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