



## TRAINING UPDATE

**Lab Location:** SGAH & WAH  
**Department:** Core

**Date Distributed:** 10/11/2012  
**Due Date:** 11/11/2012

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>													
<b>Body Fluid Module Analysis by Iris™ iQ200® Series Analyzer</b> SGAH.U07, WAH.U07 v002													
<b>Description of change(s):</b>													
<table border="1"><thead><tr><th>Section</th><th>Reason</th></tr></thead><tbody><tr><td>4.2</td><td>Change Lysing reagent temp to 2-8C</td></tr><tr><td>6.1 &amp; 6.2</td><td>Delete iQ Focus set</td></tr><tr><td>6.2</td><td>Change storage temp to 2-10C</td></tr><tr><td>6.3</td><td>Change background check tolerance limit from <math>\geq 3</math> to <math>\geq 4</math></td></tr><tr><td>6.6</td><td>Delete tolerance limits programmed in LIS</td></tr></tbody></table>		Section	Reason	4.2	Change Lysing reagent temp to 2-8C	6.1 & 6.2	Delete iQ Focus set	6.2	Change storage temp to 2-10C	6.3	Change background check tolerance limit from $\geq 3$ to $\geq 4$	6.6	Delete tolerance limits programmed in LIS
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6.3	Change background check tolerance limit from $\geq 3$ to $\geq 4$												
6.6	Delete tolerance limits programmed in LIS												

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 002)

Technical SOP

<b>Title</b>	<b>Body Fluid Module Analysis by Iris™ iQ200® Series Analyzer</b>	
<b>Prepared by</b>	Marjan Ahmadi and Demetra Collier	Date: 3/22/2011
<b>Owner</b>	Robert SanLuis	Date: 9/20/2012

<b>Laboratory Approval</b>		<b>Local Effective Date:</b>
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		

<b>Annual Review</b>		
Print Name	Signature	Date

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**TABLE OF CONTENTS**

1. Test information..... 3  
 2. Analytical principle..... 4  
 3. Specimen requirements..... 4  
 4. Reagents..... 6  
 5. Calibrators/standards..... 7  
 6. Quality control..... 9  
 7. Equipment and supplies..... 12  
 8. Procedure..... 12  
 9. Calculations..... 16  
 10. Reporting results and repeat criteria..... 16  
 11. Expected values..... 17  
 12. Clinical significance..... 17  
 13. Procedure notes..... 17  
 14. Limitations of method..... 17  
 15. Safety..... 18  
 16. Related documents..... 18  
 17. References..... 18  
 18. Revision history..... 19  
 19. Addenda..... 19

**1. TEST INFORMATION**

<b>Assay</b>	<b>Method/Instrument</b>	<b>Local Code</b>
Cell Counts, Total RBC and Total Nucleated cells, CSF	iQ®Series Iris	CCTD
Cell Counts, Total RBC and Total Nucleated cells, Body Fluid		FCCD

<b>Synonyms/Abbreviations</b>
CSF Cell Count, Body Fluid Cell Count

<b>Department</b>
Urinalysis

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## 2. ANALYTICAL PRINCIPLE

The iQ® Body Fluids Module is an in-vitro diagnostic device used by a trained human observer to examine and count red blood cells and other nucleated cells in cerebrospinal fluid and serous fluids. In addition, bacteria and crystals may be noted as present or absent. This procedure provides instructions for performing quantitative body fluid counts for CSF and serous fluid.

The iQ Series Analyzer processes specimens that are loaded into designated body fluid racks. Specimens may be identified by patient identification barcode label and a secondary fluid type/dilution label or by using Manual Orders. A portion of the diluted specimen is aspirated and is sandwiched between enveloping layers of a suspending fluid.

This fluid or “lamina” positions the specimen exactly within the depth of focus and field of view of the objective lens of a microscope that is coupled to a CCD (charge coupling device) digital camera. The iQ Lamina™ is used to position the formed elements in an orthoscopic orientation that presents asymmetric particles with their largest profile facing the direction of view. The CCD camera captures five hundred frames per sample as each field is illuminated by the flash of a strobe lamp. The pictures are digitized and sent to the instrument processor.

The iQ Series Series Analyzer running the Body Fluids Module uses two aliquots of each specimen. These aliquots are treated differently because successful analysis of body fluids with the Body Fluids Module relies on subjecting one aliquot of the specimen to a process called selective cell lysis, a process that lyses red blood cells in the sample and the other aliquot is diluted.

Selective lysis is a chemical process that destroys red blood cell’s (RBCs) membrane, causing the membrane to burst and release its contents into solution. Therefore, the difference in the number of total cells counted in the unlysed sample and the number of nucleated cells counted in the lysed sample represents the number of RBCs present in the specimen.

The iQ Body Fluids Module reports the number of cells in each of the two aliquots, calling the cells from the diluted aliquot “Total Cells” and the cells from the selectively lysed aliquot “Nucleated Cells.”

## 3. SPECIMEN REQUIREMENTS

### 3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	Not Applicable
Specimen Collection and/or Timing	Not Applicable

Component	Special Notations
Special Collection Procedures	CSF and Serous fluids are collected by a physician.
Other	Not applicable

### 3.2 Specimen Type & Handling

Criteria	
Type -Preferred -Other Acceptable	CSF-tube #1, #3 or #4, Serous fluid None
Collection Container	CSF- plastic collection tubes Serous - EDTA tubes, plain tubes (no additives).
Volume - Optimum - Minimum	500µl per specimen (equivalent to 250µl per tube) 30µl per specimen (equivalent to 15µl per tube)
Transport Container and Temperature	Plastic CSF collection tubes, sterile urine containers, EDTA tubes at room temperature
Stability & Storage Requirements	Room Temperature: 1. Rapid deterioration and cell lysis occurs on prolonged standing in CSF's, the sample should be processed STAT and the count should be performed as soon as it is received. 2. Serous fluid 48 hours
	Refrigerated: (2-8°C) 1. CSF not recommended, see above. 2. Serous fluid 48 hours.
	Frozen: Not acceptable
Timing Considerations	Not applicable
Unacceptable Specimens & Actions to Take	<b>Clotted specimens</b> - perform counts and append the comment: " <i>Specimen contains clots, counts may not be accurate.</i> " <b>Specimens received after 48 hours</b> - perform the counts and append the comment: " <i>Counts may not be accurate due to the age of the specimen.</i> " Due to the nature of these specimens, do not reject unless frozen. If the specimen is received frozen, cancel the test with the comment: " <i>Specimen unsuitable for assay; received frozen.</i> " Notify a caregiver and document the notification in the LIS.
Compromising Physical Characteristics	None defined
Other Considerations	None defined

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#### 4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering “SAFETY” for additional information.

##### 4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
iQ Lamina	Iris Diagnostics Division 800-3102
Iris Diluent	Iris Diagnostics Division 800-3202
Iris Cleanser	Iris Diagnostics Division 800-3203
iQ Body Fluids Lysing Reagent	Iris Diagnostics Division 800-3123

##### 4.2 Reagent Preparation and Storage

**NOTES:** Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

<b>Reagent</b>	<b>iQ™ Lamina™</b>
<b>Container</b>	7 Liters
<b>Storage</b>	20 –28°C
<b>Stability</b>	Date on the package
<b>Preparation</b>	Ready for use.

<b>Reagent</b>	<b>Iris System Cleanser</b>
<b>Container</b>	425 ml
<b>Storage</b>	20 –28°C
<b>Stability</b>	Date on the package
<b>Preparation</b>	Ready for use.

<b>Reagent</b>	<b>Iris Diluent</b>
<b>Container</b>	475 ml
<b>Storage</b>	20 –28°C
<b>Stability</b>	Date on the package
<b>Preparation</b>	Ready for use.

Iris iQ200 3/31/00

<b>Reagent</b>	<b>iQ™ Body Fluids Lysing reagent</b>
<b>Container</b>	125 ml
<b>Storage</b>	2 - 8°C
<b>Stability</b>	30 days open. Do not freeze
<b>Preparation</b>	Ready to use

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

<b>Calibrator / Verification Control</b>	<b>Supplier and Catalog Number</b>
IQ® Calibrator Pack, 4 x 125 ml	Iris Diagnostics Division, Ref: 475-0059
iQ™ Focus Set that includes 2 bottles of Focus, 1 Negative Control, 1 Positive Control, corresponding labels	Iris Diagnostics Division, Ref: 800-3104

### 5.2 Calibrator Preparation and Storage

**NOTE:** Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

<b>Calibrator</b>	<b>iQ Calibrator Pack</b>
<b>Preparation</b>	Ready for use
<b>Storage/Stability</b>	2-8°C. Opened: 24 hrs

<b>Control</b>	<b>iQ™ Focus Set</b> (Material used by the iQ™ to sharpen the images the camera sees, hence the name Focus.)
<b>Preparation</b>	Ready for use. Remove the controls from the refrigerator and warm to room temperature before using. To mix: Note: Do Not Mix mechanically a) Hold the vial horizontally between the palms of the hands and roll the vial back and forth for 20 to 30 seconds. b) Mix by rapid inversion to ensure that the cells are suspended. c) Vials stored for an extended period of time may require extra mixing. d) Gently invert 8 to 10 times immediately before sampling.
<b>Storage/Stability</b>	2-8°C / Open vial stability 30 days

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### 5.3 Calibration Procedure

Criteria	Special Notations	
Frequency	<b>IQ™200 module Calibrations:</b> Calibration is performed once a month. Refer to the Iris Maintenance Procedure.	
Tolerance Limits	<b>IF ...</b>	<b>THEN ...</b>
	Results fall within the assay specific guidelines and the calibration status displayed is ‘Pass’ and QC values are within acceptable range limits:	Proceed with patient analysis.
	Calibration status is displayed as failed, or QC values are outside acceptable limits	Troubleshoot the assay. Refer to instrument operation manual for specific calibration troubleshoot help, or repeat calibration and control.
Procedure	<p>Run a Focus (see section 5.2)</p> <ol style="list-style-type: none"> <li>Place provided barcode label on a sample tube. Fill the tube with 6 mL of iQ Focus material and place in position 5 of the Control rack.</li> <li>Iris Diagnostics recommends running Iris System Cleanser in position 1, Iris Diluent in position 2 and 3 before running the Focus. (See section under daily – Perform a Wash Cycle.)</li> <li>Load the Control rack onto the right side of the iQ Series sampler.</li> <li>Press Start. The rack will be processed</li> </ol> <p>Run a Calibration</p> <ol style="list-style-type: none"> <li>Transfer at least 4 mL iQ Calibrator into 10 round-bottom 16 x 100 mm glass test tubes.</li> <li>Place one provided barcode label on the tube that will be placed in the first position, and then load the tubes into the Calibration rack.</li> <li>Load the Calibration rack onto the right side of the iQ Series sampler.</li> <li>Press “START” The rack will be processed and all calculations performed automatically.</li> </ol> <p>When the calibration is successful, the date/time and new <b>REF</b> value will be displayed in the Last Calibration field on the Instrument screen.</p> <p><b>CALIBRATION VERIFICATION:</b> after each Calibration, run a Focus and Positive Control; be sure to mix vigorously 5 times and then gently 5 times. Allow the bubbles to dissipate before pouring.          If all results fall within the specific guidelines, the calibration is verified.</p>	
Dilutions	N/A	



## 6. QUALITY CONTROL

### 6.1 Controls Used

Controls	Supplier and Catalog Number
iQ Body Fluid Controls Level I and II	Iris Diagnostics Division, Ref: 800-3219

### 6.2 Control Preparation and Storage

**NOTE:** Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	iQ Body Fluid Controls
Preparation	Ready to use. Bring to room temperature for 30 minutes prior to use.
Storage/Stability	2 - 10°C / Open vial stability 30 days

### 6.3 Control Procedure and Frequency

Consult the procedure Routine Urinalysis by the Iris iQ200 procedure for running Focus, CA and CB controls.

Background Check		
Frequency	Performed every eight hours of patient testing	
Tolerance Limits	IF ...	THEN ...
	Background check is $\leq 3$	Proceed with testing controls
	Background check is $\geq 4$	Troubleshoot by: 1. Repeating background check with fresh diluent and lyse. 2. Use cleanser and diluent on the iQ rack and run 3-4 times. 3. Clean the sample filter or change the element. 4. If background still does not pass, call 1 800 PRO-IRIS
Procedure	1. Place 3 conical tubes into a QC Body Fluid Rack in positions 2, 3 and 4. 2. Pour at least 1.25 ml of iris diluent into the tubes in position 2 and 4. 3. Pour at least 1.25 ml of lyse reagent into the tube in position 3. 4. Label the tubes in position 3 and 4 with background labels. 5. Place the rack in the iQ side of the analyzer and press START.	

	6. If background exceeds limits (see above) proceed with troubleshooting.	
<b>Dilutions</b>	N/A	
<b>-Graph Type - Point of Origin - Type of Paper</b>	N/A	
<b>Quality Control Procedure</b>		
<b>Frequen cy</b>	Every eight hours of patient testing	
<b>Tolerance Limits</b>	<b>IF ...</b>	<b>THEN ...</b>
	Results exceed limits	Repeat
	Results in range	Proceed with patient testing.
<b>Procedure</b>	<ol style="list-style-type: none"> <li>1. Prepare 1:5 dilutions of Control levels I and II with the following procedure.</li> <li>2. Use the iQ Body Fluid Control Rack positions 2, 3 and 4.</li> <li>3. Pour at least 1.25 ml of diluent in tube position 2.</li> <li>4. Pipette 1000 µl of lyse reagent in tube position 3 and 1000µl of diluent in tube position 4.</li> <li>5. Pipette 250 µl control level I in tube position 3 and 250 µl of control level I in tube position 4. Wipe outside of the pipette before delivery, do not rinse the pipette tip, just expel on top of the solution. <b>DO NOT PIPETTE ONTO THE SIDE OF THE TUBE.</b></li> <li>6. Place the BF barcode label for level I on tube position 3 and 4.</li> <li>7. Gently mix the contents by gently tapping against the side of your hand.</li> <li>8. Place in the iQ side of the instrument and press START.</li> <li>9. Perform steps 2 through 7 using Level II.</li> </ol> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>• The dilution for controls I and II is 1:5</li> <li>• Once controls are diluted they must be run within 3 minutes or over lysing can occur.</li> <li>• If controls are not allowed to come to room temperature for 30 minutes or mixing is not adequate, rouleaux can occur and QC will fail.</li> </ul>	
<b>Dilutions</b>	1:5	
<b>-Graph Type - Point of Origin - Type of Paper</b>	N/A	

#### 6.4 Tolerance Limits

When the run is complete, review, as follows:

1. Find control on the worklist.

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2. Verify results in the same manner you would a patient. Refer to test procedure.
3. Move any artifact from the Total and NUCL categories into ART.
4. Move any cells found in the respective ART categories back into Total or NUCL.

**Note:** Make sure that only artifacts are found in the respective ART classifications. Any cells seen in these classifications cause the results to be falsely low and should be moved to the respective cellular classifications.

Step	Action
1.	Values obtained should fall within the range provided by the specific lot in use. Consult the package insert.
2.	Run rejection criteria <ul style="list-style-type: none"> <li>• Anytime the established parameters are exceeded, the run is considered out of control (failed) and the patient results must not be reported.</li> </ul>
3.	Corrective Action <ul style="list-style-type: none"> <li>• All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented.</li> <li>• Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program.</li> <li>• Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the medical director.</li> <li>• Consult and follow corrective action guidelines in the Laboratory QC Program.</li> </ul>

### 6.5 Review Patient Data

Review patient data for unusual patterns, trends or distributions in patient results, Such as an unusually high percentage of abnormal result.

### 6.6 Documentation

- 6.6.1 Document all out of range QC results and resolutions in the “QC Corrective action log”.
- 6.6.2 Quality control records are reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.
- 6.6.3 Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program

### 6.7 Quality Assurance Program

- 6.7.1 Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials. Performance of the new lot must be equivalent to the previous lot.
- 6.7.2 Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.

Form revised 3/31/00

- 6.7.3 The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- 6.7.4 Consult the Laboratory QC Program for complete details.

## 7. EQUIPMENT and SUPPLIES

### 7.1 Assay Platform

The iQ200 Automated Urinalysis System is an in-vitro diagnostic system composed of the AX-4280 chemistry module, the iQ200 microscopy module, computers and monitor.

### 7.2 Equipment

N/A

### 7.3 Supplies

Calibrated pipettes capable of pipeting very small volumes (15µl to 1000µ)  
Conical sample tubes (800-3215)  
Body Fluid Rack (700-3225, 700-3226, 700-3227)  
Body Fluid QC Rack (700-3228)  
Body Fluid Key Disc (800-3016)  
Dilution barcode labels

## 8. PROCEDURE

**NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.**

**The package insert for a new lot of reagents must be reviewed for any changes before the test is performed. A current Package Insert is included as a Related Document.**

8.1	Instrument Set-up Protocol
1.	At the workstation, access the Logon menu by clicking on “Instrument” which is located at the top right of the computer screen.
2.	Click on “Logon” to access the Logon screen.
3.	Use the pull down menu to select your name from the list or type your name in the identifier field. Spelling and case MUST be exact if you choose to type.
4.	Type your password in the password field.
5.	Click “OK” to logon and close the logon screen.

8.2	Specimen / Reagent Preparation																																																								
1.	All Body Fluid specimens are prepared by splitting a patient’s sample into two separate aliquots: One that will be diluted with iQ Body Fluids lysing reagent; One that will be diluted with Iris Diluent.																																																								
2.	<p>Prepare the sample tubes as follows:</p> <p>Label two conical tubes with identical Patient ID barcodes labels. The barcode labels should be oriented with the numbers reading down, with the barcode label beginning approximately ½ inch from the top of the tube. If no Patient ID barcode labels are available, the operator can use the Manual orders Work list to run the body fluids samples.</p>																																																								
3.	<p>Select the proper dilution: Note the appearance and color of the body fluid.</p> <p style="text-align: center;"><b><i>The dilution step is extremely important.</i></b></p> <ul style="list-style-type: none"> <li>• If the dilution is too low, the result may exceed the reportable range of the iQ analyzer (10,000/μL) and will require an additional dilution.</li> <li>• If the dilution is too high, too few cells may be available for counting.</li> </ul> <p><b>Determine the appropriate dilution for the specimen based on the body fluid type and the appearance of the specimen. Refer to the Recommended Body Fluid Dilution Chart below.</b></p> <table border="1" data-bbox="393 1035 1446 1900" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="7" style="text-align: center;">Recommended Body Fluid Dilution Chart</th> </tr> <tr> <th style="width: 15%;">Specimen Type</th> <th colspan="3" style="width: 35%;">CSF</th> <th colspan="3" style="width: 35%;">Serous</th> </tr> <tr> <th>Appearance</th> <th>Dilution</th> <th>Volume of Sample per tube</th> <th>Volume of Diluent or Lyse</th> <th>Dilution</th> <th>Volume of Sample per tube</th> <th>Volume of Diluent or Lyse</th> </tr> </thead> <tbody> <tr> <td>Clear Colorless</td> <td>1:5</td> <td>250 μL</td> <td>1000 μL</td> <td>1:20</td> <td>100 μL</td> <td>1900 μL</td> </tr> <tr> <td>Slightly Pink / Hazy</td> <td>1:10</td> <td>150 μL</td> <td>1350 μL</td> <td>1:20</td> <td>100 μL</td> <td>1900 μL</td> </tr> <tr> <td>Slightly Pink / Cloudy</td> <td>1:20</td> <td>100 μL</td> <td>1900 μL</td> <td>1:20</td> <td>100 μL</td> <td>1900 μL</td> </tr> <tr> <td>Red / Cloudy</td> <td>1:50</td> <td>30 μL</td> <td>1470 μL</td> <td>1:50</td> <td>30 μL</td> <td>1470 μL</td> </tr> <tr> <td>Extremely Bloody / Extremely Turbid</td> <td>1:100</td> <td>15 μL</td> <td>1485 μL</td> <td>1:100</td> <td>15 μL</td> <td>1485 μL</td> </tr> </tbody> </table>	Recommended Body Fluid Dilution Chart							Specimen Type	CSF			Serous			Appearance	Dilution	Volume of Sample per tube	Volume of Diluent or Lyse	Dilution	Volume of Sample per tube	Volume of Diluent or Lyse	Clear Colorless	1:5	250 μL	1000 μL	1:20	100 μL	1900 μL	Slightly Pink / Hazy	1:10	150 μL	1350 μL	1:20	100 μL	1900 μL	Slightly Pink / Cloudy	1:20	100 μL	1900 μL	1:20	100 μL	1900 μL	Red / Cloudy	1:50	30 μL	1470 μL	1:50	30 μL	1470 μL	Extremely Bloody / Extremely Turbid	1:100	15 μL	1485 μL	1:100	15 μL	1485 μL
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<b>8.2</b>	<b>Specimen / Reagent Preparation</b>			
4.	Label the tubes with the secondary dilution barcode labels. <ul style="list-style-type: none"> <li>• Refer to the chart below.</li> <li>• Choose secondary dilution barcodes corresponding to the dilution that was selected above.</li> <li>• Place the secondary dilution barcodes below the Patient ID barcodes on both tubes.</li> </ul>			
	<b>CSF</b>	<b>Dilution</b>	<b>Serous</b>	<b>Dilution</b>
	<b>Label #</b>		<b>Label #</b>	
	0	1:5	0	1:20
	1	1:10	1	1:20
	2	1:20	2	1:20
	3	1:50	3	1:50
	4	1:100	4	1:100
	5	1:5	5	1:20
	6	1:5	6	1:20
	7	1:5	7	1:20
	8	1:5	8	1:20
	9	1:5	9	1:20

<b>8.3</b>	<b>Test Run</b>
1.	Place the 2 tubes, now labeled with identical <b>Patient ID barcodes AND Secondary Dilution barcodes</b> in positions 3 and 4 of a body fluid patient rack. (Note: dilution barcodes are different. One is for lyse and one is for total.) <b>Designated body fluid racks are 25, 26 or 27.</b> Place an additional, unlabelled tube into position 2 of the same rack.
2.	Aliquot 1.25 ml of Iris diluent into the tube in <b>Position 2</b> .
3.	Aliquot the appropriate amount of <b>iQ Body Fluids Lysing</b> reagent into <b>position 3</b> . Refer to the recommended Dilution chart in 8.2, section 3 for proper volumes. See note section 8.4
4.	Aliquot the appropriate amount of Iris <b>Diluent</b> into <b>position 4</b> . Refer to the Recommended Dilution Chart in 8.2 section 3 for proper volumes. See note section 8.4
5.	<b>IMMEDIATELY</b> , before placing the rack on the iQ: <ul style="list-style-type: none"> <li>• Add the specified amount of specimen to the <b>iQ Body Fluids Lysing reagent in position 3</b>. Refer to the Recommended Dilution chart in 8.2, section 3. Also, see note 8.4 section 1.</li> <li>• Add the specified amount of specimen to the <b>Iris diluent in position 4</b></li> <li>• <b>Gently mix the tubes in positions 3 and 4 by slapping on side of hand several times.</b></li> </ul>
6.	Place the loaded rack on the iQ Series.
7.	Press the <b>START</b> located on the upper left side of the iQ Series:

8.3	Test Run
	<ul style="list-style-type: none"> <li>• The sample rack will be moved along the sample transport tray to the barcode reader.</li> <li>• After the barcode is read, the sample aspirator will mix the sample, aspirate an aliquot, and take the sample to the flow cell. The particle images are then captured and sent to the Results/Analysis Processor for analysis.</li> </ul>
8.	<p><b>At the Iris Workstation:</b></p> <ul style="list-style-type: none"> <li>• Highlight the specimen ID on the work list.</li> <li>• Click on the “Specimen” button. This opens the specimen screen for that specimen, which contains the results from both lysed and diluted specimen aliquots.</li> <li>• The specimen screen in the body fluids module shows the aggregate results from the two sample tubes.</li> </ul>
9.	To review images, click on the particle name. For example “Total Cells.” The initial cell counts are presented on this screen.
10.	In the “Specimen” screen, reclassify images that do not belong in that category. For example, in the “Total Cells” screen, the operator can move images to the ‘Bacteria’ or ‘Crystals’ categories to indicate that these particles may be present and tag the sample for confirmatory testing.
11.	Click the ‘ART (Total) button to reclassify images as artifacts. <b>NOTE:</b> <i>Although the Body Fluids module does allow you to classify images as Bacteria or Crystals, it does not report a concentration for these particles. Placing images into either of these categories indicates in the report that the user observed the presence of Bacteria and/or crystals. It also reminds the user to confirm the presence or absence of these particles by other methods.</i>
12.	After completing the review and reclassification process, a final report is generated by returning to the “Results’ screen and clicking on the “accept’ button.

8.4	Special Handling
1.	<b>NOTE:</b> <i>Always add the iQ Body Fluids lysing Reagent or Iris Diluent to the tube first. It is very important to add the specimen to the iQ Body Fluids Lysing Reagent or Iris Diluent and not vice versa. Specimens that are added directly to empty tubes can adhere to the wall of the tube, which can prevent them from mixing properly into solution. For the same reason, it is important not to apply the specimen to the wall of the conical tube.</i>
2.	Each specimen is run in its own Body Fluids rack.
3.	Position 1: When testing a body fluid specimen after urine samples, especially a bloody or turbid urine sample, run an additional tube of Iris Diluent in position 1 (1.25 ml) for the first body fluid specimen processed.
4.	Position 5: An additional tube of Iris Diluent may be processed in Position 5 (1.25 ml) in cases where a bloody or turbid body fluid specimen is being run. This tube is added to ensure that there is no carryover in the next sample tube.

8.4	Special Handling
5.	<b>Sample must always be run in BOTH positions 3 and 4 and both tubes must be included in the same run.</b> If the tube in position 4 is missing, the sample will be lost.
6.	<b>Neonatal CSF:</b> If the Total count is high but no RBC count is calculated, place a drop of fluid under the microscope. If RBCs are present, cell counts must be performed manually because cells are resistant to lysing due to HgbF.

**9. CALCULATIONS**

None

**10. REPORTING RESULTS AND REPEAT CRITERIA**

After accepting the final results the report generated indicates the body fluid type tested, specimen identifier, operator, and microscopy notes.

The count of nucleated cells comes directly from the verified count in the “Nucleated cells” screen; whereas, the red blood cell count is the result of a calculation that subtracts the number of nucleated cells from the number of total cells.

Selective lysis causes RBC’s to burst completely; but incomplete lysis due to high concentration of RBCs can leave the outer cell membrane partially intact and create “ghost cell” images that could be misinterpreted. These specimens should be rediluted with a larger dilution to eliminate these ghost cells.

**10.1 Interpretation of Data**

None required

**10.2 Rounding**

N/A

**10.3 Units of Measure**

µL

**10.4 Clinically Reportable Range (CRR)**

Extended linearity for the iQ series Analyzer for body fluid dilutions are as follows:

- 1:5 Dilution = 50,000 cells/µl
- 1:10 Dilution = 100,000 cells /µl
- 1:20 Dilution = 200,000 cells/µl
- 1:50 Dilution = 500,000 cells /µl
- 1:100 = 1,000,000 cells/µl

Form revised 3/31/00



## 11. EXPECTED VALUES

### 11.1 Reference Ranges

CSF

Parameter/Units of Measurement	Both Male and Female	
	< 60 Days	≥ 60 days to Adult
RBC cells/μL	<10	<10
Total Nucleated Cells/μL	<20	<6

Serous Fluid Total Nucleated Cells	<b>All genders and ages</b> none established
Serous Fluid RBC	none established

### 11.2 Critical Values

None established

### 11.3 Priority 3 Limit(s)

None established

## 12. CLINICAL SIGNIFICANCE

Cerebrospinal fluid analysis is utilized to diagnose meningitis, intracranial hemorrhage, leukemias, malignancies and central nervous system disorders. Serous fluid analysis is ordered by physicians to diagnose infections, hemorrhages, malignancies and other disorders. Cell count determination is part of these analyses.

## 13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

## 14. LIMITATIONS OF METHOD

### 14.1 Analytical Measurement Range (AMR)

Linearity 0 to 10,000 cells/μl

### 14.2 Precision

N/A

### 14.3 Interfering Substances

N/A

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

## 15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needle sticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

## 16. RELATED DOCUMENTS

Iris Quality Control Procedure  
Iris iQ Series Automated Urinalysis System Procedure  
Iris iQ Series Automated Urinalysis System Maintenance Procedure  
Iris iQ Series Operator's Manual  
Laboratory Quality Control Program  
Current package insert for Iris reagents, QC and calibrators

## 17. REFERENCES

1. Iris AX-4280 Operator's Manual, 700-3093 Rev D
2. Iris iQ200 Operator's Manual, 300-4426 Rev B 08/2006
3. Todd-Sanford, Davidsohn, Clinical Diagnosis and Management by Laboratory Methods, 15<sup>th</sup> Edition, Vol I, W.B. Saunders Company, 1974, pp 1254-1279.
4. Kjeldsberg, Carl and Joseph Knight, Body Fluids, American Society of Clinical Pathologist, Chicago, 1982, pp 48-55,68.
5. Strasinger, Susan King, Urinalysis and Body Fluids, Philadelphia, F.A. Davis Company: 1989, pp 166-180.
6. Brunzel, Nancy A., Fundamentals of Urine and Body fluid Analysis, 2<sup>nd</sup> Edition, 2004.
7. Iris iQ200 Operators Manual, 300-4320 Rev B 09/2010
8. McPherson, Richard and Pincus, Matthew, Henry's Clinical Diagnosis and Management by Laboratory Methods, 21<sup>st</sup> Edition, Saunders Elsevier Inc, 2007 pp427,441.
9. Cell count and Differential, QDHE747, v1.3, Quest Diagnostics intranet.
10. Body Fluid Analysis, QDHE749, v1.2, Quest Diagnostics intranet.

**18. REVISION HISTORY**

Version	Date	Section	Reason	Reviser	Approval
000	8/24/11	1,3,11.1	Remove synovial fluid	L Barrett	C Reiedenauer
000	8/24/11	4	Remove Hyaluronidase reagent	L Barrett	C Reiedenauer
000	8/24/11	6.7	Remove testing with samples	L Barrett	C Reiedenauer
000	8/24/11	8.2	Remove pretreatment of synovial fluid	L Barrett	C Reiedenauer
000	8/24/11	15	Update to approved content	L Barrett	C Reiedenauer
001	9/20/12		Update owner	L Barrett	R SanLuis
001	9/20/12	4.2	Change Lysing reagent temp to 2-8C	A Chini	R SanLuis
001	9/20/12	6.1 & 6.2	Delete iQ Focus set	A Chini	R SanLuis
001	9/20/12	6.2	Change storage temp to 2-10C	A Chini	R SanLuis
001	9/20/12	6.3	Change background check tolerance limit from $\geq 3$ to $\geq 4$	A Chini	R SanLuis
001	9/20/12	6.6	Delete tolerance limits programmed in LIS	A Chini	R SanLuis

**19. ADDENDA**

N/A