TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	5/12/2014
Department:	Core	**Due Date:**	5/31/2014
		Implementation:	**6/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Body Fluid Module Analysis by Iris™ iQ200® Series Analyzer SGAH.U07, WAH.U07 v3

Description of change(s):

Section	Reason
8.2	Re-formatted tables (*separated CSF & Serous fluid dilution info in steps 3 & 4*)
8.5	Added differential count process (*to match the manual fluid SOPs*)

This revised SOP will be implemented on June 1, 2014

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

Approved draft for training (version 3)

Technical SOP

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

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Annual Review		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. TEST INFORMATION

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

Synonyms/Abbreviations
CSF Cell Count, Body Fluid Cell Count

Department
Urinalysis

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	CSF-tube #1, #3 or #4, Serous fluid	
-Other Acceptable	None	
Collection Container	CSF- plastic collection tubes Serous - EDTA tubes, plain tubes (no additives).	
Volume - Optimum	500µl per specimen (equivalent to 250µl per tube)	
- Minimum	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	**Clotted specimens** - perform counts and append the comment: *"Specimen contains clots, counts may not be accurate."* **Specimens received after 48 hours -** perform the counts and append the comment: *"Counts may not be accurate due to the age of the specimen."* Due to the nature of these specimens, do not reject unless frozen. If the specimen is received frozen, cancel the test with the comment: *"Specimen unsuitable for assay; received frozen."* 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.

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

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

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

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

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator / Verification Control	Supplier and Catalog Number
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.

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

Control	**iQ™ Focus Set** (Material used by the iQ™ to sharpen the images the camera sees, hence the name Focus.)
Preparation	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.
Storage/Stability	2-8°C / Open vial stability 30 days

5.3 Calibration Procedure

Criteria	**Special Notations**	
Frequency	**IQ™200 module Calibrations:** Calibration is performed once a month. Refer to the Iris Maintenance Procedure.	
Tolerance Limits	**IF …**	**THEN …**
	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 troubleshooting help. Repeat calibration and control.
Procedure	Run a Focus (see section 5.2) 1. 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. 2. 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.) 3. Load the Control rack onto the right side of the iQ Series sampler. 4. Press Start. The rack will be processed Run a Calibration 1. Transfer at least 4 mL iQ Calibrator into 10 round-bottom 16 x 100 mm glass test tubes. 2. 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. 3. Load the Calibration rack onto the right side of the iQ Series sampler. 4. Press "START" The rack will be processed and all calculations performed automatically. When the calibration is successful, the date/time and new **REF** value will be displayed in the Last Calibration field on the Instrument screen. **CALIBRATION VERIFICATION**: 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.	
Dilutions	N/A	

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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 ≤ 3	Proceed with testing controls
	Background check is ≥ 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.	
Dilutions	N/A	
-Graph Type - Point of Origin - Type of Paper	N/A	
Quality Control Procedure		
Frequency	Every eight hours of patient testing	
Tolerance Limits	**IF …**	**THEN …**
	Results exceed limits	Repeat
	Results in range	Proceed with patient testing.
Procedure	1. Prepare 1:5 dilutions of Control levels I and II with the following procedure. 2. Use the iQ Body Fluid Control Rack positions 2, 3 and 4. 3. Pour at least 1.25 ml of diluent in tube position 2. 4. Pipette 1000 µl of lyse reagent in tube position 3 and 1000µl of diluent in tube position 4. 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. DO NOT PIPETTE ONTO THE SIDE OF THE TUBE. 6. Place the BF barcode label for level I on tube position 3 and 4. 7. Gently mix the contents by gently tapping against the side of your hand. 8. Place in the iQ side of the instrument and press START. 9. Perform steps 2 through 7 using Level II. **NOTES**: • The dilution for controls I and II is 1:5 • Once controls are diluted they must be run within 3 minutes or over lysing can occur. • 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.	
Dilutions	1:5	
-Graph Type - Point of Origin - Type of Paper	N/A	

6.4 Tolerance Limits

When the run is complete, review as follows:
1. Find control on the work list.
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.

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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 • Anytime the established parameters are exceeded, the run is considered out of control (failed) and the patient results must not be reported.
3.	Corrective Action • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. • Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. • Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the medical director. • Consult and follow corrective action guidelines in the Laboratory QC Program.

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.

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 (800-3211)

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.	Prepare the sample tubes as follows: Label two conical tubes with identical Patient ID barcode 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.
3.	Select the proper dilution: Note the appearance and color of the body fluid. ***The dilution step is extremely important.*** • 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. • If the dilution is too high, too few cells may be available for counting. **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 Charts below.**

CSF

Recommended Body Fluid Dilution Chart

Appearance	Dilution	Sample Volume	Volume of Diluent or Lyse
Clear Colorless	1 : 5	250 µL	1000 µL
Slightly Pink / Hazy	1 : 10	150 µL	1350 µL
Slightly Pink / Cloudy	1 : 20	100 µL	1900 µL
Red / Cloudy	1 : 50	30 µL	1470 µL
Extremely Bloody /Extremely Turbid	1 : 100	15 µL	1485 µL

Serous

Recommended Body Fluid Dilution Chart

Appearance	Dilution	Sample Volume	Volume of Diluent or Lyse
Clear Colorless	1 : 20	100 µL	1900 µL
Slightly Pink / Hazy	1 : 20	100 µL	1900 µL
Slightly Pink / Cloudy	1 : 20	100 µL	1900 µL
Red / Cloudy	1 : 50	30 µL	1470 µL
Extremely Bloody /Extremely Turbid	1 : 100	15 µL	1485 µL

8.2	Specimen / Reagent Preparation
4.	Label the tubes with the secondary dilution barcode labels. Refer to the charts below. • Choose secondary dilution barcodes corresponding to the dilution that was selected in previous step. • Place the secondary dilution barcodes below the Patient ID barcodes on both tubes.

CSF

Label #	Dilution
0	1 : 5
1	1 : 10
2	1 : 20
3	1 : 50
4	1 : 100
5	1 : 5
6	1 : 5
7	1 : 5
8	1 : 5
9	1 : 5

Serous

Label #	Dilution
0	1 : 20
1	1 : 20
2	1 : 20
3	1 : 50
4	1 : 100
5	1 : 20
6	1 : 20
7	1 : 20
8	1 : 20
9	1 : 20

8.3	Test Run
1.	Place the 2 tubes, now labeled with identical **Patient ID barcodes AND Secondary Dilution barcodes** 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.) **Designated body fluid racks are 25, 26 or 27.** Place an additional, unlabelled tube into position 2 of the same rack.
2.	Aliquot 1.25 ml of Iris diluent into the tube in **Position 2.**

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8.3	Test Run
3.	Aliquot the appropriate amount of **iQ Body Fluids Lysing** reagent into **position 3.** 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 **Diluent** into **position 4** Refer to the Recommended Dilution Chart in 8.2 section 3 for proper volumes See note section 8.4
5.	**IMMEDIATELY,** before placing the rack on the iQ: • Add the specified amount of specimen to the **IQ Body Fluids Lysing reagen**t in **position 3**. Refer to the Recommended Dilution chart in 8.2, section 3. Also, see note 8.4 section 1. • Add the specified amount of specimen to the **Iris diluent** in **position 4** • **Gently mix the tubes in positions3 and 4 by slapping on side of hand several times.**
6.	Place the loaded rack on the iQ Series.
7.	Press the **START** located on the upper left side of the iQ Series: • The sample rack will be moved along the sample transport tray to the barcode reader. • 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.
8.	**At the Iris Workstation:** • Highlight the specimen ID on the work list. • Click on the "Specimen" button. This opens the specimen screen for that specimen, which contains the results from both lysed and diluted specimen aliquots. • The specimen screen in the body fluids module shows the aggregate results from the two sample tubes.
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. **NOTE:** *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.*
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.	**NOTE:** *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.*
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.
5.	**Sample must always be run in BOTH positions 3 and 4 and both tubes must be included in the same run.** If the tube in position 4 is missing, the sample will be lost.
6.	**Neonatal CSF:** 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.

8.5 Differential Count

For All Body Fluids other than CSF:

IF	THEN
Cell count is <10	Do not perform differential. Result with **NOTP-;**due to an insufficient number of cells in the sample.
Cell count is >10	Perform a 5 part differential of 100 cells on a cytocentrifuged specimen using Wescor slide stainer, or a manual stain (GEC). The nucleated cells are classified and reported as a percentage. Examine smear for the presence of immature or abnormal cells, crystals and bacteria. Refer to a Pathologist if abnormal or immature cells are noted.

All CSF specimens regardless of the Total Nucleated Cells count must have a Differential performed.

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

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

	All genders and ages
Serous Fluid Total Nucleated Cells	none established
Serous Fluid RBC	none established

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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. 15th 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, 2nd 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, 21st 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 Reidenauer
000	8/24/11	4	Remove Hyaluronidase reagent	L Barrett	C Reidenauer
000	8/24/11	6.7	Remove testing with samples	L Barrett	C Reidenauer
000	8/24/11	8.2	Remove pretreatment of synovial fluid	L Barrett	C Reidenauer
000	8/24/11	15	Update to approved content	L Barrett	C Reidenauer
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 ≥ 3 to ≥ 4	A Chini	R SanLuis
001	9/20/12	6.6	Delete tolerance limits programmed in LIS	A Chini	R SanLuis
002	4/9/14	8.2	Re-formatted tables	A Chini	R SanLuis
002	4/9/14	8.5	Added differential count process	C Reidenauer	R SanLuis
002	4/9/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis

19. ADDENDA

N/A