Quest Diagnostics

TRAINING UPDATE

Lab Location:	SGAH	**Date Distributed:**	9/25/2012
Department:	Core	**Due Date:**	10/25/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Body Fluid pH Analysis by Corning pH Meter 530 SGAH.U15 v000

Description of change(s):

SOP standardized to current format, given new number
Changes to content listed below

Section	Reason
3	Additional info added
5.3	Calibration Frequency changed
6.3	QC entry into LIS added
10.5	CRR added
10.6	Action for result outside of CRR
19	QC log revised & added

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

Approved draft for training (version 000)

Technical SOP

Title	**Body Fluid pH Analysis by Corning pH Meter 530**	
Prepared by	Hollie Genser	Date: 8/27/2012
Owner	Robert SanLuis	Date: 8/27/2012

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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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
pH	Corning pH meter	FPH

Synonyms/Abbreviations
Fluid pH, FPH

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

pH is the measurement of the effective hydrogen ion concentration in a solution. The Corning pH meter measures the pH using ion barrier technology produces the fast response of an AG/AGCL electrode without the use of AG/Cl in the reference fill solution. The result is an electrode that is compatible with, a non-toxic biological buffer.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing body fluid may be used for samples to be analyzed by this method.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Fluid None
Collection Container	Sterile Container
Volume - Optimum **- Minimum**	3.0 mL 1.0 mL
Transport Container and Temperature	Sterile Container, at room temperature
Stability & Storage Requirements	Room Temperature: Not established
	Refrigerated: (2 - 8C) 7 days
	Frozen: Unacceptable
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	None defined
Other Considerations	None defined

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	Supplier & Catalog Number
KCL	Pinnacle 477006

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	3 M KCL
Container	6 bottles 125mL each
Storage	Room Temperature, 18-25˚C
Stability	Until the expiration date printed on the label
Preparation	None

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
pH 7.00 Buffer Solution	Fisher Scientific Cat. No. SB 107-500
pH 10.00 Buffer Solution	Fisher Scientific Cat. No. SB 115-500

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	pH buffer 7.00
Preparation	No preparation is required. Calibrator is ready for use.

Storage/Stability	Calibrator is stored at room temperature (20-25° C) and is stable until expiration date stamped on the bottle.

Calibrator	pH buffer 10.00
Preparation	No preparation is required. Calibrator is ready for use.
Storage/Stability	Calibrator is stored at room temperature (20-25° C) and is stable until expiration date stamped on the bottle.

5.3 Calibration Procedure

Criteria	Special Notations	
Frequency	• Run Calibration with every patient testing • Anytime a result is questionable • Anytime QC does not come in within acceptable range. • After connecting another electrode • When the sensor symbol flashes on the display • After the calibration interval has expired • After a voltage interruption (empty batteries)	
Procedure	1. Turn the pH meter ON. The electrode should have the fill solution in it. 2. Allow the meter to go through its electronic checks. 3. Press CAL until you see CAL 1 at the bottom right hand corner. 4. Immerse the pH electrode in the 7.0 buffer and the meter starts measuring. The decimal point flashes during calibration measurement. When the electrode output has stabilized, the stability indicator appears. Once reached, the stability /auto endpoint indicator (located in the left-hand corner [A]) will appear and a beep will follow. 5. Rinse the electrode with deionized water and blot dry. 6. Press CAL again until the CAL3 (10.0 CAL) appears. Repeat step 4 with 10.0 buffer. 7. Note: If the meter has not been in use for an extended period of time, it may take a few minutes for the first calibration buffer to register.	
Tolerance Limits	**IF …**	**THEN …**
	the calibration fails	repeat using freshly poured pH Buffer Solutions 7.00 and 10.00
	the calibration fails again	bring it to the attention of the Supervisor or Group Lead and call company's tech support

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6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
pH 6.00 Buffer Solution	Ricca Chemical Company Cat. No. 1510-16
pH 8.00 Buffer Solution	Fisher Scientific Cat. No. SB 112-500

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	pH buffer 6.00
Preparation	No preparation is required. Control is ready for use.
Storage/Stability	Control is stored at room temperature (20 - 25° C) and is stable until expiration date stamped on the bottle.

Control	pH buffer 8.00
Preparation	No preparation is required. Control is ready for use.
Storage/Stability	Control is stored at room temperature (20 - 25° C) and is stable until expiration date stamped on the bottle.

6.3 Frequency

Quality Control is performed with each patient test.

To enter QC results in the LIS:
Function: MEM
Worksheet: SUR3
Use C-PH6S for pH QC 6.00 and C-PH8S for pH QC 8.00

6.4 Tolerance Limits

IF the result is …	THEN…
If QC is not acceptable	Repeat with fresh control. If repeat is acceptable, discard previous QC material and report patients. If repeat is unacceptable, recalibrate the meter and rerun control after calibration.

- All corrective action must be documented as outlined in the Laboratory Quality Control Program.
- No patient results are to be reported until acceptable QC results are obtained.

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6.5 Review Patient Data

Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

- QC tolerance limits are programmed into the LIS. The LIS calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- All buffers are certified and traceable. Crosschecks are not indicated.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Corning 530 pH meter

7.2 Equipment

Epoxy Body Three-in-one Combination pH Electrode

7.3 Supplies

- Deionized water
- Kimwipes
- Borosilicate Glass Tubes 16x100mm

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 kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-up Protocol
1.	The electrode requires routine maintenance to keep the electrode clean. The electrode requires changing the 3M-KCL fill solution every 1-2 months. The electrode is supplied with fill solution and a plastic pipette for the use when changing the fill solution. Never store the electrodes in distilled water. For long periods remove the bulb protector, fill the wetting cap with KCL solution and push the wetting cap onto the tip of the electrode.

8.2	Test Run
1.	To analyze QC buffers or specimen, press MODE until the pH appears in the window. Pour 1-2 ml of the specimen or buffer into a 16 X 100 mm tube, and immerse the probe into the sample. Let the pH meter stabilize until the [A] appears in the left-hand corner followed by the beep. This is the reading for the sample.
2.	Rinse the probe with deionized water and blot the electrode at the beginning and end of testing.
3.	Turn the instrument off.

8.3	Special Handling
1.	Do not allow the electrode reference solution to run dry. Add fill solution whenever the level falls more than 25mm below the fill hole. Change the electrode reference solution every 1-2 months.
2.	Do not use KCL saturated with AGCL as the fill solution as it can damage the reference.
3.	Do not use the electrode in any fluoride or hydrofluoric acid solution where the pH is less than 5.0 as it will dissolve the pH membrane.
4.	Do not leave epoxy body electrodes in organic solvents as the electrode tip and body may be damaged.
5.	Do not remove the orange rubber plug at the tip of the epoxy body electrode for any reason.
6.	Always blot the electrode tip with lint free tissue. Wiping can produce a static charge.
7.	Not for industrial use. Persons knowledgeable in safe laboratory practices design these electrodes for the use in general laboratory applications. They are not designed for constant monitoring in process or manufacturing application.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None

10.2 Rounding

Report to 2 decimal places

10.3 Units of Measure

None

10.5 Clinically Reportable Range (CRR)

1-10

Note: See 8.3.3 under special handling above.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
Outside of the CRR	Repeat the patient sample
Still outside of the CRR	Bring it to the attention of Supervisor or Group Lead before releasing the result.

To record results in the LIS:
Function: MEM
Worksheet: SUR3
Report Fluid Type with each sample result

11. EXPECTED VALUES

11.1 Reference Ranges

None established

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

PH is a measurement of the acid-base balance in the regulation of body fluids. Many studies make comparisons between measurements of analytes in body fluids and concurrent measurements of those analytes in serum to determine whether the body fluids have similar

concentrations or markedly higher ones as indicators of specific etiology or organ damage. Studies have indicated that measurement of peritoneal or pericardial fluid pH is of no clinical value.

12.1 Pleural Fluid

The pleural fluid pH is useful in effusions secondary to pneumonia. Values below 7.0 indicate a complicated effusion and require drainage. Values above pH 7.2 usually do not require drainage. If the pH is low, an arterial pH may be performed to rule out systemic acidosis. The pleural fluid pH is low in a number of conditions, including malignancy, tuberculosis, rheumatoid disease, hemothorax, and urinothorax.

12.2 Synovial Fluid

In inflammatory fluids, hydrogen ion concentration increases secondary to glucose utilization with an increase in lactic acid. The pH decrease correlates inversely with the leukocyte count.

12.3 Cerebrospinal Fluid

Cerebrospinal fluid pH was slightly lower than arterial blood by about 0.1 unit in one study. It is maintained at baseline levels despite fluctuations in arterial pH, except in clinical conditions with sustained acidosis or alkalosis. Regulation of the pH involves compensatory mechanisms that control the CSF bicarbonate concentration.

Primary CSF acidosis also occurs in conditions involving CNS pathology (e.g., subarachnoid hemorrhage, bacterial meningitis, and trauma).

Notes: *Although pH has been determined in body fluids in disease, there is little information on normal reference ranges. The studies of normal fluid have few subjects and preclude studies of its normal composition.*

Suggested reference ranges from normal control subjects are listed below:

Fluid	**pH**
Pericardial	7.35-7.79
Synovial	7.32-7.64
Cerebrospinal	7.30-7.36

There are no studies of normal peritoneal or pleural fluid; thus, sterile fluid from cirrhotic patients and pleural fluid transudates may be clinically useful reference values.

Fluid	**pH**
Pleural fluid transudates	7.36-7.56
Sterile ascites	7.35-7.59

Fluids with a pH >7.30 resolve spontaneously, whereas a pH <7.20 is an indication for tube drainage.

13. PROCEDURE NOTES

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

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

None defined

14.2 Precision

N/A

14.3 Interfering Substances

N/A

14.4 Clinical Sensitivity/Specificity/Predictive Values

None defined

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 the learn 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 needlesticks 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

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. Quest Diagnostics Records Management Procedure
5. Current package insert for KCL

17. REFERENCES

1. Corning Pinnacle M530 Instruction Manual.
2. Kaplan,Lawrence A. and Psesce Amadeo J., Clinical Chemistry theory, analysis and correlation 1984 393.
3. Race, George J., Laboratory Medicine Vol 4. 1982 6:2.
4. CLSI, C49-A. Analysis of Body Fluids in Clinical Chemistry; Approved Guideline, Vol. 27. No.14

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes U018.001		

19. ADDENDA

Body Fluid pH Log (see Attachment Tab of Infocard)

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Quest Diagnostics

☐ Germantown Emergency Center
☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

Body Fluid pH Log

Inspect the pH electrode:

Tech _____ Date _____	Check reference electrode fluid. Add or replace KCL if needed.

Record Calibrator Data:

Tech _____ Date _____		Calibration Results: Pass / Fail	
pH Buffer 7.00 Lot:	Exp:	**pH Buffer 10.00** Lot:	Exp:

Record QC and Patient Data:

Tech _____ Date _____			Record Results
Must be run in this order - Bracket with each patient run			
pH Buffer 6.0	Lot no.	Expiration	
Patient Name / MR#			
Patient Name / MR#			
Patient Name / MR#			
pH Buffer 8.0	Lot no.	Expiration	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: