TRAINING UPDATE

Lab Location:	WAH	**Date Distributed:**	1/5/2015
Department:	Core	**Due Date:**	1/31/2015
		Implementation:	**2/1/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Body Fluid pH Analysis by Pinnacle Series M530P pH Meter WAH.U16 v1

Description of change(s):

Change is documenting QC in Unity instead of SQ

Section	Reason
6.3	Replace QC entry instruction for LIS with Unity Real Time
6.6	Replace LIS with Unity Real Time

This revised SOP will be implemented on February 1, 2015

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

Approved draft for training (version 1)

Technical SOP

Title	**Body Fluid pH Analysis by Pinnacle Series M530P pH Meter**
Prepared by	Ashkan Chini Date: 8/28/2012
Owner	Robert SanLuis Date: 8/28/2012

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

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

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
pH	Pinnacle Series pH meter	FPH

Synonyms/Abbreviations
Fluid pH, FPH

Department
Chemistry

2. ANALYTICAL PRINCIPLE

pH is the measurement of the effective hydrogen ion concentration in a solution. Pinnacle Series pH meter and electrode are used for pH measurements.

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 / Clean container
Volume - Optimum **- Minimum**	3.0 mL 1.0 mL
Transport Container and Temperature	Collection container at room temperature
Stability & Storage Requirements	Room Temperature: Not established
	Refrigerated: (2 - 8° C) 7 days
	Frozen: Not recommended
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	N/A
Other Considerations	N/A

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 Series Cat. No. 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 7.00 Buffer Solution
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

<table>
<tr><th>Criteria</th><th colspan="2">Special Notations</th></tr>
<tr><td>Frequency</td><td colspan="2">• 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)</td></tr>
<tr><td>Procedure</td><td colspan="2">1. Turn the meter on and press the CAL button.
2. On this page “Set” and “Buffer” are shown. “Set” has number 2 (meaning a two point calibration will be performed) and “Buffer” has number 1 (indicates it is ready to read the first calibrator which is buffer solution pH 7.00).
3. Rinse the electrode with DI water and use a kimwipe to dry it. Immerse the pH electrode in a freshly poured and labeled pH 7.00 solution glass tube and press OK. The “AR” (Auto Read) flashes until the stable value is measured (Measurement is stable when the AR stops flashing).
4. Now the screen shows “Set 2” and “Buffer 2”, which indicates it is ready to read the second calibrator (buffer solution pH 10.00).
5. Use pH 10.00 buffer solution and repeat the instructions in step 3.
6. At the end of the calibration if the message “Cal Error” appears it means the calibration has failed and needs to be repeated. Otherwise if numbers appear that is indication of a successful calibration.</td></tr>
<tr><td rowspan="3">Tolerance Limits</td><td>IF …</td><td>THEN …</td></tr>
<tr><td>the calibration fails</td><td>repeat using freshly poured pH Buffer Solutions 7.00 and 10.00</td></tr>
<tr><td>the calibration fails again</td><td>bring it to the attention of the Supervisor or Group Lead and call company’s tech support</td></tr>
</table>

Form revised 2/02/2007

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 6.00 Buffer Solution
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 8.00 Buffer Solution
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

Both levels of controls are performed with each patient testing.

To enter QC results in Unity Real Time:

1. Log into Unity Real Time
2. Select Lab “216442 WAH Centaur”
3. Select “pH”
4. pH 6 Buffer Solution results are entered as Level 1
5. pH 8 Buffer Solution results are entered as Level 2
6. SAVE

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.

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- 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.

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 Unity Real Time; it 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

Pinnacle Series M530P

7.2 Equipment

pH meter electrode

7.3 Supplies

- Kimwipe
- DI water

- Large glass tubes 16 x 100 mm

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 refillable electrode requires changing the KCL fill solution every 1 – 2 months.
2.	Do not allow the electrode reference solution to run dry. Add fill solution, KCL, whenever the level falls more than 1 inch below the fill hole.

8.2	Test Run
1.	Turn the pH meter on and perform the calibration first (refer to calibration procedure section 5.3)
2.	After a successful calibration, press the "**AR**" button to activate the Auto Read.
3.	Obtain a large glass tube, label appropriately with patient information and pour 1-2 mL of patient sample into the tube.
4.	The pH electrode is stored in the pH 7.00 Buffer Solution. Rinse the pH electrode using DI water and blot dry with a kimwipe.
5.	Immerse the pH electrode in the patient's tube prepared in step 1 and press the **OK** button on the pH meter. The "**AR**" (Auto Read) display indicator flashes until a stable value is measured.
6.	Once the "**AR**" display stops flashing, it means the measurement is final.
7.	Record the results.
8.	Rinse the pH electrode with DI water, dry it using a kimwipe and store it back in a 7.00 Buffer Solution.
9.	Turn the pH meter 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 1 inch 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.

8.3	Special Handling
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

The result is reported up to two decimal points.

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

1 – 10

Note: See 8.3.3 under special handling above.

10.5 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: WUR3
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:** 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 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 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
6. Body Fluid pH Log (AG.F188)

17. REFERENCES

1. Pinnacle Series M530P Instruction Manual, revised 06/2007
2. Pinnacle Series Electrodes Instruction Manual
3. Kaplan, Lawrence A. and Psesce Amadeo J., Clinical Chemistry theory, analysis and correlation 1984 393.
4. Race, George J., Laboratory Medicine Vol 4. 1982 6:2
5. 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
000	10/14/14	6.3	Replace QC entry instruction for LIS with Unity Real Time	A Chini	R SanLuis
000	10/14/14	6.6	Replace LIS with Unity Real Time	A Chini	R SanLuis
000	10/14/14	16	Move log from section 19		
000	10/14/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None