

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0030156	<b>(X3) Date Survey Completed</b>  10/17/2019
<b>Name of Provider or Supplier</b>  Pearl River County Hospital	<b>Street Address, City, State</b>  305 West Moody Street, Poplarville, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Abbott i-Stat-Stat analyzer since installation on 12-5-17 and confirmation by Technical Consultant #2, the laboratory failed to document, as performed, calibration verification for blood gas testing--pH, pO2, and pCO2--on the Abbott i-Stat analyzer at least every six months. Findings include: Review of calibration verification records for the Abbott i-Stat analyzer since installation on 12-5-17 revealed calibration verification was performed</p>

on 12-5-17 and 8-20-19. Technical Consultant #2 confirmed i-Stat calibration verification was not performed from 12-5-17 until 8-20-19.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of evaluations of the competency of testing personnel since the last survey on 9-14-17, the Centers for Medicare and Medicaid Services (CMS) 209 Laboratory Personnel forms, and confirmation by Technical Consultant #2, the technical consultant failed to include direct observations of routine patient test performance, patient preparation, if applicable, specimen handling, processing, and testing in evaluating the competency of testing personnel for performing moderate complexity testing. Findings include: Review of evaluations of the competency of testing personnel since the last survey on 9-14-17 and confirmation by Technical Consultant #2 revealed the technical consultant failed to include direct observations of routine patient test performance, patient preparation, if applicable, specimen handling, processing, and testing in evaluating the competency of the following testing personnel for performing moderate complexity testing: 1. Annual competency evaluations for Clinical Laboratory Personnel #1, #2, #3, #4, #5, #6, #7, #8, #9, #11 and Blood Gas Laboratory Personnel #1 through #13. 2. Semi-annual competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas Laboratory Personnel #1 through #13. 3. Initial competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas Laboratory Personnel #1 through #13.

**D6050**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on review of evaluations of the competency of testing personnel since the last survey on 9-14-17, the CMS 209 Laboratory Personnel forms, and confirmation by Technical Consultant #2, the technical consultant failed to include direct observation of performance of instrument maintenance and function checks in evaluating the competency of testing personnel for performing moderate complexity testing. Findings include: Review of evaluations of the competency of testing personnel since the last survey on 9-14-17 and confirmation by Technical Consultant #2 revealed the technical consultant failed to include direct observation of performance of instrument maintenance and function checks in evaluating the competency of the following testing personnel for performing moderate complexity testing: 1. Annual competency evaluations for Clinical Laboratory Personnel #1, #2, #3, #4, #5, #6, #7, #8, #9, #11 and Blood Gas Laboratory Personnel #1 through #13. 2. Semi-annual competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas

Laboratory Personnel #1 through #13. 3. Initial competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas Laboratory Personnel #1 through #13.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of evaluations of the competency of testing personnel since the last survey on 9-14-17, the CMS 209 Laboratory Personnel forms, and confirmation by Technical Consultant #2, the technical consultant failed to include assessment of problem solving skills in evaluating the competency of testing personnel for performing moderate complexity testing. Findings include: Review of evaluations of the competency of testing personnel since the last survey on 9-14-17 and confirmation by Technical Consultant #2 revealed the technical consultant failed to include assessment of problem solving skills in evaluating the competency of the following testing personnel for performing moderate complexity testing: 1. Annual competency evaluations for Clinical Laboratory Personnel #1, #2, #3, #4, #5, #6, #7, #8, #9, #11 and Blood Gas Laboratory Personnel #1 through #13. 2. Semi-annual competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas Laboratory Personnel #1 through #13. 3. Initial competency evaluations for Clinical Laboratory Personnel #6, #9, and #10 and Blood Gas Laboratory Personnel #1 through #13.