

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0874986	<b>(X3) Date Survey Completed</b>  02/10/2022
<b>Name of Provider or Supplier</b>  St Helena Parish Hospital-Respiratory	<b>Street Address, City, State</b>  16874 Hwy 43, Greensburg, LA	
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>D0000</b>	A Recertification survey was performed on February 10, 2022 at St. Helena Parish Hospital-Respiratory, CLIA ID # 19D0874986. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of policies and procedures and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Employee Competency Evaluations" policy revised August 19, 2019 revealed the the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on February 10, 2022 at 11:26 am, the Respiratory Director confirmed the laboratory's revised personnel competency policy did not include the indicated information. II. Based on review of the laboratory's policies, personnel records, and interview with personnel, the laboratory</p>

failed to perform a complete semi-annual competency assessment for one (1) of one (1) new hire personnel. Findings: 1. Review of the laboratory's "Employee Competency Evaluations" policy revised August 19, 2019 revealed the laboratory did not include the required six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing. Refer to D5209 I. 2. Review of personnel records revealed Testing Personnel 6 was hired in April 1, 2021. 3. Further review of personnel records for Testing Personnel 6 revealed the laboratory utilized a "Semiannual Evaluation of epoc Analyzer" form for semi-annual competency assessments. 4. Review of the "Semiannual Evaluation of epoc Analyzer" revealed the laboratory included the following "abbreviation key" on the form: 1-DO = Direct Observation or Verbal 2-MTR = Monitoring Test Results 3-RR= Record Review 4-PT = Proficiency Testing of Unknown 5-PM= Performance of Maintenance 6-PS= Problem Solving Skills 5. Review of the "Semiannual Evaluation of epoc Analyzer" for Testing Personnel 6 revealed the following procedures were assessed by "1-DO": Operation and function of epoc Instrument Specimen Handling, Processing & Testing Documenting & Reporting Test Results Documenting & Reporting Critical Values Disposal of Waste Retention of Records Policy on Performing Quality Controls Use of Liquid Quality Controls Maintenance of equipment Eye Wash Use and Location Temperature & Humidity Log 6. Further review of the "Semiannual Evaluation of epoc Analyzer" for Testing Personnel 6 revealed the following procedures were not assessed: a) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. b) Direct observation of performance of instrument maintenance and function checks. c) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. d) Assessment of problem solving skills. 7. In interview on February 10, 2022 at 12:30 pm, the Respiratory Director confirmed the semi-annual competency assessment did not include the minimum six (6) procedures.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
 Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Refer to D5209 I and D5209 II.