

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0713341	<b>(X3) Date Survey Completed</b>  01/25/2024
<b>Name of Provider or Supplier</b>  Richardson Medical Center	<b>Street Address, City, State</b>  254 Hwy 3048, Rayville, 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 Certification survey was performed on January 25, 2024 at Richardson Medical Center Respiratory, CLIA ID # 19D0713341. 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: Based on review of the laboratory's policy, CMS 209 form, personnel records and interview with personnel, the laboratory failed to follow their established competency assessment policy for nine (9) of nine (9) testing personnel reviewed in 2022 and 2023. Findings: 1. Review of the laboratory's "Arterial Blood Gas Specimen Collection Competency and Checklist" policy revealed "Competency for each person to perform his/her duties must be assessed: Following training within 90 days; During the first year of employment that an individual tests specimens, competency must be assessed at least every six months; Annually thereafter (usually done in conjunction with employee annual performance evaluation); If an employee fails to demonstrate satisfactory performance on a competency assessment must be reassessed following corrective action and retraining". 2. Further review of the laboratory's "Arterial Blood Gas Specimen Collection Competency and Checklist" policy revealed the following: "Some elements of competency assessments include, but are not limited to: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance</p>

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". 3. Further review of the CMS 209 form (Laboratory Personnel Report) revealed the following serves as Testing Personnel: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 e) Personnel 5 f) Personnel 6 g) Personnel 7 h) Personnel 8 i) Personnel 10 4. Review of the personnel records for competency assessments revealed the laboratory did not follow their established policy for the assessment of personnel including the six (6) elements for the following nine (9) of nine (9) testing personnel in 2022 and 2023: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 e) Personnel 5 f) Personnel 6 g) Personnel 7 h) Personnel 8 i) Personnel 10 5. In interview on January 25, 2024 at 9:50 am, Testing Personnel 10 stated that competency assessments were performed with supporting documentation in the personnel records but no formal assessment format was included to show how the competencies were completed. Testing Personnel 10 confirmed the identified competencies were not performed as required by laboratory policy.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on observation by surveyor, review of performance verification records, test menu and interview with personnel, the laboratory failed to ensure verification of performance studies for Arterial Blood Gas (ABG) on the GEM Premier 5000 analyzer were complete. Findings: 1. Observation by surveyor during the laboratory tour on January 25, 2024 at 10:30 am revealed the laboratory performs Arterial Blood Gas (ABG) testing on the GEM Premier 500 analyzer. 2. Review of the laboratory's "GEM Premier Family Performance Verification Plan" revealed the laboratory did not have documentation of operator variance to support precision studies. 3. In interview on January 25, 2024 at 10:56 am, Personnel 10 confirmed the laboratory did not show operator variance in the performance verification studies 4. Review of the task 1&3 form provided to surveyor revealed the laboratory performs one hundred fifty nine (159) ABG tests annually.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on observation by surveyor, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies for Arterial Blood Gas testing was complete. Refer to D5421.

**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 review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to follow their established competency assessment policy for nine (9) of nine (9) testing personnel reviewed in 2022 and 2023. Refer to D5209. 2. The Technical Consultant failed to evaluate competency annually for nine (9) of nine (9) testing personnel reviewed. Refer to D6054.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, CMS 209 form, personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually for nine (9) of nine (9) testing personnel reviewed. Findings: 1. Review of the laboratory's "Arterial Blood Gas Specimen Collection Competency and Checklist" policy revealed " Competency for each person to perform his/her duties must be assessed: Following training within 90 days; During the first year of employment that an individual tests specimens, competency must be assessed at least every six months; Annually thereafter (usually done in conjunction with employee annual performance evaluation); If an employee fails to demonstrate satisfactory performance on a competency assessment must be reassessed following corrective action and retraining". 2. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form provided to surveyor revealed the following personnel serves as Laboratory Director and Technical Consultant: \* Personnel 9 3. Review of the personnel records

from 2022 and 2023 revealed the laboratory did have supporting documentation for annual competencies; however, the laboratory did not have a complete competency assessment for each of the following nine (9) of nine (9) testing personnel reviewed: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 e) Personnel 5 f) Personnel 6 g) Personnel 7 h) Personnel 8 i) Personnel 10 4. In interview on January 25, 2024 at 9:50 am, Personnel 10 confirmed the Technical Consultant did not perform competency assessments for the identified personnel in 2022 and 2023.