

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 19D0896631	<b>(X3) Date Survey Completed</b> 04/09/2024
<b>Name of Provider or Supplier</b> La Family Practice	<b>Street Address, City, State</b> 2300 Hospital Drive, Suite 200, Bossier City, 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 Validation Survey was conducted on April 9, 2024 at LA Family Practice - CLIA # 19D0896631. The laboratory was found in compliance with 42 CFR 493 Requirement 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 policies and procedures, and interview with personnel, the laboratory failed to establish complete procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Personnel Process" policy revealed the policy did not include how the laboratory will evaluate the following six (6) procedures minimally required for the assessment of competency for testing personnel: 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 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 April 9, 2024 at 3:00 pm, the Technical Consultant confirmed the laboratory's policy for competency did not detail how competency is to be evaluated for testing personnel.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p>

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 the laboratory's policy and procedures and performance verification records as well as interview with personnel, the laboratory failed to verify the performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Findings: 1. Observation by surveyor on April 9, 2024 at 3:00 pm during the laboratory tour revealed the laboratory utilizes the Beckman Coulter DxH 520 hematology analyzer for Complete Blood Count (CBC) patient testing. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for performance verification to include accuracy, complete precision, reportable range, and reference range along with the acceptability criteria for each. 3. Review of the laboratory's performance verification records performed in April 2023 revealed the laboratory did not perform the following: a) Complete Precision to include run-to-run, within run, day-to-day, operator variance and the raw data to support studies b) Reference Range 4. In interview on April 9, 2024 at 4:00 pm, the Technical Consultant confirmed the laboratory did not include the identified data for the verification studies. 5. Review of the Task 1&3 form provided to surveyor revealed the laboratory performs 2856 Complete Blood Count (CBC) tests annually.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of maintenance logs and interview with personnel, the laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for four (4) of twelve (12) months reviewed in 2023 and 2024. Findings: 1. Observation by surveyor during the laboratory tour on April 9, 2024 at 3:00 pm revealed the laboratory utilizes the Beckman Coulter DxH 520 hematology analyzer for Complete Blood Count (CBC) patient testing. 2. Review of the maintenance logs for the Beckman Coulter DxH 520 hematology analyzer revealed the laboratory performs the following monthly maintenance: a) Bleach Cycles b) Cleaning the WBC Bath Filter 3. Further review of the laboratory's April 2023 through March 2024 maintenance logs for the Beckman Coulter DxH 520 hematology analyzer revealed the monthly maintenance was not performed for the following four (4) of twelve (12) months reviewed: a) March 2023 - Bleach Cycles; Cleaning the WBC Bath Filter b) May 2023 - Bleach Cycles; Cleaning the WBC Bath Filter c) June 2023 - Cleaning the WBC Bath Filter d) January 2024 - Bleach Cycles; Cleaning the WBC Bath Filter 4. In interview on April 9, 2024 at 4:45 pm, the

	<p>Technical Consultant confirmed the identified monthly maintenance was not performed as required by the manufacturer.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>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;</p> <p>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 were complete. Findings: 1. The laboratory failed to verify the performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Refer to D5421.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and maintenance records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for four (4) of twelve (12) months reviewed in 2023 and 2024. Refer to D5429.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>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;</p>

	<p>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 establish complete procedures to assess competency for testing personnel. Refer to D5209. 2. The Technical Consultant failed to perform annual competencies in 2022 and 2023 for two (2) of eight (8) testing personnel reviewed. Refer to D6046.</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for four (4) of twelve (12) months reviewed in 2023 and 2024. Refer to D5429.</p>
<p><b>D6040</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy and performance studies as well as interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Findings: 1. The laboratory failed to verify the performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Refer to D5421.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report), personnel records and interview with personnel, the Technical Consultant failed to perform annual competencies in 2022 and 2023 for two (2) of eight (8) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed</p>

the following eight (8) of eight (8) serve as Testing Personnel: \* Personnel 2 \* Personnel 3 \* Personnel 5 \* Personnel 6 \* Personnel 7 \* Personnel 8 \* Personnel 9 \* Personnel 10 2. Review of the laboratory's personnel records revealed the Technical Consultant did not perform competency assessments in 2022 and 2023 for the following two (2) of eight (8) testing personnel: \* Personnel 2 \* Personnel 3 3. In interview on April 9, 2024 at 5:00 pm, the Technical Consultant confirmed competency assessments for the identified personnel were not performed in 2022 and 2023.