

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0712259	(X3) Date Survey Completed 04/26/2024
Name of Provider or Supplier Family Medicine Clinic	Street Address, City, State 2309 East Main Street Suite 400, New Iberia, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on April 25, 2024 through April 26, 2024 at Family Medicine Clinic, 19D0712259. Family Medicine Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratory Director, Moderate Complexity
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's American Proficiency Testing (API) proficiency testing records and CASPER 155D report as well as interview with personnel, the laboratory failed to achieve satisfactory performance in two (2) of three (3)</p>

	<p>consecutive testing events in the subspecialty of Routine Chemistry for the analyte Sodium (NA), resulting in a initial unsuccessful performance. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the CASPER 155D report and American Proficiency Institute (API) as well as interview with personnel, the laboratory failed to achieve a score of at least 80% for the subspecialty Routine Chemistry in the analyte Sodium in two (2) of three (3) consecutive events in 2023, resulting in an initial unsuccessful performance. Findings: 1. Review of American Proficiency Institute (API) proficiency testing results and CASPER Report 155D revealed the laboratory received unsatisfactory score for the following two events resulting in the first unsuccessful performance for Sodium (Na): Event 1 of 2023 received a score of 60% Event 3 of 2023 received a score of 0% 2. In interview on April 25, 2024 at 1:44 p.m., the Technical Consultant confirmed the laboratory received unsatisfactory scores for Sodium in the events identified above.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 policies and procedures and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel and the Technical Consultant. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a policy addressing competency assessment for testing personnel and the Technical Consultant. 2. In interview on April 25, 2024 at 12:20 p.m., the Technical Consultant confirmed the laboratory did not have a competency assessment policy.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to document the review and evaluation of the ungraded results for Bilirubin testing for one (1) of nine (9) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy</p>

revealed "In the event that an analyte(s) is not graded or that is scored as 100% due to non-consensus or lack of peer group, the laboratory will perform a self-evaluation to verify the accuracy of analyte(s) and test(s). Self-evaluation, when possible, will be accomplished by comparison of actual performance against the target value and acceptable range of the PT specimen as defined in the participant summary from the PT provider." 2. Review of the laboratory's 2023 and 2024 American Proficiency Institute (API) proficiency testing records revealed the following ungraded results: a) 2024 Chemistry - Core - 1st Event - Bilirubin, Total: CH-02, CH-03, CH-05 3. In interview on April 25, 2024 at 12:45 p.m., the Technical Consultant confirmed the laboratory did not evaluate the ungraded PT results identified above.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to verify the accuracy of performance for Wet Prep and Potassium Hydroxide (KOH) testing at least twice per year. Findings: 1. Review of the laboratory's Task 1 & 3 form detailing test menu and volume revealed the laboratory performed Wet Prep and KOH testing. 2. Review of the laboratory's 2023 proficiency testing records revealed the laboratory failed to provide documentation of verification of the accuracy of performance at least twice annually for Wet Prep and KOH testing. 3. In interview on April 25, 2024 at 1:53 p. m., the Technical Consultant stated he thought the urinalysis sediment proficiency testing was sufficient for verifying the accuracy of the Wet Prep and KOH tests. He confirmed the laboratory did not have twice a year verification of Wet Prep and KOH testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation; review of manufacturer's storage requirements and laboratory's temperature records; as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for laboratory supplies stored in one (1) of one (1) storage areas. Findings: 1. Observation by surveyor during the laboratory tour on April 25, 2024 at 9:42 a.m. revealed supplies stored in the laboratory to include, but not limited to, the following: a) BD Vacutainer K2EDTA Blood Collection Tubes - Manufacturer's storage requirements 4-25 degrees Celsius b) BD Vacutainer SST Blood Collection Tubes -

Manufacturer's storage requirements 4-25 degrees Celsius 2. Review of the laboratory's temperature logs from January 2023 through December 2023 revealed the laboratory defined the room temperature acceptable upper limit as 32 degrees Celsius which exceeded the manufacturer's acceptable upper limit. 3. In interview on April 25, 2024 at 2:45 p.m., the Technical Consultant confirmed the upper limit room temperature exceeded the manufacturer's acceptable upper limit.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, review manufacturer's package insert and laboratory calibration verification records, as well as interview with personnel, the laboratory failed to perform calibration verification procedures for Sodium (Na) at least every six (6) months for the Ortho Vitros 350 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on April 25, 2024 at 9:42 a.m. revealed the laboratory utilized an Ortho Vitros 350 for chemistry testing. 2. Review of the "Vitros Instructions for Use" for sodium under the section "When to Calibrate" revealed "When government regulations require. For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months." 3. Review of 2023 and 2024 calibration verification records revealed the laboratory did not have documentation of calibration verification for Sodium at least every six months. 4. In interview on April 25, 2024 at 3:15 p.m., the Technical Consultant stated the laboratory did not perform a calibration verification on Sodium at least every six (6) months.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6016.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of performance for Wet Prep and Potassium Hydroxide (KOH) testing at least twice per year. Refer to D5217. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for laboratory supplies stored in one (1) of one (1) storage areas. Refer to D5413. 3. Based on observation by surveyor, review of calibration and calibration verification records, and interview with personnel, the laboratory failed to perform calibration verification procedures for Sodium (Na) at least every six (6) months for the Ortho Vitros 350 analyzer. Refer to D5439.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for Sodium in two (2) of three (3) consecutive events in 2023, resulting in an initial unsuccessful performance. Refer to D2096.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the proficiency testing evaluations were reviewed. Refer to D5211.

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 maintained. Refer to D5209.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for laboratory supplies stored in one (1) of one (1) storage areas. Refer to D5413. 2. Based on observation by surveyor, review of calibration and calibration verification records, and interview with personnel, the laboratory failed to perform calibration verification procedures for Sodium (Na) at least every six (6) months for the Ortho Vitros 350 analyzer. Refer to D5439.

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing microalbumin testing on the DCA Vantage analyzer included monitoring the recording and reporting of test results for one (1) of one (1) testing personnel. Findings: 1. Review of the personnel records for 2023 and 2024 annual competency revealed the laboratory did not include documentation of monitoring the recording and reporting of test results. 2. In interview on April 25, 2024 at 1:54 p.m., the Technical Consultant confirmed the laboratory did not have the documentation as identified above.</p>
<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing microalbumin testing on the DCA Vantage analyzer included review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance for one (1) of one (1) testing personnel. Findings: 1. Review of the personnel records for 2023 and 2024 annual competency revealed the laboratory did not include documentation of review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance. 2. In interview on April 25, 2024 at 1:54 p.m., the Technical Consultant confirmed the laboratory did not have the documentation as identified above.</p>
<p>D6050</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing microalbumin testing on the DCA Vantage analyzer included direct observation of performance of instrument maintenance and function checks for one (1) of one (1) testing personnel. Findings: 1. Review of the personnel records for 2023 and 2024 annual competency revealed the laboratory did not include documentation of direct observation of performance of instrument maintenance and function checks. 2. In interview on April 25, 2024 at 1:54 p.m., the Technical Consultant confirmed the laboratory did not have the documentation as identified above.</p>
<p>D6052</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi)</p>

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 the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessments for one (1) of one (1) laboratory testing personnel included assessment of problem solving skills for moderate complexity testing in 2023 and 2024. Findings: 1. Review of personnel records for 2023 and 2024 competency revealed the laboratory did not include documentation to support assessment of problem solving. 2. In interview on April 25, 2024 at 12:35 p.m., the Technical Consultant confirmed the laboratory did not have documents to support the assessment of problem solving skills.