

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397620	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Tc Fam Med Clintonville	Street Address, City, State 370 S Main Street, Clintonville, WI	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION 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 surveyor review of laboratory records and procedures and interview with the Technical Consultant, the laboratory did not perform calibration verification procedures every six months in 2023 and 2024. Two of the last three calibration verifications did not meet the six-month requirement. Findings include: 1. Review of calibration verification records for the Siemens epoc analyzer showed the laboratory completed calibration verification on July 19, 2024, December 21, 2023, and May 18,</p>

2023. 2. Review of the "Siemens Epoc BGEM Orange Test Card" procedure, Section V. b. iv., 'Epoc Calibration Verification': "1. Perform every six months or after troubleshooting, and analyzer replacement." 3. Interview with the Technical Consultant on September 19, 2024, at 1:00 PM confirmed staff did not perform the calibration verification procedures within six months as required.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature records from January to August 2024, observation of reagent storage, and interview with the Technical Consultant, personnel did not document corrective actions on three of three days when they documented refrigerator temperatures that were not in the acceptable range for reagent storage. Findings include: 1. Review of the 'ThedaCare Physicians Clintonville Lab Temperature Logs' for January through August 2024 showed the logs identified the acceptable refrigerator temperature as 2-8 degrees Celsius (C). Review of the logs showed the following dates with unacceptable temperatures. The records showed no evidence personnel took corrective actions on days the temperatures were not acceptable. Date / Temperature (degrees C) March 27 / 1 April 8 / 10 July 5 / 1 2. Observation of the laboratory refrigerator on September 19, 2024, at 12:45 PM revealed the refrigerator contained reagents and controls requiring storage at 2 - 8 degrees C. 3. Interview with the Technical Consultant on September 19, 2024, at 1:00 PM confirmed personnel did not document corrective actions when they recorded refrigerator temperatures outside the acceptable range.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs and analyzer maintenance records, and interview with the Manager Laboratory Services (Staff A), the quality assessment review of worksheets and logs did not identify problems with documentation of temperatures and maintenance in six of eight months in 2024. Findings include: 1. Review of temperature logs and maintenance records for the DxH 520 and DCA Vantage analyzers from January through August 2024, showed testing personnel did not document required quality assessment activities on the following worksheets and the Technical Consultant did not identify the missing documentation during their review of the worksheets. Temperature logs: Testing personnel did not document temperatures on February 8. Testing personnel did not document corrective actions when temperatures were not within the acceptable range on March 27, April 8, and July 5. See D5785. DxH analyzer maintenance records: Testing personnel did not

document daily maintenance on May 30 or August 8. Testing personnel did not document monthly maintenance in May. DCA Vantage maintenance records: The log showed the quarterly optics test was due in January, April, July, and October. Documentation showed testing personnel performed the optics test on April 3, 2024, and August 21, 2024. The July log did not document an optics test and did not show the Technical Consultant identified testing personnel had not performed the optics test in July. 2. Interview with Staff A on September 19, 2024, at 11:20 AM confirmed the Technical Consultant did not document identification of the missed items and confirmed the quality assurance program did not identify problems that required correction.

D6067

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of personnel records and interview with the Manager of Laboratory Services (Staff A), the laboratory did not complete documentation of training for two of two new Testing Personnel (Staff B and C) to ensure testing personnel had the skills and knowledge required to ensure accurate testing. Findings include: 1. Review of personnel records for two new testing personnel showed no documented evidence of training for testing on the Siemens epoc, Beckman Coulter DxH 520, or Siemens DCA Vantage analyzers. Further record review showed staff C had documented training for the Siemens DCA Vantage analyzer at another ThedaCare facility. 2. Interview with Staff A on September 19, 2024, at 9:20 AM confirmed the laboratory did not complete documentation of training for Staff B and C for the laboratory's non-waived test systems.