

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1078297	(X3) Date Survey Completed 05/21/2018
Name of Provider or Supplier Corinth Family Medical Center	Street Address, City, State 1921 Droke Road, Corinth, MS	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records since last survey, 5/17/16 through 5/21/18 and confirmation with test personnel #2 at 3:30 pm on the day of survey 5/21/18, the laboratory failed to monitor and document the temperature of the laboratory room and refrigerator. Findings include: On the following days temperatures of the laboratory room and refrigerator were not documented as performed: July 16, 2016 through July 29, 2016 February 28, 2017 through May 21, 2018 Maintaining appropriate temperatures according to the instructions of the manufacturer is essential for optimal test performance. A. The Medonic CA 620 rinse and diluent should be stored at temperature of 4-35 degrees Celsius(C). B. The Medonic CA 620 hematology analyzer instrument specifications require a room temperature of 18-32 degrees C. C. The Medonic CA 620 Quality Control and calibration material refrigerator storage requirement is 2-10 degrees C and needs to warm up each day at room temperature before testing.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on Boule Medonic CA 620 calibration documentation and interview with testing personnel at 4:30 pm on the day of survey, 5/21/18, the laboratory failed to perform calibration on the Medonic CA 620 hematology analyzer at least once every 6 months according to the frequency required by the manufacturer. Calibration has not been documented as performed since 4/26/17. This time frame exceeds the 6 month manufacturer's calibration requirement. THIS IS A REPEAT DEFICIENCY

D6019

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records and lack of documentation available for review, the laboratory director failed to ensure an approved corrective action plan was followed when the results were found to be unacceptable. The following proficiency test was graded less than 80% with no corrective action taken: Hematology was scored at 68% for the 2nd event of 2016.

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 personnel records since last survey and confirmation with staff at 4:30 pm, the day of survey, the technical consultant failed to evaluate annually and document the performance of testing personnel #1 (as listed on the Centers for Medicare & Medicaid 209 form) for the years 2017 and 2018.

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 testing personnel records the day of survey and interview with testing personnel listed as #1 and #2 on the CMS (Centers for Medicare & Medicaid Services) 209 Personnel Form, testing personnel #2 had no documented training for proper instrument use on the Medonic CA 620 hematology analyzer, collection and labeling of specimens or reporting of laboratory test results.