

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2106196	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier My Family Healthcare, Llc	Street Address, City, State 1708 Delivery Lane, Durant, OK	
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	The findings were reviewed with the technical consultant, testing person #1 and the clinic office manager at the conclusion of the survey.
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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Medonic M Series analyzer. (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the room temperature be maintained within the range of 18 - 32 degrees celsius (C); (3) The surveyor reviewed laboratory temperature records from November 2016 through May 2018 which verified the room temperature readings were less than 18 degrees C for 3 of 18 months as follows: (a) December 2017 - 1 of 31 room temperature readings were documented as less than 18 degrees C (day 26); (b) January 2018 - 14 of 31 room temperature readings were documented as less than 18 degrees C (days 2,3,4,5,8,9,10,11,12,16,22,24,25,26); (c) February - 2 of 28 room temperature readings were documented as less than 18 degrees C (days 5,13); (4) The surveyor reviewed the records with the technical consultant who stated the room</p>

temperature of the laboratory had been maintained below 18 degrees C as indicated above.

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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M Series analyzer; (2) The surveyor reviewed October 2016 through May 2018 (19 months) manufacturer's maintenance logs for the analyzer with the following identified: (a) Monthly Cleaning (Hypochlorite) and Clot Prevention (Enzymatic) (i) The monthly cleaning procedure had not been documented as performed during: (aa) December 2016 (bb) October 2017 (3) The surveyor reviewed the records with the technical consultant who stated there was no evidence the above maintenance had been performed as required.

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 a review of records and interview with the technical consultant, the laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2016, 2017, and 2018 proficiency testing records. It was identified for 1 of 5 events, the attestation statement had been signed approximately 2 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2018 Hematology Event - The samples had been tested on 03/23/18 and the attestation statement had not been signed by the laboratory director or designee until 05/06/18. (2) The surveyor reviewed the findings with the technical consultant that the attestation statement must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.