

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1043999	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Family Care Center Of Durant	Street Address, City, State 2149 Ed F Davis Rd, 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 recertification survey was performed on 11/16/2021. The findings were reviewed with the technical consultant, testing person #1, and clinic manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to verify the stated value of control materials before they were put into use for 3 of 9 lot numbers. Findings include: (1) On 11/16/2021 at 11:45 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of manufacturer control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) The surveyor reviewed records for 9</p>

control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 3 of 9 lot numbers as follows: (a) Low control lot #22103-31, Normal control lot # 22103-32 and High control lot #22103-33 used from 06/01/2021 through 06/30/2021. (3) The findings were reviewed with the technical consultant and testing person #1. Testing person #1 stated on 11/16/2021 at 02:05 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.

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 a review of records and interview with the technical consultant and testing person #1, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for 1 of 2 persons. Findings include: (1) On 11/16/2021 at 11:45 am, testing person #1 stated to the surveyor routine CBC (Complete Blood Count) testing was performed in the laboratory using the Medonic M Series analyzer; (2) The surveyor reviewed personnel records for 2 persons who performed moderate complexity testing during 2019, 2020, and to date in 2021. For 1 of the 2 persons (testing person #3), there was no evidence an annual evaluation had been performed as follows: (a) Testing Person #3 - Between 09/19/2019 and 04/16/2021 (3) The surveyor reviewed the findings with the technical consultant who stated on 11/16/2021 at 12:25 pm, the annual evaluation had not been performed as indicated above.