

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0984680	<b>(X3) Date Survey Completed</b>  06/26/2018
<b>Name of Provider or Supplier</b>  Family Medical Center	<b>Street Address, City, State</b>  1121 Neo Loop, Grove, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the technical consultant, the laboratory failed to have complete written policies and procedures. 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</p>

performed on the Diatron Abacus 3 CP analyzer. (2) Later during the survey, the surveyor reviewed written hematology policies and procedures. The following could not be located: (a) Reference intervals (normal values) (3) The surveyor reviewed the findings with the technical consultant, and asked if the above was available. The technical consultant stated a policy defining the reference intervals had not been written.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on a review of records, and interview with the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Diatron Abacus 3CP analyzer; (2) Later during the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 06/01/18 at 09:13 am; the second report was for an adult male patient with the testing performed on 03/15/18 at 09:19 am. Both reports included the same reference intervals for the CBC parameter of RBC (Red Blood Cell which was: (a) RBC - 3.80 - 6.10 M/UL (3) The surveyor reviewed the findings with the technical consultant who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.