

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0996152	<b>(X3) Date Survey Completed</b>  03/14/2018
<b>Name of Provider or Supplier</b>  Family First Medical Center	<b>Street Address, City, State</b>  3820 Crestwood Ln, Idaho Falls, ID	
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>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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 an interview with the laboratory manager and a procedure manual review, the laboratory procedure for complete blood count (CBC) testing on the Sysmex XP-100 failed to include criteria for specimen rejection, control and calibration procedures, panic values, and corrective actions when the test system fails the laboratory's established criteria since December 2017. Findings: 1. A review of the laboratory procedure manual revealed the lab failed to include quality control and calibration criteria, corrective action procedures, panic values, and specimen rejection criteria since the Sysmex was established in December 2017. 2. An interview on</p>

March 14, 2018 at 12:30 PM, with the laboratory manager, confirmed the laboratory failed to include the requirements for the procedure manual.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to establish and follow a written procedure for assessing employee competency at least semiannually during the first year of patient testing on the Sysmex analyzer used to test complete blood counts (CBCs) since the last survey on July 12, 2016. Findings: 1. A record review of personnel documents revealed 6 out of 12 testing personnel listed on the CMS-209 Personnel Report form, failed to have competency assessments performed at least semiannually during the first year of patient testing. 2. An interview on March 14, 2018 at 11:45 AM, with the laboratory manager, confirmed the laboratory failed to perform competency at least semiannually on 8 testing personnel.