Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021708	(X3) Date Survey Completed 11/30/2021
Name of Provider or Supplier Family Medical Group Of Texarkana, Llp	**Street Address, City, State** 2101 Galleria Oaks, Texarkana, TX	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records and interview facility personnel found that the laboratory failed to include the procedure for establishing acceptable ranges for quality control materials in their own policy titled Quality Control Policy. The findings included: 1. Review of the policy titled Quality Control Policy found no instruction included for the establishment of acceptable limits for each new lot of quality control material used for ensuring the accuracy and reliability of results obtained using the Abbott Architect Chemistry analyzer 2. Review of quality control records for the Technopath Multichem S Plus chemistry controls lots

	19409190 and 10005200 (currently in use) found the laboratory failed to have evidence supporting the acceptable ranges in use. 3. Interview of testing person 1 conducted November 30, 2021 at 2:36 PM confirmed that she did not receive the new lot in a timely fashion to establish new means and limits before the expiration of the previous lot of control material. Interview of the Technical Consultant conducted on November 30, 2021 at 2:31 PM confirmed that the laboratory policy did not include instructions for establishing acceptable limits for each new lot of quality control material.