Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1030098	**(X3) Date Survey Completed** 07/11/2018
Name of Provider or Supplier Family First Medical Center	**Street Address, City, State** 2046 S Mccoll Road, Edinburg, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for preparation of urine for microscopic examination. The findings were: 1. Direct observation in the laboratory on July 11, 2018 at 09:30 hours revealed the laboratory's primary testing person preparing a urine for microscopic examination. She was observed pouring 6 cc of urine into a conical centrifuge tube. She proceeded to spin the urine at 1800 rpm for 10 minutes. 2. Review of the laboratory's policy titled, "Qualitative Technique for Examining Urine Sediment" approved by the laboratory director on January 2, 2014,

	stated, "1. Mix the specimen well, and pour 10 to 15ml into a conical centrifuge tube. Centrifuge at speeds form [sp] 1500 to 2000 RPM for 5 minutes." 3. According to the CLIA 116 form, approved by the laboratory director on July 6, 2018, the laboratory performs 300 urine microscopics annually. 4. The above findings were confirmed in interview of testing personnel one (as listed on Form CMS-209) on July 11, 2018 at 09:30 hours in the laboratory. She stated, "Yes" when asked if she always spins the urines for 10 minutes. She further revealed that she normally uses 6 to 7 cc of urine, "about half full." Key: RPM - rotations per minute
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory polices, review of patient results, and confirmed in staff interview, it was revealed that the laboratory failed to have documentation that their policies and procedures reflected current laboratory practice. The findings were: 1. Review of the laboratory's policy titled, "Policy for Abnormal Differentials" approved by the laboratory director on October 15, 2004 stated, "It will be the policy of this laboratory to send out all abnormal differentials. This laboratory will perform only normal differentials. A normal differential will be described as having only normal cells: lymphocytes, monocytes, basophels [sp], eosinophils, neutrophils, and normal size and shape RBC and platelets. If your CBC instrumentation is showing alarms (RI, R2, M3, ETC,) in the differential section of the report, it will be considered an abnormal differential and should be send out." 2. Random review of patient results from March, April, and May 2018 revealed the laboratory's current practice was to invalidate differential flags prior to providing results to the healthcare provider. The provider would then determine if the specimen should be sent for confirmation. 3. The policy did not reflect the laboratory's current practice and referred to flags from a previous analyzer, 4. The findings were confirmed in an interview with the technical consultant on July 11, 2018 in the laboratory director's office at 10:20 hours.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), and confirmed in interview of facility personnel, the laboratory failed to provide documentation that the QA (quality assessment) portion of the IQCP included

	procedures for ongoing monitoring of the effectiveness of its IQCP. The findings were: 1. Review of the laboratory's IQCP revealed it was approved by the laboratory director on January 4, 2016. 2. Further review of the study revealed, "B.___The IQCP continues to be sufficient to mitigate risk in my laboratory." This portion was also signed on January 4, 2016. 3. Review of the quality assessment portion of the IQCP failed to include procedures for ongoing monitoring of the IQCP. 4. The above findings were confirmed in interview of the technical consultant on July 11, 2018 at 11:30 hours in the laboratory director's office.