Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D1083412	04/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Fe Family Clinic Llc	8305 N La Homa Blvd, Suite B, Mission, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure Henry Schein Helicobacter pylori tests were performed only on patients 19 years of age or older. The findings were: 1. Review of manufacturer's instructions stated, "This assay has not been established for patients less than 19 years of age." 2. Review of patient test logs revealed the following 3 of 3 patients who were tested when they were less than 19 years of age (see patient alias list). 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to test only patients 19 years of age or older. No documentation was provided. 4. An interview with the technical consultant on 04/19 /2048 at 1245 hours in the patient exam room confirmed the findings.
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: Based on review of laboratory policy, review of manufacturer's instructions, review of patient test results, and staff interview, it was revealed the laboratory failed to follow its own policy to resolve abnormal flags on CBC (complete blood count) results. The findings were: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" approved by the laboratory director on 02/20/2015 stated, " ...If the flags persist, then report and have the clinician review the patient's results in totality and review the patient clinically. The lab will then perform whatever follow-up action the clinician requests." 2. A review of the manufacturer's instructions for the Mindray 3200 hematology analyzer under, Histogram flags" stated, "The system will flag abnormal historgrams." The operator's manual went on to state: "Abnormal WBC histograms will be flagged by one of the markings: R1, R2, R3, R4, and Rm." R1: indicates abnormality on the left side of the lymphocyte hump and possible presence of platelet clumps, giant platelets, nucleated red blood cells, insolvable red cell, protein and lipoid debris in sample, or electrical noise. R2: indicates abnormality between the lymphocyte hump and the mid-sized cell are and possible presence of abnormal lymphocyte, plasma cell, atyplical lymphocyte, original granulocytes in the sample and eosinophilia or basophilia. R3: indicates abnormality between the mid-sized cell area and the granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or eosinophilia. R4: indicates abnormality on the right side of the granulocytes hump and neutrophilia. Rm: indicates at least two R flags. 3. Random review of patient test results from March and April 2018 revealed the following 5 of 17 patients whose results were reported to the healthcare provider prior to the flags being resolved. Date Patient ID Flag 03-09-2018 RV777093 R2 03-09-2018 4436 R2 03-09-2018 5650 R2 03-09-2018 3473 R2 03-10-2018 DA393824 R2 4. The laboratory was asked to provide documentation of a policy that resolved abnormal flags on CBC results prior to their release to the healthcare provider. No documentation was provided. 5. An interview with the technical consultant on 04/19 /2018 at 0955 hours in the patient exam room confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation made during the tour of the facility at 0910 hours on 04/19 /2018 and confirmed in interview, the laboratory failed to ensure that expired supplies

	were not available for patient testing. The findings included 1. Observations made during the tour of the facility found two boxes of (12 vials each) Cary Blair w /indicator. Lot 695846 Expiration Date: 12-12-2016 Lot 524325 Expiration Date: 01-05-2016 2. In an interview of testing personnel one as listed on Form CMS-209 on 04 /19/2018 at 0915 hours in the laboratory, she agreed that the supplies were expired but said they were not used for patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of maintenance records, and confirmed in interview, it was revealed that the laboratory failed to perform daily shutdown for 11 of 25 days in October 2017 on the Mindray 3200 hematology analyzer. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on 02/20/2015 stated, "Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations. Document all maintenance performed on the test systems in use. Also, document repairs and remedial action on all test systems" 2. A review of the manufacturer's instructions for the Mindray 3200 hematology analyzer under, "Shutdown" stated, "Perform the Shutdown procedure to shut down the analyzer daily." 3. A review of the laboratory's maintenance records from July 2017 to April 2018 revealed the laboratory failed to document the Shutdown procedure for the following 11 consecutive testing days out of 25 in October 2017: 10-04-2017 10-05-2017 10-06-2017 10-07-2017 10-09-2017 10-10-2017 10-11-2017 10-12-2017 10-13-2017 10-14-2017 10-15-2017 4. The laboratory was asked to provide documentation of the missing maintenance records. No documentation was provided. 5. An interview of the technical consultant on 04/19 /2018 at 1131 hours in the patient exam room confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- 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. This STANDARD is not met as evidenced by:

	Based on direct observation, review of the manufacturer's instructions for R & D Systems CBC-3D hematology controls for the Mindray 3200 hematology analyzer, review of the laboratory's quality control records from July 2017 to March 2018, and staff interview, it was revealed the laboratory failed to have documentation of establishing its own means and acceptable ranges as required by the manufacturer. The findings were: 1. Direct observation made in the laboratory on 04/19/2018 at 1100 hours revealed the following means and ranges were entered into the Mindray 3200 hematology analyzer: Lot B0218 (normal control) WBC 7.6 +/- 1.0 RBC 4.77 +/- 0.24 HGB 13.8 +/- 0.6 HCT 40.1 +/- 2.0 PLT 261 +/- 40 2. A review of the manufacturer's instructions for the CBC-3D hematology controls under, "Performance Characteristics" stated, "For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean ..." 3. Review of the laboratory's quality control records from July 2017 to March 2018 revealed the laboratory implemented the following lot numbers: Lot B02118 Expiration Date: 05-05-2018 In use: 03-29-2018 Lot B1117 Expiration Date: 02-05-2018 In use: 10-30-2017 Lot B0817 Expiration Date: 11-05-2017 In use: 07-03-2017 4. The laboratory was asked to provide documentation of establishing its own means and acceptable ranges as required by the manufacturer. No documentation was provided. 5. An interview with the technical consultant on 04/19/2018 at 1110 hours in the patient exam room confirmed the findings.