Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1083412	07/14/2026
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from 2025 and 2026, and staff interview, the laboratory failed to retain package inserts for 6 of 7 lots. The findings included: 1. A review of the laboratory's CDS Boule Con diff hematology quality control records from October 2025 to July 2026 identified the laboratory utilized the following lots of quality control material: Lot: 22502 Lot: 22505 Lot: 22507 Lot: 22509 Lot: 22510 Lot: 22601 Lot: 22603 2. The laboratory failed to retain the package inserts for 6 of the 7 lots. They were: Lot: 22502 Lot: 22505 Lot: 22507 Lot: 22509 Lot: 22510 Lot: 22601 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 07 /14/2026 at 0945 hours in the laboratory.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) (b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Boule Con Diff hematology controls, surveyor observation of control material currently in use in the laboratory, and staff interview, the laboratory failed to have documentation of revised expiration dates on opened control material on 3 of 3 vials. The findings included: 1. The manufacturer's instructions for the Boule Con Diff hematology controls (201043L, R03.31.15) under the sections titled "Storage and Stability" stated: "Open vial stability 14 days after opening when returned to refrigerator after each use." 2. Surveyor observation of control material currently in use in the laboratory on 07/14/2026 at 0950 hours in the laboratory identified 3 levels of Boule Con Diff controls: Lot: 22602 Low control: no opened date no revised expiration date Normal control: no opened date no revised expiration date High control: no opened date no revised expiration date 3. The laboratory failed to have a mechanism in place to monitor the revised expiration date on control material once opened. 4. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 07 /14/2026 at 0950 hours in the laboratory.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's Medonic calibration records from 2024, 2025 and 2026, and staff interview, the laboratory failed to have documentation of performing 3 of 5 calibrations. The findings included: 1. The laboratory' policy titled "Instrument Operation and Maintenance" stated: "Calibration of all laboratory instruments will be every six months..." 2. A review of the laboratory's Medonic calibration records from 2024, 2025 and 2026 determined calibrations were performed at the following times: January 2024 November 2024 (10 months later) 3. The laboratory did not have documentation of performing calibrations in 2025 and 2026. 4. Testing personnel number 1 (as listed on Form CMS 209) on 07 /14/2026 at 1030 hours in the laboratory confirmed the findings.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from 2025 and 2026, and staff interview, the laboratory failed to have documentation of verifying 7 of 7 lots prior to use. The findings included: 1. A review of the laboratory's CDS Boule Con diff hematology quality control records from October 2025 to July 2026 identified the laboratory utilized the following lots of quality control material: Lot: 22502 Lot: 22505 Lot: 22507 Lot: 22509 Lot: 22510 Lot: 22601 Lot: 22603 2. Further review of the records determined the laboratory did not have documentation of verifying each new lot of quality control material prior to use. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 07/14/2026 at 0945 hours in the laboratory.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's room temperature records from December 2025 to April 2026, and staff interview, the laboratory failed to have documentation of performing corrective actions on 5 of 5 days when the documented room temperature was outside the laboratory's established acceptable range. The findings included: 1. A review of the laboratory's room temperature records from December 2025 to April 2026 determined the laboratory acceptable room temperature range was defined as 73 to 77F. 2. Further review of the room temperature records identified the following days where the documented room temperature was outside the laboratory's acceptable range: a) December 2025 Date Temp 12/1 72F 12/2 72F 12/5 72F b) April 2026 Date Temp 4/06 72F 4/07 72F 3. The laboratory failed to have documentation of performing corrective actions on the identified days. 4. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings on 07/14/2026 at 1045 hours in the laboratory.
D5813	TEST REPORT CFR(s): 493.1291(g) (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test

	result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's Critical Value Notification Logs from January 2025 to April 2026, and staff interview, the laboratory failed to document the time of the notification of critical values and result read back for 30 of 30 panic values. The findings included: 1. The laboratory's Critical Value Notification Logs from January 2025 to April 2026 required documentation of the following information: Date Time Report called Patient name Test Requested Test Result Name of person calling Name of person receiving results Results read back 2. Further review of the records determined the laboratory failed to have documentation of time of the notification and read back to ensure accuracy in reporting for 30 of 30 panic values identified (see Patient Alias List number 2). 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the finding in an interview conducted on 07/14/2026 at 1009 hours in the laboratory.