Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1083412	06/06/2024
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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1215 Condition: Hematology; 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director; 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; testing personnel.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory failed to meet the requirements for the specialty of hematology. Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control material prior to testing 78 patient specimens on 10 of sixty one days in August and September of 2023. (See D 5447) Based upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory quality assurance program failed to identify that 78 patient specimens were tested and reported on 10 of sixty one days in August and September of 2023 without testing at least two level of quality control materials. (See D 5791)
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control material prior to testing 78 patient specimens on 10 of sixty one days in August and September of 2023. The findings included: 1. Review of the laboratory's quality assurance plan found on page 3 under the heading QUALITY CONTROL: "Quality control samples are analyzed each day of patient testing (as outlined in the technical procedure manual), and must be within acceptable limits before patient samples may be analyzed." 2. Review of the laboratory's own written policy titled Control Policy (dated 09/27/23) found on page 1: "For Quantitative testing, two levels of controls shall be run for every procedure on each day of use or for every eight hours of operation. Control materials should correlate with the specimen matrix. Controls will be evaluated daily against expected range then remedial actions must also be recorded. All control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All controls results and remedial actions must be recorded and records kept for at least two years. Patient testing must not be performed or reported when control test results are outside the expected range." 3. Review of monthly quality control records for August and September 2023 found the laboratory failed to test at least two levels of quality control materials on 10 days as follows: August 1, 2023 August 2, 2023 August 3, 2023 August 4, 2023 August 7, 2023 August 8, 2023 August 9, 2023 September 25, 2023 September 26, 2023 September 27, 2023 4. Review of patient Sample Summary Reports found the laboratory tested 78 patient specimens in August and September without testing quality control materials as follows: August 1, 2023 - Patient sequence 543, 544, 545, and 546 August 2, 2023 - Patient sequence 553 and 554 August 3, 2023 - Patient sequence 559 August 4, 2023 - Patient sequence 565, 566, 567 and 568 August 7, 2023 - Patient sequence 574, 575, 576 and 577 August 8, 2023 - Patient sequence 582, 583, 584, 585, 586, 587, 588, 589 and 590. August 9, 2023 - Patient sequence 597, 598, 599 and 560 September 25, 2023 - Patient sequence 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074 and 1075 September 26, 2023 - Patient sequence 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094 and 1095 September 27, 2023 - Patient sequence 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115 and 1116 5. During interview of the clinical consultant conducted June 6, 2024 at 10:46 AM, he stated he did not know patient specimens were tested and reported without testing at least two levels of quality control materials
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory quality assurance program failed to identify that 78 patient specimens were tested and reported on 10 of sixty one days in August and September of 2023 without testing at least two level of quality control materials. The findings included: 1. Review of the laboratory's quality assurance plan found on page 3 under the heading QUALITY CONTROL: "Quality control samples are analyzed each day of patient testing (as outlined in the technical procedure manual), and must be within acceptable limits before patient samples may be analyzed." 2. Review of the laboratory's own written policy titled Control Policy (dated 09/27/23) found on page 1: "For Quantitative testing, two levels of controls shall be run for every procedure on each day of use or for every eight hours of operation. Control materials should correlate with the specimen matrix. Controls will be evaluated daily against expected range then remedial actions must also be recorded. All control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All controls results and remedial actions must be recorded and records kept for at least two years. Patient testing must not be performed or reported when control test results are outside the expected range." 3. Review of monthly quality control records for August and September 2023 found the laboratory failed to test at least two levels of quality control materials on 10 days as follows: August 1, 2023 August 2, 2023 August 3, 2023 August 4, 2023 August 7, 2023 August 8, 2023 August 9, 2023 September 25, 2023 September 26, 2023 September 27, 2023 4. Review of patient Sample Summary Reports found the laboratory tested 78 patient specimens in August and September without testing quality control materials as follows: August 1, 2023 - Patient sequence 543, 544, 545, and 546 August 2, 2023 - Patient sequence 553 and 554 August 3, 2023 - Patient sequence 559 August 4, 2023 - Patient sequence 565, 566, 567 and 568 August 7, 2023 - Patient sequence 574, 575, 576 and 577 August 8, 2023 - Patient sequence 582, 583, 584, 585, 586, 587, 588, 589 and 590. August 9, 2023 - Patient sequence 597, 598, 599 and 560 September 25, 2023 - Patient sequence 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074 and 1075 September 26, 2023 - Patient sequence 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094 and 1095 September 27, 2023 - Patient sequence 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115 and 1116. 5. Review of the monthly quality assurance reports for September and October 2023 found: September 10, 2023 - " I visited your office on September 6, 2023 and this is the monthly report. Hematology: Patient run and QC was compatible and suitably documented. The Levine Jennings curve was done and filed correctly. The maintenance was performed and placed in the books. The comparison report was done and logged accordingly." The review failed to identify patients tested between August 1-9, 2023 without testing quality control material and no remedial actions taken. October 27, 2023 - "I visited your office on October 27, 2023 and this is the monthly report. Hematology: Patient run and QC was compatible and suitably documented. The Levine Jennings curve was done and filed correctly. The maintenance was performed and placed in the books. The comparison report was done and logged accordingly." The review failed to identify patients tested between September 25-27, 2023 without testing quality control material and no remedial actions taken. 6. During interview of the technical consultant conducted June 6, 2024 at 11:57, he confirmed that he was hired as the technical consultant September 27, 2023. During his monthly visit in October 2023 he did not discover that patients had been tested and reported without quality control being tested.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory director failed to provide oversight and direction of the moderate complexity laboratory performing Hematology testing. Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control material prior to testing 78 patient specimens on 10 of sixty one days in August and September of 2023. (See D6020) Based upon review of policies and procedures, quality control records, patient test records, quality assurance reports and interview of facility personnel, the laboratory quality assurance program failed to identify that 78 patient specimens were tested and reported on 10 of sixty one days in August and September of 2023 without testing at least two level of quality control materials. (See D6021)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control material prior to testing 78 patient specimens on 10 of sixty one days in August and September of 2023. (See D 5447)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test

	records, quality assurance reports and interview of facility personnel, the laboratory quality assurance program failed to identify that 78 patient specimens were tested and reported on 10 of sixty one days in August and September of 2023 without testing at least two level of quality control materials. (See D 5791)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory director failed to ensure one of three testing personnel met minimum education requirements and had received appropriate training before testing patient specimens in Hematology. (See D 6065 and D6066)
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that one of three testing personnel failed to have documentation available for review to ensure they met minimum education requirements and had received appropriate training before testing patient specimens in Hematology. (See D 6065 and D6066)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

	high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that one of three testing personnel failed to have documentation available to ensure they met minimum education requirements for performing moderate complexity testing in Hematology. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified three testing personnel performing moderately complex testing. 2. Review of personnel records for testing person three (hired 05/13/2024) found no documentation of education available for review. 3. During interview of the technical consultant conducted June 6, 2024 at 12:10 PM, he confirmed that no education records were available for review for testing person three.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that one of three testing personnel failed to have documentation of initial training for performing moderate complexity testing in Hematology. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified three testing personnel performing moderately complex testing. 2. Review of personnel records for testing person three (hired 05/13 /2024) found no documentation of initial training available for review. 3. During interview of the technical consultant conducted June 6, 2024 at 12:10 PM, he confirmed that no training records were available for review for testing person three.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the testing personnel failed to test at least two levels of Hematology quality control material prior to testing 78 patient specimens on 10 of sixty one days in August and September of 2023. The findings included: 1. Review of the laboratory's quality assurance plan found on page 3 under the heading QUALITY CONTROL: "Quality control samples are analyzed each day of patient testing (as outlined in the technical procedure manual), and must be within acceptable limits before patient samples may be analyzed." 2. Review of the laboratory's own written policy titled Control Policy (dated 09/27/23) found on page 1: "For Quantitative testing, two levels of controls shall be run for every procedure on each day of use or for every eight hours of operation. Control materials should

	correlate with the specimen matrix. Controls will be evaluated daily against expected range then remedial actions must also be recorded. All control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All controls results and remedial actions must be recorded and records kept for at least two years. Patient testing must not be performed or reported when control test results are outside the expected range." 3. Review of monthly quality control records for August and September 2023 found the laboratory failed to test at least two levels of quality control materials on 10 days as follows: August 1, 2023 August 2, 2023 August 3, 2023 August 4, 2023 August 7, 2023 August 8, 2023 August 9, 2023 September 25, 2023 September 26, 2023 September 27, 2023 4. Review of patient Sample Summary Reports found the laboratory tested 78 patient specimens in August and September without testing quality control materials as follows: August 1, 2023 - Patient sequence 543, 544, 545, and 546 August 2, 2023 - Patient sequence 553 and 554 August 3, 2023 - Patient sequence 559 August 4, 2023 - Patient sequence 565, 566, 567 and 568 August 7, 2023 - Patient sequence 574, 575, 576 and 577 August 8, 2023 - Patient sequence 582, 583, 584, 585, 586, 587, 588, 589 and 590. August 9, 2023 - Patient sequence 597, 598, 599 and 560 September 25, 2023 - Patient sequence 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074 and 1075 September 26, 2023 - Patient sequence 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094 and 1095 September 27, 2023 - Patient sequence 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115 and 1116 5. During interview of the clinical consultant conducted June 6, 2024 at 10:46 AM, he stated he did not know patient specimens were tested and reported without testing at least two levels of quality control materials