Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1083412	04/30/2021
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 surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions for storage of AimStep Pregnancy test kits. The findings were: 1. Surveyor observation made on April 30, 2021 at 09:10 hours during the initial tour of the facility found two boxes of AimStep Pregnancy test kits stored in the small Kenmore refrigerator. Box 1 (two tests left in box) Lot # 91762 Expiration Date: 09-30-2021 Box 2 (30 of 30 tests left in box) Lot # 00993 Expiration Date: 09-30-2021 2. Review of the manufacturer's instructions (6#62-97030, Revised 02/11) under "Storage and Stability" it stated, "Store at room temperature (15 to 30 degrees Celsius). 3. The laboratory was asked to provide documentation of following the manufacturer's storage instructions for AimStep Pregnancy test kits. No documentation was provided. 4. An interview with the technical consultant on April 30, 2021 at 11:15 hours in the office 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: I. Based on surveyor observation, review of manufacturer's instructions, review of quality control records, manufacturer's reagent specifications, patient test records, and confirmed in interview of facility personnel, the laboratory used expired quality control materials after their two-week opened and revised expiration date. The findings were: 1. Surveyor observation on April 30, 2021 at 09:10 hours during the initial tour of the facility found one set of Boule Con-Diff controls in the small Kenmore refrigerator with an open date of 04-29-2021. The surveyor then observed a second set of Boule Con-Diff controls in the large Kenmore refrigerator (same lot) with an open date of 04-09-2021. Because of the two-week opened and revised expiration date, the set of controls with an open date of 04-09-2021 expired on 04-22-2021. 2. Review of Sysmex EIGHTCHECK 3WP X-TRA manufacturer's instructions (AQ578643C) under, "Storage and shelf life after first opening" it stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees Celsius after being re-capped." 3. Review of the laboratory's quality control records from April 1, 2021 to April 30, 2021 (the date of the onsite survey), found that the laboratory used expired quality control material on the following dates: April 23, 2021 April 26, 2021 April 29, 2021 4. Review of patient records found the following patients were tested when the laboratory used expired controls: Sequence # 3981 Test Date: 04-23-2021 Sequence # 3987 Test Date: 04-26-2021 Sequence # 3991 Test Date: 04-26-2021 Sequence # 3990 Test Date: 04-26-2021 Sequence # 3989 Test Date: 04-26-2021 Sequence # 4004 Test Date: 04-28-2021 Sequence # 4005 Test Date: 04-28-2021 Sequence # 4006 Test Date: 04-28-2021 Sequence # 4007 Test Date: 04-28-2021 5. The findings were confirmed in interview with the primary testing person April 30, 2021 at 11:15 hours in the laboratory. When asked if these were the only controls she had used in the last two weeks, she stated, "Yes." II. Based on review of quality control records, patient test records, and confirmed in interview of facility personnel, the laboratory used expired quality control materials the Medonic hematology analyzer on September 24, 2020 and then proceeded to test two patient samples. The findings were: 1. Review of the laboratory's quality control records from January 2020 to March 2021 found that the laboratory used expired quality control materials on the following patient test date: September 24, 2021 Note: The laboratory tested the expired controls on September 23, 2020, September 25, 2020, and September 28, 2020 but did not test any patients on those dates. 2. Review of patient records found the following patients were tested when the laboratory used expired controls: Sequence # 2874 Test Date: 09-24-2020 Sequence # 2873 Test Date: 09-24-2020 3. The findings were confirmed in interview with the technical consultant on April 30, 2021 at 11:15 hours in the office. III. Based on surveyor observation, and confirmed in interview of facility personnel, the laboratory failed to ensure that expired EDTA test tubes were not available for use in patient testing. The findings were: 1. Surveyor observation made on April 30, 2021 at 09:10 hours during the initial tour of the facility found 8 expired EDTA test tubes in a Styrofoam rack with two other lot numbers. Lot # 9260544 Expiration Date: 01-31-2021 It could not be determined on the day of the survey that the test tubes had been used for patient testing. 2. An interview with the technical consultant on April 30, 2021 at 11:15 hours in the office confirmed the findings. Key: EDTA - ethylenediaminetetraacetic acid
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel records and confirmed in interview of facility personnel, the technical consultant failed to perform competency assessments at least twice annually for 1 of 3 testing persons who required one. The findings were: 1. Review of personnel records for testing personnel #3 (as listed on Form CMS-209) revealed she had a hire date of 02-2019. By 02-2020 two competency assessments should have been available for review. There was only one competency assessment available for review. 2. An interview with the technical consultant on April 30, 2021 at 11:15 hours in the patient exam room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services