Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2111385	08/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Four Tech Laboratory Llc	5132 N Peck Rd, El Monte, CA	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory's reagent materials and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to label reagents to indicate the opening, preparation, and expiration dates when such reagents are used. The findings included: 1. Based on the surveyor's observation during the laboratory tour on August 31, 2021 at approximately 11:40 a.m., the TP indicated that no opening, preparation, or expiration date labels were documented for all the reagents used in the laboratory. 2. The laboratory's TP affirmed in an interview conducted August 31, 2021 at approximately 11:45 a.m. that the reagents currently used to test patients' samples were not labeled with opening, preparation, and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 70,389 samples annually
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 the surveyors' observation, examination of laboratory reagents, and interview with the technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, August 31, 2021 at approximately 11:30 a.m. the surveyor found the STAT stain used for blood cells manual differential stain Lot number 361 being used beyond its expiration date (07/2017). 2. The TP affirmed on 08/31/2021 at approximately 11:45 p.m. using STAT stain reagent beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 18,308 Hematology samples which include blood cells manual differentials.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of quality control (QC) documentation, observation of culture media used in the bacteriology section and interview with the technical supervisor (TS) and general supervisor (GS); it was determined that the laboratory failed to perform QC testing on all culture media. The findings included: 1. The laboratory did not check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures. 2. The laboratory must document all control procedures performed. 3. Based on the laboratory's annual declaration submitted at the time of the survey, the laboratory analyzed and reported 975 cultures which results cannot be assured. 4. The TS and GS confirmed on august 31, 2021 at approximately 1:00 p.m. that the laboratory failed to perform and document; check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of reagent labels on day of use, expiration date of reagents, quality control logs for culture media, and interview with the testing personnel and general supervisor, it was determined that the testing personnel performing high complexity testing did not follow the laboratory's

	established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. See D5414, D5417, and D5477.