Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2111385	12/14/2018
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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on the request for patient/test records and confirmation by the technical consultant, the laboratory failed to record the time patient samples were received. Findings include: a. The laboratory was unable to provide the time of specimen receipt for all patient samples choosen (sampling consisted of six random patients, for the period January 4, 2017 to June 11, 2018). b. The technical consultant confirmed (December 14, 2018, 11:00 A.M.) that the laboratory did not record the time of specimen receipt.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of temperature charts, reagent/control package inserts and interview with the technical consultant, the laboratory failed to store control material according to manufacturer's instructions. Findings include: a. The laboratory provided

	the surveyor with a photocopy of the BIO-RAD Liquichek, Immunoassay Plus Control 1, 2, and 3 package insert (LOT 40951, 40952, and 40953, respectively, all lots have the expiry of 2019-10-31). All three controls has the manufacturer specifing storage temperature as between -20C to -70C. Controls are used in the Free Thyroxine test (FT4). b. The daily freezer temperature chart (for the above controls), the laboratory recorded 32 temperature readings (beginning at November 1,2018 through December 14, 2018). For the defined period, 3 days temperature were recorded as -20 C; the other 29 days had temperature recorded which were outside acceptable range (either -18C or -19C). c. The laboratory performs approximately 10 FT4 tests a month, even though they do not store the tests controls according to manufacturer's instructions.
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 discovery of expired vacutainer tubes and interview with the technical consultant, the laboratory failed to ensure that expired vacutainer tubes were not used. Findings included: a. During the Four Tech Laboratory LLC onsite CLIA recertification survey, discovered in the laboratory's supply area were a handful of BD Vacutainer tubes: Sodium Fluoride Potassium Oxolate 10mg/8mg, Lot #7100990, expiry 2018-08-31. b. The technical consultant confirmed (December 14, 2018, 11:20 A.M.) that the above grey top vacutainer tubes found were indeed expired and should not be used. c. The technical consultant and an owner of the laboratory stated that the laboratory does not run any tests off using grey tops; never the less, if a patient had Doctor's orders for a sendout test that requires collection be performed with a grey top vacutainer tube - there would be a chance that those expired tubes would be used.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on the lack of documents and an interview with the technical consultant, the laboratory failed to retain testing records for a proficiency testing sample. Findins include: a. The laboratory has a policy to repeat hemoglobin (HGB) samples when they are either less than 11.0 g/dL or greater than 18.0 g/dL. b. The laboratory initially tested their American Association of Bioanalysts (AAB) hematology sample #4 for HGB on 10/26/2018 at 10:23:28 P.M. The test result was 6.3 g/dL. c. The testing person confirmed (December 14, 2018, 11:55 A.M.) that the above proficiency testing sample was repeat tested due to the low initial HGB value, but was unable to produce the testing records. d. From an owner of the laboratory, the laboratory performs approximately 125 Complete Blood Counts (CBC, which include a HGB test) per month, even though the above test record could not be found.