Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2111385	04/29/2026
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
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the AAB - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) reports, five (5) randomly selected patients results, and interviews with the laboratory director (LD) and laboratory owner (LO); the laboratory failed to attain a score of at least 80 percent in Endocrinology for Prostate Specific Antigen, Total (PSA) for the second event of 2025 (Q2-2025). The findings included: 1. The laboratory obtained a score of 0% for the PSA analyte as reported by AAB-MLE PT for the Q2-2025 event. 2. The LD and LO affirmed on the day of the survey, April 29, 2025, at approximately 11:30 a. m. that the laboratory obtained the unsatisfactory proficiency score as mentioned on statement#1 for the PSA analyte. 3. Based on the laboratory's annual test volume declaration (LAB Form 144-A) signed by the laboratory director on April 28, 2026, the laboratory analyzed and reported approximately 198 PSA patient tests annually. The reliability and quality of patient tests reported during the time PT was unsuccessful cannot be assured.
D2122	HEMATOLOGY CFR(s): 493.851(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's AAB- Medical Laboratory

	Evaluation (AAB) proficiency testing (PT) records and interviews with the laboratory director (LD) and laboratory owner (LO); the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the second event for 2025 (Q2-2025) and on the first event of 2026 (Q1-2026). The findings included: 1. The AAB PT program reported an overall unsatisfactory score of 70% for the specialty of Hematology for Q2-2025 and Q1-2-26 events as follow: Q2-2025 event: a. Red Blood Cells (RBC) = 0% b. Hematocrit (NON-Waived) (HCT) = 20% c. Hemoglobin (NON-WAIVED) (HGB) = 40% Q1-2026 event: a. WBC Count (WBC) = 60% b. Partial Thromboplastin Time (PTT) = 60% c. Prothrombin Time (PT) = 60% 2. The LD and LO affirmed by interviews on April 29, 2026 at approximately 11:15 a.m. that the laboratory received the overall unsatisfactory score for the specialty of Hematology as mentioned in statement #1. 3. According to the testing declaration form CMS-116 submitted at the time of survey, the laboratory performed and reported 43,000 tests in the specialty of Hematology annually including RBC, HCT, HGB, WBC, PT and PTT during the time when the unsatisfactory PT scores were obtained. The reliability and quality of Hematology results reported could not be assured.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, five (5) randomly selected patient test results, and interviews with the laboratory director (LD) and laboratory owner (LO); the laboratory failed to have written procedures manuals for all tests, assays, and examinations performed by the laboratory available and followed by laboratory personnel .The findings included: 1. The laboratory lacked written and LD approved policies and procedure for all tests, assays and examinations currently performed in the laboratory. 2. The laboratory written procedures for the following test were missing or incomplete; Validation and Verification of new tests, Hematology procedures reflecting the current practice including Prothrombin Time, Partial Thromboplastin Time, INR calculation, urinalysis and the test performed in the Horiba Instrument. 4. Reliability of the laboratory tests' performance based on a complete laboratory procedure manual to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 5. The LD and LO affirmed by an interview on April 29, 2026, at 3:45 p.m. that the laboratory failed to provide LD signed, dated, and approved laboratory procedures for all the current tests and examinations performed in the laboratory 6. According to the testing declaration form (CMS-116) submitted at the time of survey, the laboratory processed, tested, and reported approximately a total of 138,017 patient tests annually when the laboratory lacked written and approved policies and procedures manuals.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those

	established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of verification of performance specifications for Routine Chemistry, lack of a verification protocol, and interviews with the laboratory director (LD) and laboratory owner (LO) on April 29, 2026; the laboratory failed to provide documentation for verification of performance specifications for new analytes. 1. The laboratory added to their Routine Chemistry tests two analytes: Total Prostatic Surface Antigen (PSA) and Total Iron Binding Capacity (TIBC) in the year 2025. 2. The surveyor requested the verification of performance specifications for the added analytes for which no documentation was available. 3. The documentation presented on verification of performance specifications did not include PSA or TIBC analytes. 4. The LD and LO affirmed by interview on the day of the (April 29, 2026) at approximately 3:00 p.m. that the verification for performance specifications for PSA and TIBC documentation was not found. 5. According to the testing declaration submitted at the time of survey (LAB Form 144-A) and signed by the laboratory director the laboratory performed and reported approximately 198 PSA and 162 TIBC tests annually without verification of performance specifications.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the proficiency testing results documentation, randomly selected patient test records, and interviews with the laboratory personnel and laboratory owner on April 29, 2026; the laboratory director is herein cited due to failure to ensure that several aspects of the analytic phase of the laboratory testing were monitored. The findings include See D2099, and D2122.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, validation and verification of performance specifications records, and interview with the laboratory's testing personnel and laboratory owner on April 29, 2026 ; the laboratory failed to have a va;idation/verification procedure and perform verification/validation procedures for various analytes such as PSA and TIBC analytes . The findings include: See D5421.

D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, survey findings, and interviews with testing personnel and laboratory owner on April 29, 2026 the laboratory director is herein cited for failure to ensure that a CLIA compliant, approved, signed, and dated, procedure manual that accurately reflects current laboratory practices is available for all personnel. See D5401.