

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2111385	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Four Tech Laboratory Llc	Street Address, City, State 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Association of Bioanalysts (AAB) proficiency testing (PT) records, interview with the technical consultants (TC), and testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent which is unsatisfactory performance for the Nonchemistry first event in 2022 (Q1-2022) for the coagulation Prothrombin Time analyte. The findings included: 1. On the date of the survey March 22, 2023, at approximately 12:0 p.m. based on review of the Prothrombin Time scores, the laboratory obtained for Q-1 2022 an overall score of 0% The results were as follow: PT-Q Overall score 0% Sample Reported Expected 1 33.7 4.8 - 27.13 2 13.8 2.2 - 11.42 3 13.7 7.7 - 11.25 4 24.0 5.0 - 19.81 5 14.4 5.2 - 12.3 2. The TC and TP affirmed on March 22, 2023, at approximately 12:30 p.m. that the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 115 Prothrombin Time samples quarterly during the time the laboratory received unsatisfactory PT performance scores.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on the lack of documentation, review of testing personnel competency assessment records, and interview with the technical consultant (TC) and testing personnel (TP) on March 22, 2023, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the TP competency for the year 2021. Findings include: 1. Based on review of the laboratory's policies and procedure and competency evaluations' records the laboratory failed to follow written policies and procedures for competency assessment of the TP. 2. The laboratory fail to provide documentation of training and competency assessment for the TP performing Routine Chemistry and Hematology moderate complexity sample processing and testing at the laboratory for the year 2021. 4. This deficient practice was affirmed by interview with the TC and TP on March 22, 2023, at approximately 1:45 p.m.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory test records for seven (7) out of seven (7) randomly chosen patients from 11/15/2021 to 1/20/2023 and interviews with laboratory technical consultant (TC) and testing personnel (TP), the laboratory failed to include in the final report the identification of the personnel performing testing. The findings include: 1. The following patients reviewed at the time of the survey 3/22/2023 did not have the identification of the TP performing the tests: Date Pt# Test 01/15/2021 Pt # 1 Chemistry, CBC 12/22/2021 Pt # 2 CBC 02/17/2022 Pt # 3 PT 10/20/2022 Pt # 4 Chemistry, CBC 01/20/2023 Pt # 5 CBC, ESR, Chemistry 01/12/2023 PT # 6 PT 02 /18/2022 PT# 7 PT 2. The TC and TP affirmed on 3/22/2023 at approximately 1:30 p. m. of the aforementioned in 1 above. 3. Based on the stated annual test volume, the laboratory reported approximately 118,710 patients test results without identifying the TP performing the tests for the years 2021, 2022, and up to the time the survey took place.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on lack of documentation for competency assessments for the year 2021 and interview with the testing personnel; it was determined that the technical consultant /director failed to perform and document the performance evaluation of all testing

personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: see D5209.