

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0925712	(X3) Date Survey Completed 04/08/2026
Name of Provider or Supplier Epic Care	Street Address, City, State 400 Taylor Blvd Ste 302-B, Pleasant Hill, 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
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with the testing personnel-1 (TP1), testing personnel-2 (TP2) and supervisor on April 8, 2026, the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the CA 15-3 analyte for the third event of 2025 (Q3-2025). The findings include: 1. The surveyor reviewed the API PT performance evaluation documentation and found that the laboratory obtained an unsatisfactory score of 60% for the CA 15-3 analyte in Q3-2025 event. The report as followed: a. T3 Uptake analyte score for the Q2-2025 event: Sample Result Expected TM-11 129.0 113.0 - 130.6 TM-12 46.3 40.3 - 48.4 TM-13 19.0 16.2 - 19.9 TM-14 *105.0 88.8 - 104.7 TM-15 *78.8 65.1 - 76.4 Legend: * = unsatisfactory score 2. The TP1, TP2 and supervisor affirmed by an interview on April 8, 2026, at approximately 10:20 a.m. that the laboratory obtained the unsatisfactory PT scores for the CA 15-3 analyte during the Q3-2025 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 572 CA 15-3 patient test samples annually including the time the laboratory received unsatisfactory proficiency testing scores. .</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program</p>

within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) reports and an interview with the testing personnel-1 (TP1), testing personnel-2 (TP2) and supervisor on April 8, 2026; it was determined that the laboratory failed to return the proficiency testing results for Hematology for the second event of 2025 (Q2-2025) within the time frame specified resulting to an unsatisfactory performance score of zero percent (0%). The findings include: 1. The laboratory received an unsatisfactory score of 0% for the Q2-2025 event after failure to submit results within the time frame as mandated by the API PT program. 2. The TP1, TP2 and supervisor affirmed on April 8, 2026, at approximately 10:20 a.m. that the laboratory received the unsatisfactory score as mentioned in statement #1 due to failure to participate in the Q2-2025 event. 3. The laboratory analyzed and reported approximately 219,037 Hematology patient test samples annually during the time when the laboratory failed to submit the PT results within the timeframe resulting to an unsatisfactory score.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy and procedure, proficiency testing (PT) records, lack of corrective action documentation, and an interview with the testing personnel-1 (TP1), testing personnel-2 (TP2) and supervisor on April 8, 2026, it was determined that the laboratory failed to perform and document a corrective action for the Magnesium analyte that achieved an unsatisfactory score of less than 100 percent during the third event of 2025 (Q3-2025). The findings include: 1. The laboratory's policy was limited to perform corrective action documentation for unsatisfactory scores that were obtained less than 80%. 2. The laboratory was enrolled with the American Proficiency Institute (API) PT program and obtained an unsatisfactory score of 80% for the Magnesium analyte during the Q3-2025 event. 3. The surveyor's review of the PT documentation revealed that the laboratory lacked a corrective action report for Magnesium analyte. 4. The TP1, TP2 and supervisor affirmed by an interview on April 8, 2026, at approximately 10:20 a.m., that the corrective action documentation was not performed for the Magnesium analyte during the Q3-2025 event with an unsatisfactory score of 80%. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 1,542 Magnesium tests annually, including the time when unsatisfactory PT scores were received and no corrective action was performed.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's proficiency testing documentation and interviews with the testing personnel-1, testing personnel-2 and supervisor on April 8, 2026, this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. The findings include: 1. The laboratory obtained an unsatisfactory score for the CA-15-3 analyte in the third event of 2025. See D2098 2. The laboratory failed to participate in the second event of 2025 for Hematology. See D2127 .

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing documentation, lack of corrective action documentation, and interviews with the testing personnel-1, testing personnel-2 and supervisor on April 8, 2026, the laboratory director is herein cited for failing to ensure that the established laboratory policy and procedure to perform corrective actions were followed when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.