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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D2331564                  | <b>(X3) Date Survey Completed</b><br><br>08/04/2026 |
| <b>Name of Provider or Supplier</b><br><br>Sutter Pamf East Santa Clara Laboratory                                         | <b>Street Address, City, State</b><br><br>2441 Mission College Blvd 1st Fl, Santa Clara, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| D2087              | <p>ROUTINE CHEMISTRY<br/>CFR(s): 493.841(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:<br/>Based on the surveyor's review of the laboratory's policy and procedure, the College of American Pathologists (CAP) proficiency testing (PT) documentation, and interviews with the director of operations (DOO), laboratory manager (LM), testing personnel 1 (TP1), and testing personnel 2 (TP2) on August 4, 2026, the laboratory failed to attain at least 80 percent acceptable responses for the Total Bilirubin analyte for the first PT event of 2026 (Q1 2026). The findings include: 1. The surveyor reviewed the laboratory's policy and procedure and the CAP PT documentation and found that the laboratory obtained an unsatisfactory score of 60 percent for the Total Bilirubin analyte for the Q1-2026 event. 2. During an interview on August 4, 2026, at approximately 9:20 a.m., the DOO, LM, TP1 and TP2 confirmed that the laboratory obtained the unsatisfactory score as mentioned in statement #1. 3. According to the laboratory's testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed and reported approximately 283 patient samples annually including the time when the laboratory obtained unsatisfactory scores for Total Bilirubin during the Q1-2026 event. .</p> |
| D5221              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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|              | <p>This STANDARD is not met as evidenced by:<br/>Based on the review of the laboratory's policy and procedure, College of American Pathologists (CAP) proficiency testing (PT) records, lack of corrective action documentation, and an interview with the laboratory manager (LM), testing personnel-1 (TP1) and testing personnel-2 (TP2) on August 4, 2026, it was determined that the laboratory failed to perform and document a corrective action for the Total Bilirubin analyte that achieved an unsatisfactory score during the first event of 2026 (Q1-2026). The findings include: 1. The surveyor requested the corrective action report for the Total Bilirubin analyte, which had resulted in a 40 percent score during the Q1 2026 event. 2. The surveyor reviewed the laboratory's protocol, which required staff to perform and document corrective actions when unsatisfactory scores were obtained. However, at 1:47 p.m., the LM and TP1 stated that the documentation could not be located. 3. During an interview on August 4, 2026, at approximately 1:47 a.m., the LM, TP1 and TP2 stated that a corrective action was performed but were unable to present the record. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 283 Total Bilirubin tests annually, including during the period when it received the unsatisfactory PT score and could not locate the corrective action documentation. .</p> |
| <b>D6016</b> | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's review of the laboratory's proficiency testing documentation for Total Bilirubin analyte during the first event of 2026, and interviews with the laboratory manager, testing personnel-1 and testing personnel-2 on August 4, 2026, the laboratory director is herein cited due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2087</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>D6018</b> | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's review of the laboratory's proficiency testing (PT) records from the College of American Pathologists (CAP) for 2026, lack of corrective action documentation and interviews with the laboratory manager testing personnel-1 and testing personnel-2 on August 4, 2026, the laboratory director failed to ensure that all graded proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. See D5221.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |