| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2044827 | 05/13/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sutter Pacific Medical Foundation | 3883 Airway Dr Ste 203, Santa Rosa, 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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| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's observation during the laboratory's tour and an interview with the histology technologist (HT); it was determined that the laboratory failed to label various reagent materials used in the laboratory to indicate, as appropriate, the identity, opening, and expiration dates when such materials are used in the laboratory. The findings include: 1. Observations during the tour found all tissue marking dyes, optical coherence tomography (OCT) mediums, reagent materials, and solutions used for Mohs processing of samples and slides lacked open dates and corrected expiration dates due to open stability per manufacturer's instructions, as appropriate. 2. The laboratory's HT affirmed in an interview on May 13, 2025, at approximately 11:43 a. m., that the various reagent materials and solutions mentioned in statement #1 lacked the appropriate label. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory processed and reported approximately 2,388 Dermatopathology samples during the time when there were no established or monitored labeling protocols in place. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test |

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| | result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's protocol for the retention and storage requirements, seven (7) patient test records for Mohs, preventive maintenance (PM) records, and an interview with the histology technologist (HT); it was determined that the laboratory failed to document PM records for 2021. The findings include: 1. One out of 7 records reviewed had one missing entry for the cryostat PM log performed on December 30, 2021. 2. The HT affirmed by interview on May 13, 2025, at approximately 10:40 a.m. that the PM was missed to be documented as mentioned in statement #1. 3. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported 2,388 Dermatopathology samples during the time the missed entry occured. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policies & procedures for quality assessment (QA), randomly chosen patient test records, and interviews with the office manager (OM), practice supervisor (PS), medical assitant (MA), and histology technologist (HT); it was determined that the laboratory failed to establish a complete QA protocol necessary for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytical, analytical, and postanalytical phases of testing. The findings include: 1. Surveyor's review of the laboratory's policies and procedures for quality assessment showed that it was limited to performing personnel competencies, peer review, and preventive maintenance tracking. It lacked protocols to identify problems in the preanalytical, analytical, and postanalytical systems as it occur. 2. A review of seven randomly chosen patients for Mohs yielded the following findings: a. Documentation for the cryostat preventive maintenance log for Patient 21-559 was missing. b. The slides for Patient 24-00001 could not be located. 3. Another set of seven randomly chosen patients for pathology were selected for review. The samples are sent to an external laboratory for processing, and slides are returned for pathology interpretation. The dates for Patient SDP-23-00-235 were inconsistent across all reviewed records, and no corrective action report was available at the time of the survey. 4. During an interview on May 13, 2025, at approximately 10:00 a.m., the OM, PS, MA and HT affirmed that their current quality assessment policy and procedure were lacking protocols to help identify problems as it occur. This led to errors found mentioned in statements #2 and #3. 5. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed approximately 2,388 tests annually for Dermatopathology during the time when there was no protocol established to monitor, assess, and correct problems as it occur in all phases of testing. |
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| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the office manager, practice supervisor, medical assistant and histology technologist on May 13, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Lack of appropriate label. See D5415. 2. Missing entry for preventive maintenance. See D5435. 3. Incomplete QA resulting in errors and inconsistencies. See D5891. |