Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0943625	(X3) Date Survey Completed 09/15/2025
Name of Provider or Supplier Outpatient Biopsy Center	**Street Address, City, State** 10632 Daines Dr, Temple City, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control records, and interview with the laboratory technical supervisor on September 15, 2025, at 11:47 a.m., the laboratory failed to retain quality control records for the sample SP23-481. The findings include: 1. The laboratory performed Giemsa and Mucicarmine special staining for the sample SP23-481. However, the laboratory failed to retain quality control records. Therefore, the laboratory may did not perform quality control and the accuracy of the laboratory's reported test results cannot be assured and may have potential to harm patients. 2. The laboratory technical supervisor on September 15, 2025, at 11:47 a.m., affirmed that the laboratory did not have the quality control records and may have been misplaced. 3. The laboratory performed approximately 400 histopathology tests, annually.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the

	specimen. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's testing records, and interview with the laboratory technical supervisor on September 15, 2025, at 11:57 a.m., the laboratory failed to retain histopathology slides as required for 1 sample out of 10 samples reviewed. The findings include: 1. The laboratory reported the results for the sample SP25-285 but did not have slide. Therefore, it cannot be determined if the laboratory read the slide before reporting the results and the accuracy of the reported results cannot be assured which may potentially harm patients. 2. The laboratory technical supervisor on September 15, 2025, at 11:57 a.m., affirmed that the laboratory did not have the above sample slide. 3. The laboratory performed approximately 400 histopathology tests, annually.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's testing records, policy & procedures and interview with the laboratory technical supervisor on September 15, 2025, at 11:28 a. m., the laboratory failed to report 1 sample out of 10 samples, reviewed. The findings include: 1. The laboratory received 3 H&E- stained slides together with the gross description, SP24-108-1 to -3. The samples on those 3 slides were from different sites of GI biopsied tissue. However, the laboratory reported only 1 sample (sigmoid colon) and failed to report the other 2 samples (ascending colon and rectal). The laboratory's failure to report sample results potentially harmed patients. 2. The laboratory technical supervisor on September 15, 2025, at 11:28 a.m., affirmed that the laboratory did not report those samples. 3. The laboratory performed approximately 400 histopathology tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Based on Surveyor review of laboratory's testing records, policy & procedures and interview with the laboratory technical supervisor on September 15, 2025, at 11:28 a.m., the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D3031, D3043 and D5203.