

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0998287	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier Yosemite Pathology	Street Address, City, State 3000 Sillect Ave, Bakersfield, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure manuals, competency assessment records, a review of ten (10) Histopathology patient test records, and interviews on September 17, 2026, it was determined that one (1) of four (4) testing personnel (TP) who performed high complexity gross examination did not have competency assessment prior to testing patient. The findings included: 1. The laboratory conducted high-complexity histopathology tests, including both gross (macroscopic) and microscopic examinations. Four testing personnel (TP) were responsible for performing gross examinations. 2. On the day of the survey, the laboratory did not maintain records documenting competency training and assessment for TP #4. The TP #4 performed at least one gross examination of pericardial tissue on March 6, 2026. 3. On September 17, 2026, at approximately 1:30 p.m. laboratory compliance manager and general supervisor confirmed the laboratory failed to maintain competency assessment for TP#4. 4. The laboratory's testing declaration form, signed by the laboratory director on August 24, 2026, stated that the laboratory performed approximately 21,385 tests including gross examination annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure manuals, proficiency testing (PT) records, a review of ten (10) Histopathology patient test records, and interviews on September 17, 2026, it was determined that the laboratory did not follow the laboratory's policy and procedure for PT testing review in 2024, 2025 and 2026. The findings included: 1. The laboratory participated in the College of American Pathologists (CAP) Proficiency Testing (PT) Program for HER2 immunohistochemistry (HER2) and ER/PGR immunohistochemistry TMA. The testing included both microscopic and macroscopic examinations. The laboratory's PT procedure manual required the director to review and sign the final reports. 2. On the day of the survey, the surveyor reviewed randomly selected laboratory PT evaluation records. The histopathology testing evaluation reports for 2024, 2025, and 2026 had been reviewed and signed by the histologic technician supervisor. The laboratory maintained no documentation showing that the laboratory director or a delegated pathologist had reviewed the PT evaluation reports. 3. On September 17, 2026, at approximately 1:00 p.m. laboratory compliance manager and histologic technician supervisor confirmed the PT evaluation report did not sign by the laboratory director or delegated staff. 4. The laboratory's testing declaration form, signed by the laboratory director on August 24, 2026, stated that the laboratory performed approximately 21,385 tests including gross examination annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (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 This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, a review of ten (10) Histopathology patient test records, and interviews on September 17, 2026, the laboratory director of high complexity testing failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. See D5401
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure manuals, competency assessment records, a review of ten (10) Histopathology patient test records, and interviews on September 17, 2026, the laboratory director of high complexity testing

failed to ensure that all testing personnel have documents for education, experience and the appropriate training for gross examination prior to testing patient specimens. The findings included: On the day of the survey, the laboratory did not maintain records documenting the education, experience, appropriate training, and competency assessment of one of its four testing personnel. See D5209.