Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0696576	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ucsb Student Health Services Laboratory	Bldg 588, Santa Barbara, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) results and an interview with the technical consultant (TC); it was determined that the laboratory failed to obtain an overall testing event score of at least 80 percent (%) in Bacteriology. The findings include: 1. The laboratory was enrolled in API PT program and received an unsatisfactory score of 67% for susceptibility testing in the second event of 2022 (Q2-2022). 2. A corrective action report was available for review. 3. The TC affirmed by interview on May 29, 2025, at approximately 12:15 p.m. that the laboratory obtained the unsatisfactory score as mentioned in statement #1. The quality and accuracy of patient testing results cannot be assured. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 76 patient sample for susceptibility testing during the time the laboratory obtained the unsatisfactory scores for proficiency testing. .
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 the surveyor's review of the laboratory's quality assessment (QA) policies and procedures, personnel competency documentation, ten (10) randomly chosen patient records, and an interview with the technical consultant (TC); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for all testing personnel (TP) for the years 2023, 2024 and 2025. The findings include: 1. The laboratory's practice was to use all six guidelines under 493.1413(b)(8) as the criteria for competency assessment. However, upon surveyor's review for all documentation for the years 2023, 2024, and 2025, this was not correctly followed invalidating all competency assessments performed. 2. None of the four testing personnel listed in the CMS-209 form had complete records of competency assessment for the years 2023, 2024, and 2025 for the Microbiology, Immunology, Chemistry, and Hematology specialties. 3. The reliability and accuracy of patient tests reported cannot be assured including the 10 randomly chosen patient records performed and reported by all TP for the years 2023, 2024, and 2025. 4. This deficient practice was affirmed by an interview with the TC on May 29, 2025, at approximately 2:00 p.m., that all competency assessments performed for testing personnel were invalid for 2023, 2024, and 2025. No corrective action was available for review at the time of survey. 5. According to the laboratory's annual testing declaration form submitted at the time of the survey, the laboratory reported and performed approximately 41,505 tests for Microbiology, Immunology, Chemistry, and Hematology specialties during the time competency assessments for all TP were invalid.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on the surveyor's review of patient test records and an interview with the technical consultant (TC) on May 29, 2025, it was determined that the laboratory failed to have an adequate system in place to ensure test results and other patient-specific data are accurately and reliably transcribed manually or electronically transmitted. The findings include: 1. The laboratory used Orchard Harvest and Point and Click (PnC) information systems to manage records of test results perfomed and final reports kept in electronic medical charts. 2. Rapid plasma reagin (RPR) is a manual test performed by testing personnel and results are manually entered in the laboratory information system (LIS), including quality control data. 3. The surveyor reviewed ten patient records including Patient 776452. The quality control for the needle used for RPR test was missed to be entered on 9/28/2023. The laboratory did not retain any hardcopies for further review. The quality and reliability of patient test reported could not be assured. 4. The TC stated in an interview on May 29, 2025, at approximately 1:30 p.m. that all quality control and patient test results are manually entered in the LIS for RPR test. No corrective action was available for review at the time of survey. 5. According to the testing declaration form submitted at the time of

	survey, the laboratory performed and reported 149 RPR tests annually including the time the missing entry for quality control occured.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on the surveyor's review of randomly selected patient test records, proficiency testing results from the American Proficiency Institute, and an interview with the technical consultant (TC) on May 29, 2025, this deficient practice is cited due to failure of TC to provide technical and scientific oversight of the laboratory. The findings include: 1. Unsatisfactory proficiency testing score. See D2020. 2. Missing quality control entry. See D5801.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the invalid documentation of competency assessments for all testing personnel performed for the years 2023, 2024, and 2025, and an interview with the technical consultant, the laboratory director is herein cited for the deficient practice for not assuring competency assessments were complete and followed the establish policy/procedure. See D5209.