

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0881670	(X3) Date Survey Completed 08/12/2026
Name of Provider or Supplier Care Bioclinical Laboratory	Street Address, City, State 16311 Ventura Blvd Ste 888, Encino, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) (a) The laboratory must be constructed, arranged, and maintained to ensure the following: (a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on the observations during the laboratory tour, lack of service report, review of four patient records from July 10, 2026, and interview with the manager on August 12, 2026, The laboratory failed to ensure that the ESCO Class II biological safety cabinet (BSC) used for patient sample processing was properly maintained and functioning within acceptable manufacturer specifications prior to use. The findings include: 1. Observations during the tour revealed that except for the ESCO Class II BSC, all equipment were calibrated and maintained by an external service company. 2. The laboratory provided only four patient records for review, which represented all patient specimens processed since the start of testing. All four specimens were processed in the ESCO Class II BSC during a period when the BSC filter was already known by the laboratory to be outside acceptable performance thresholds. 3. During an interview on August 12, 2026, at approximately 11:06 a.m., the manager stated that when the laboratory received the ESCO Class II BSC, the external service company arrived in June 2026 and determined that the BSC filter was not within acceptable threshold. The manager further stated that the service company could not perform the preventive maintenance because the laboratory did not have a replacement filter available. Despite this knowledge, the laboratory continued to use the ESCO Class II BSC to process patient specimens for PCR testing.
D3005	FACILITIES CFR(s): 493.1101(a)(3)

(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

This STANDARD is not met as evidenced by:

Based on direct observation of the facility layout and of the laboratory's Polymerase Chain Reaction (PCR) testing for the presumptive detection of SARS CoV-2 (COVID19), RSV A/B and Influenza A/B and interview with the manager on August 12, 2026, the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings include: 1. The laboratory performed PCR testing for the detection of COVID19, RSV A/B and Influenza A/B using manual and automated methods for specimen processing, preparation of the master-mix, controls, reagents, and addition of template. 2. During the laboratory tour on August 12, 2026, at approximately 11:06 a.m., the surveyor observed that access to the ESCO Class II biosafety cabinet (specimen processing area) was limited to a single shared doorway, which served as both the entrance and exit. This arrangement caused staff to move bidirectionally through the same space. After specimen processing, testing personnel proceeded through the same doorway to another area used for master-mix and reagent preparation and extraction procedures. Personnel were then required to retrace their steps through the same shared hallway before entering a different room containing the Applied Biosystems 7500 Fast Real-Time PCR System for amplification and detection. This repeated forward-and-back movement through multiple testing steps did not provide unidirectional flow, contrary to CLIA requirements for molecular procedures. 3. During an interview on August 12, 2026, at approximately 11:06 a.m., the manager confirmed that the laboratory's physical design did not support the unidirectional workflow required by CLIA for molecular amplification procedures.

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 competency assessment policy and procedure, four patient records, lack of personnel competency documentation, and an interview with the testing personnel on August 12, 2026, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to follow the written personnel competency assessment policy and procedure. The findings include: 1. The laboratory's policy and procedure for testing personnel competency assessment aligned with CLIA requirements but was not followed. 2. Record review showed that the testing personnel lacked competency assessment documentation prior to testing the four patient samples on July 10, 2026, which represented all the patient specimens processed since testing began. a. Patient samples processed and tested on July 10, 2026: i. G126-00122 ii. G126-00119 iii. G126-00120 iv. G126-00121 3. During an interview on August 12, 2026, at approximately 11:06 a.m., the testing personnel confirmed that the laboratory failed to conduct and document the initial competency

	assessment prior to testing patient samples on July 10, 2026. 4. No corrective action was available for review at the time of the survey. .
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on the surveyor's direct observations of the laboratory workflow during the tour and an interview with the manager on August 12, 2026, the laboratory director failed to ensure that the risk of cross-contamination was minimized during polymerase chain reaction (PCR) and non-PCR testing processes, and failed to ensure that a unidirectional workflow was maintained for PCR testing. The findings include: 1. The laboratory processed patient specimens using equipment that was not functioning within acceptable manufacturer-specified performance thresholds. See D3001. 2. The laboratory did not maintain a unidirectional workflow required for PCR testing procedures. See D3005. .
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory documents, lack of competency assessment records, and an interview with the manager-who also functioned as the testing personnel-on August 12, 2026, it was determined that the laboratory director, who also served as the technical supervisor, failed to assess and document initial training and competency evaluations for the testing personnel prior to performing patient testing. See D5209.