Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1052619	02/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
University Of California Irvine,	850 Health Sciences Rd, 2nd Fl, Irvine, 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 policies and procedures, lack of competency assessment records, and an interview with the laboratory on February 23, 2026, at approximately 12:30 p. m., the laboratory failed to establish and follow written policies and procedures to assess employee competencies in 2023, 2024, and 2025. The findings included: 1. It was practice of the laboratory to perform mycology and Mohs Micrographic Surgery. The laboratory had eleven testing personnel (TP) responsible for performing KOH skin preparations, and seven TP who reviewed histopathology slides. 2. On February 23, 2026, the laboratory failed to provide documentation of competency evaluations for 11 of 11 TP who conducted KOH testing and 7 of 7 TP who performed histopathology testing. The laboratory requested an extension to locate and submit the required documentation via email to the surveyor. The documents were not submitted within the extended timeframe. 3. The laboratory's testing declaration form, signed by the laboratory director on February 13, 2026, stated that the laboratory performed approximately 2,185 tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals and an interview with the laboratory staff on February 23, 2026, it was determined that the laboratory director failed to approve and sign the procedure manuals before laboratory began using it. The findings included: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery and mycology testing. 2. On February 23, 2026, at approximately 12:00 p.m., the laboratory staff confirmed that the director had not reviewed, signed, or dated the histopathology procedure before it was used in the lab. 3. The laboratory's testing declaration form, signed by the laboratory director on February 13, 2026, stated that the laboratory performed approximately 2,100 histopathology tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals and an interview with the laboratory staff on February 23, 2026, the Laboratory Director failed to ensure that there were approved procedure manual available to all personnel responsible for mycology testing process. The findings included: 1. It was the practice of the laboratory to perform histopathology testing including Mohs Micrographic Surgery and mycology testing. 2. On February 23, 2026, at approximately 12:30 p.m., the laboratory failed to provide policies or procedures manuals regarding preanalytic, analytic or postanalytic testing for KOH prep procedures that are performed on site. 3. The laboratory's testing declaration form, signed by the laboratory director on February 13, 2026, stated that the laboratory performed approximately 85 mycology tests annually.