Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1052619	05/04/2023
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's Cryostat temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to follow the laboratory 's stated performance specification for Cryostat acceptable temperature range in a manner that provided test results as determined. The findings included: a. The laboratory failed to follow the laboratory's stated performance specification for Cryostat acceptable temperature range. b. The laboratory performed Mohs surgery and employed two outside histology laboratory services, A and B. c. The A and B histology laboratory services has established its Cryostat acceptable temperature ranges. d. The A established the acceptable temperature for its operation between - 29 to -15 o C e. The B established the acceptable temperature for its operation between --35 to -18 o C f. The laboratory's Cryostat temperature records indicated the acceptable temperature range is between - 30 to -18 o C which is inconsistent between the A or B services' acceptable temperature range. h. The laboratory failed to be consistent with the histology laboratory services' policies and procedures stated.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Policy 2.06 and the laboratory's BIANNUAL QUALITY ASSESSMENT (Mohs slides), and interview with the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and to ensure the accuracy of the patient test result reports. The findings included: a. The laboratory has established "MOHS MICROGRAPHICSURGERY NEGATIVE SLIDE REVIEW" (POLICY 2.06) b. It states V. PROCEDURES 1. Five random patients' slides from a Bi-Annual period of procedures are selected. 2. For each of four patients, one positive and one negative slide are selected for review. 3. All slides for the fifth patient are selected. 4. The selected patients' slides ... .(Form# MMS-02) c. Review of the MMS-008 (no MMS-01 and MMS-02) records for the period of Month/Year: June 2022 and July-Dec 2022 (BIANNUAL QUALITY ASSESSMENT/Mohs slides), they indicated six patients' cases worksheets and slides were selected in each MMS-08, d. Review of the copies of Biannual assessments of June 2022 and July-Dec 2022, there were SIX patients selected and attached all the slides including positive and negative slides in the review records which were inconsistent with its written procedures above. e. Review of MMS-08 record, the case identified as M22-118, specimen collected on 03/02/22 with a diagnosis of BCC, showed NO signature and date under "Initial/Date Reviewer indicated that this particular case selected was missed and NOT been assessed by a second qualified testing personnel among the six cases/slides selected. f. The laboratory failed to follow its written policies and procedures to monitor, assess, and to ensure the accuracy of patient test result reports.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, Biannual Assessment policies and procedures (P&P), Cryostat temperature records and the histology laboratory's policies and procedures, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. b. The laboratory performed Mohs surgery and qualified dermatopathologists performed diagnoses of tissue slides prepared by outside histology laboratory services onsite. c. The laboratory failed to follow its written P&P to perform Bi-annual review (Policy 2.06) see (D-5891) d. The laboratory failed to follow histology laboratory services' P&P in recording the Cryostat temperature, see D-5411