Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0562804	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Alta Dermatology Medical Group	7365 Carnelian St, Ste 137, Cucamonga, 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**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Mobile Tek Process and Procedure", a Mohs surgery histopathology policies and procedures (PNP) and the "Mobile Tek Daily Temperature Log", the Cryostat temperature monitoring records, and interview with the laboratory personnel (TP), it was determined that the laboratory failed to follow Mohs PNP written criteria to monitor the Cryostat acceptable temperature range when in preparing and cutting the skin tissue for histopathology examination, which is essential to ensure the accuracy and reliability of the test system operation and the test result reporting. The findings included: a. The laboratory failed to monitor and record the Cryostat temperature consistently with the written temperature range in the PNP, and to ensure accurate and reliable Mohs surgery. b. The laboratory employed a Mohs histology laboratory service, Mobile Tek, onsite to prepare, cut, and stain the skin tissue slides for histopathology examination. c. Mobile Tek Process and Procedure states: "Make sure cryostat is at an optimum cutting temp (between -20 to -30 degrees Celsius). d. Review of Mobile Tek Daily Temperature Log recorded between 7-31-14 and 12-16-15 indicated that its "Acceptable Range" was between -30 oC to -18 oC on the Log sheet, which was inconsistent with the established acceptable temperature range (-20 to -30 oC) in the Mobile Tek's PNP. e. Further review of Mobile Tek Daily Temperature Log dated between 11-6-18 and 10-30 -19 did not indicate its

	"Acceptable temperature Range" for the "Cryostat Temperature" and "Room Temperature". f. Missing the acceptable temperature range for Cryostat temp daily log provided no valuable information of the temperature recorded to ensure accurate and reliable operation. h. The laboratory personnel acknowledged (5/12/21 @ 11:30 am) that the inconsistency of the acceptable temperature for Cryostat between the MObile Tek's PNP and its Daily Temperature Log. i. The laboratory personnel acknowledged (5/12/21 @ 11:30 am) that the Mobile Tek Daily Temperature Log without the criteria identified on the Log sheet provided no real value for monitoring the temperature to assure accurate and reliable test system operation and test reporting. j. The laboratory performed in approximately 2,400 yearly.
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 Mohs maps with tissue slides, and the patient test result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to follow written policies and procedures (PNP) for an ongoing mechanism to monitor, assess and failed to assure the accuracy of the tissue slide labelling and to ensure the accuracy, reliability and timely of the laboratory operations. The findings included: a. This laboratory performed Mohs surgery and biopsy tissue slide for histopathology examinations. b. The laboratory employed Mohs Tek, a histology laboratory service to prepare and stain the skin tissue slides while in Mohs surgery. c. Review of five Mohs and biopsy patient test reports along with its skin tissue slides, one of the 5 cases tissue slides, ID as 04-22-68 with date of service on 2/12/20 had indicated that a "Rt" 5th knuckle on a frozen section slide labeling which was inconsistent with other two Mohs skin tissue slides labelled as "Lt" 5th knuckle. d. The Mohs map worksheet identified for the ID # 04-22-68 on 2/12/20 indicated that site of the skin tissue was "L" 5th knuckle. e. The laboratory personnel affirmed (5/12/21 @ 11:45 am) that the laboratory failed to monitor, assess and quality assure the accuracy and reliability of the tissue slide labelling by the histology laboratory tech including frozen tissue slides. f. The laboratory performed histopathology testing in approximately 2,400 annually.
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 Mohs map with slides, the patient testing histopathology result reports, "Mobile Tek Process and Procedure", a Mohs policies and procedures (PNP), and the "Mobile Tek Daily Temperature Log", the Cryostat temperature monitoring records, and interview with the laboratory personnel (TP), it was determined that the laboratory director failed to ensure that the quality assessment

	programs were maintained and followed to ensure the accuracy and reliability test system operation and test result reporting, and to assure the quality of laboratory services provided and/or to identify failures in quality as they occur. The findings included: a. The laboratory director failed to maintain quality assessment and to ensure the accuracy and reliability reporting test results. b. The Mohs Tek, a histology laboratory service failed to monitor the temperature-controlled Cryostat equipment temperature against the acceptable range in written consistently, see D-5413 and failed to label the slide with accurate site of tissue D-5891. c. The TP noted (5/12/21 @ 11:45 AM) that the inconsistency of acceptable temperature range monitored between the PNP in written and in actual Daily Log sheet, see D-5413 and failed to quality assess the slide labeling by the Mobile Tek, D-5891.