Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 03D2230205	**(X3) Date Survey Completed** 07/15/2024
Name of Provider or Supplier Summit View Dermatology	**Street Address, City, State** 8405 E Baseline Rd Ste 104, Mesa, AZ	
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**
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs logs, Mohs maps, patient slides and final test reports maintained in the patient's Electronic Medical Record (EMR), and interview with the laboratory director (LD), the laboratory failed to ensure positive identification of a patient's dermatopathology specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with an annual test volume of 288. 2. It is the practice of the laboratory to label each Mohs slide with two patient identifiers: accession number and patient name to ensure positive patient identification throughout the testing process. 3. Two out of four Mohs slides (all Stage II slides) for patient A.T. from 4/18/24 were only labeled with the patient's initials. 4. The LD interviewed on 7 /15/24 at 11:00 AM confirmed the patient's slides indicated above did not properly identify the patient.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through 493.1289. Findings include: 1. No QA documentation was provided for review during the survey conducted on 7/15/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The LD interviewed on 7/15/2024 at 11:20 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(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 review of patient test results maintained in the Electronic Health Record (EHR) and interview with the laboratory director (LD), the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (entered manually) to final report destination, in a timely manner. Findings include: 1. Patient-specific data and the final test result information from testing performed in conjunction with the Mohs procedure is manually transcribed by laboratory personnel into the patient's EHR. 2. The laboratory failed to present documentation during the survey conducted on 7/15/2024 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are manually entered into the EMR. 3. The LD interviewed on 7/15/2024 at 11:20 AM confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are manually entered into the EMR.