

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2111120	<b>(X3) Date Survey Completed</b>  12/14/2023
<b>Name of Provider or Supplier</b>  Center For Dermatology, Pllc	<b>Street Address, City, State</b>  6316 W Union Hills Dr Ste 200, Glendale, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>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.</p> <p>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 facility personnel, the laboratory failed to ensure positive identification of patient's dermatopathology specimens from the time of collection through completion of testing and reporting of test results for one out of six patients reviewed. Findings include: 1. The laboratory performs Mohs testing and Frozen Biopsy testing under the subspecialty of Histopathology, with an annual test volume of 840. 2. The laboratory assigns a unique accession (case) number to each Mohs and Frozen Biopsy specimen. The laboratory differentiates between Mohs cases and Frozen Biopsies by utilizing the letter "M" for Mohs cases and by utilizing the letter "F" for Frozen Biopsies. 3. The laboratory failed to ensure positive identification of a patient's specimen for Frozen Biopsy testing throughout the entire test process for patient J.H. for testing performed on 12/22/21 as evidenced by: a Frozen Biopsy case being recorded in the patient log as Case: "RGM21-03". The slides, Mohs Map, and documentation reviewed in the EMR for this patient listed the case as RGF21-03. 4. The facility personnel interviewed on 12/14/23 at 10:05 AM acknowledged the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results, as evidenced by the specimen identification error indicated above.</p>
<b>D5891</b>	<b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b>

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 Quality Assessment (QA) documentation, review of post-analytic QA policies, review of electronic test records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings include: 1. Patient-specific data and the final test result information for Mohs interpretations and Frozen Biopsy testing is manually transcribed by laboratory personnel into the patient's Electronic Health Record (EHR). 2. The laboratory's established Quality Assessment policy states, "Biannually, 5 cases will be reviewed and randomly selected. All frozen sections will be pulled for review. If any issues noted they will be documented, and corrective actions taken as appropriate for the findings." 3. No documentation from 2021 was presented for review to indicate the laboratory followed the policy referenced above to ensure patient test results and patient-specific data were accurately and reliably transcribed into the patient's EHR. 4. The facility personnel interviewed on 12/14/2023 at 10:45 AM confirmed the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 5. The laboratory performs approximately 840 tests annually under the subspecialty of Histopathology.