

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1029386	(X3) Date Survey Completed 10/28/2021
Name of Provider or Supplier Advanced Dermatology	Street Address, City, State 210 S Grand Ave, Ste 208, Glendora, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory current written policies and procedures and interview with the laboratory personnel, it was determined that the laboratory failed to have available and follow written procedures for Histopathology (Mohs testing) test procedure performed in the laboratory. The findings included: 1. On the day of the survey on October 28, 2021 at approximately 11:00 a.m. the laboratory failed to provide written policies and procedures for Histopathology test procedures currently performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed covering period from 09/30/2019 to 09/28/2021 all the patients had Mohs test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available for the current practice. 3. The laboratory staff confirmed on October 28, 2021 at approximately 11:30 a.m.. that the laboratory did not have written policies and procedures available for the current Mohs test performed in the laboratory.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manual and interview with the laboratory personnel (LP); it was determined that the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey October 28, 2021 at approximately 11:30 a.m. the procedure manual in place had not being updated to reflect current Mohs procedure performed in the laboratory. 2. The existing protocols presented to the surveyor included testing no longer performed in the laboratory. 3. The LP affirmed on October 28, 2021 at approximately 12:00 p.m. that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 1,000 Histopathology samples annually including the Mohs procedure.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on interview with the laboratory staff on October 28, 2021 at approximately 12:00 p.m., the laboratory director failed to ensure that an approved, signed, and dated, procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: D5401 and D5407.