

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2282705	(X3) Date Survey Completed 01/09/2024
Name of Provider or Supplier Dermatology And Skin Care Associates	Street Address, City, State 7249 Liberty Way, West Chester, OH	
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: ITEM 1 Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to follow their Mohs QA/QC policy and procedure. This deficient practice had the potential to affect 350 out of 350 patients tested under the subspecialty of Histopathology from 10/17/2023 through 01/09/2024. Findings Include: 1. Review of the "Mohs QA/QC" policy and procedure provided on the date of the inspection, found the following statements: "...3. All information filled out on the mohs Map including time in/out" 2. Review of four out of four Mohs maps did not find any record of time in/out. 3. TP#1 confirmed the laboratory did not document time in/out on the Mohs maps as stated in the "Mohs QA/QC" policy and procedure. The interview occurred 01/09/2023 at 2:10 PM. ITEM 2 Based on record review, direct observation, and an interview with Testing Personnel (TP) #1, the laboratory failed to follow their "Mohs Specimen Handling Procedure and Mapping Procedure". This deficient practice had the potential to affect 350 out of 350 patients tested under the subspecialty of Histopathology from 10/17/2023 through 01/09/2024. Findings Include: 1. Review of the "Mohs Specimen Handling Procedure and Mapping Procedure" provided on the date of the inspection, found the following statements: "3. The surgeon dyes the tissue and marks the corresponding map" 2. Direct observation on the date of inspection found TP#1 inking and grossing three out of three Mohs tissue specimens. 3. TP#1 confirmed they performed all inking and grossing, and the laboratory was not following the "Mohs Specimen Handling Procedure and Mapping Procedure". The interview occurred 01/09/2023 at 2:15 PM.</p>