

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2142743	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Oakview Dermatology	Street Address, City, State 80 Star Drive, Chillicothe, 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: Based on document review and an interview with the Laboratory Manager (LM), laboratory personnel failed to follow the written procedure manual for Quality Assurance. This deficient practice had the potential to affect all patients tested under the subspecialty of histopathology. Findings include: 1. Review of the Mohs laboratory policy titled, "Quality Assurance", approved by the Laboratory Director 01/04/2019, found the following statement: "Procedure: Monthly, lab personnel will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-Analytic Systems, Analytic Systems, and Post Analytic Systems." 2. The surveyor requested the monthly checklists from the LM at 10:08 AM, 09/12/2019. 3. The LM stated there were no monthly quality assurance checklists and was unable to provide the requested documents.</p>