

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2158186	(X3) Date Survey Completed 09/19/2019
Name of Provider or Supplier Dermatology And Cosmetic Physicians, Sc	Street Address, City, State 2102 Continental Dr, West Bend, WI	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of slides, review of laboratory records, and interview with the laboratory director, the laboratory did not retain documentation identifying what stains and reagents the laboratory used for slide preparation since July 2, 2019. Findings include: 1. Observation of slides on September 19, 2019 at 1:45 PM from Mohs procedures from July 2, 2019 through August 6, 2019 showed irregular staining of the tissue samples. 2. Review of laboratory records showed no record of the type, lot number, or expiration date of the stains, mounting media, or coverslip media the laboratory used for slide preparation and staining. 3. During interview with the laboratory director on September 19, 2019 at 2:00 PM the director confirmed the laboratory did not retain records to identify the stains and other reagents used in slide preparation and staining since testing began on July 2, 2019.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory had not documented the time of receipt of Mohs specimens in the laboratory. Findings include: 1. Review of Mohs maps and the Mohs specimen log</p>

	<p>showed no indication of the time the laboratory received tissue specimens for Mohs testing. 2. Interview with the laboratory director on September 19, 2019 at 2:00 PM confirmed the laboratory did not document the time of specimen receipt for Mohs specimens.</p>
<p>D5401</p>	<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 surveyor review of laboratory procedures and interview with the laboratory director, the laboratory did not have a procedure for the performance of KOH (potassium hydroxide) testing. Findings include: 1. Review of procedures showed no evidence of a procedure for KOH testing. 2. Interview with the laboratory director on September 19, 2019 at 1:00 PM confirmed the director performed KOH testing on patient specimens and confirmed the laboratory had not developed a procedure for KOH testing.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records, observation of specimen slides and interview with the laboratory director, the director had not developed a quality assessment program to ensure the quality of laboratory services and to identify failures in quality as they occur. Findings include: 1. Review of laboratory procedures showed no evidence of a documented quality assessment program. 2. Comparison of laboratory records and observation of Mohs slides on September 19, 2019 at 1:00 PM for Case One (see F-2-62552 Statement of Deficiencies Identifier Key) showed the Mohs log and slides identified the tumor type as SCC (Squamous Cell Carcinoma). The Mohs map for Case One identified the tumor type as BCC (Basal Cell Carcinoma). 3. Observation of specimen slides on September 19, 2019 at 1:00 PM showed slides from July 2019 exhibited irregular staining of the specimens. No documented record of evaluation or resolution of the problem was available. 4. Interview with the laboratory director on September 19, 2019 at 2:00 PM confirmed the identified quality issues and confirmed the director had not established a quality assessment program to ensure the quality of laboratory services and identify failures in quality as they occur.</p>