

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2077429	(X3) Date Survey Completed 05/08/2018
Name of Provider or Supplier Dermatology Specialists Of Shelby	Street Address, City, State 50505 Schoenherr Road, Ste 325, Shelby Township, MI	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the monthly maintenance for the histology microscope for 17 (2017 and January - May 2018) of 24 months reviewed. Findings include: 1. On May 8, 2018 at 10:15 AM, record review of the microscope maintenance log revealed the laboratory did not perform and document 17 (2017 and January - May 2018) of 24 months the monthly cleaning of the microscope. 2. During the interview on May 8, 2018 at 10:15 AM, the office manager confirmed the monthly maintenance was not documented.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic laboratory systems for two (2016 and 2017) of two years reviewed.</p>

Findings include: 1. On May 8, 2018 at 11:00 AM, record review of the twice a year "Quality Assurance Checklist" revealed there was no documentation for two (2016 and 2017) of two years. 2. When queried on May 8, 2018 at 11:00 AM, the office manager was unable to provide the surveyor with the documentation requested. 3. During the interview on May 8, 2018 at 11:00 AM, the office manager confirmed the "Quality Assurance Checklist" was not performed and documented in 2016 and 2017.