Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2163113	(X3) Date Survey Completed 10/21/2019
Name of Provider or Supplier Center For Surgical Dermatology, Inc	**Street Address, City, State** 235 West Schrock Road, Westerville, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director (LD) and Testing Personnel (TP) #1, the laboratory failed to verify performance specifications of the Periodic Acid-Schiff (PAS) stain test system before reporting patient test results. This deficient practice has the potential to affect 360 patients tested in the sub-speciality of histopathology. Findings Include: 1. Review of the laboratory's policies and procedures failed to locate instructions to verify performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range of test results, and reference intervals for the newly implemented PAS stain prior to reporting patient results. 2. Review of the laboratory's performance specification documentation failed to locate evidence that the lab conducted and documented performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range of test results, and reference intervals for the newly implemented PAS stain prior to reporting patient results. 3. An interview with the LD and TP #1, on 10/21/19 at 2:57 pm, confirmed that the laboratory failed to verify performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range of test results, and reference intervals for the newly implemented PAS stain prior to reporting patient results.