

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2166853	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Orsini Surgical Dermatology	Street Address, City, State 1519 Legacy Circle, Naperville, IL	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, record review, and interview with testing personnel (TP) #3 the laboratory failed to perform control procedures specified by the laboratory for Hematoxylin and Eosin (H&E) Stain testing from June of 2023 though the survey date of June 25th, 2025. Findings include: 1.Review of the laboratory's policy and procedure manual identified the procedure, "Hematoxylin and Eosin Stain ", which indicated the frequency of reagent change out required for H&E staining at the facility. Under the Section titled "Quality Assurance" it stated "Be sure to label and document when new solutions are opened and expire. Daily change Fixative and Scotts Bluing. daily empty first 95% alcohol, move second 95% alcohol to empty space, fill fresh 95 % alcohol." 2.Review of laboratory Quality Control records revealed that the laboratory failed to change out the alcohol and Scotts Bluing agent daily as required from June 2023 to the date of survey 6/27/25. 3.Interview with TP#3, on 06-25-2025, at 10:50 am, confirmed that the laboratory failed to follow quality control procedures for changing out reagents daily as required.</p>