

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0676451	(X3) Date Survey Completed 05/08/2023
Name of Provider or Supplier Dermatology Associates Of Oak Ridge	Street Address, City, State 599 Oak Ridge Turnpike, Oak Ridge, TN	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, record request, and interview with the laboratory liaison, the laboratory failed to document hematoxylin and eosin (H&E) stain quality assessment for three of three patients performed on 10.21.2022. The findings include: 1. Observation of the laboratory on 05.08.2023 at approximately 11:00 am revealed processing and staining of tissue for histopathology using hematoxylin and eosin (H&E) stains. 2. Review of randomly selected patient test reports/dates revealed patient histopathology cases reported as follows: 102122-907H--reported on 10.21.2022 102122-908H--reported on 10.21.2022 102122-909H--reported on 10.21.2022 3. Request made to the laboratory liaison on 05.08.2023 at approximately 11 am for H&E stain quality assessment records revealed no documented H&E stain quality assessment on 10.21.2022. 4. Interview with the laboratory liaison on 05.08.2023 at approximately 11 am confirmed the laboratory failed to document H&E stain quality assessment for three of three patients on 10.21.2022.</p>