

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0860277	(X3) Date Survey Completed 04/22/2021
Name of Provider or Supplier Hickory Dermatology	Street Address, City, State 1899 Tate Boulevard Se, Suite 2110, Hickory, NC	
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 review of the laboratory's procedures, review of quality control records, and interview with the Histology Technician 4/22/21, the laboratory failed to document quality control each day of use for the H&E(Hematoxylin and Eosin) stain. Findings: The laboratory's Histopathology-Mohs surgery procedure states, "Frequency and Record of Quality Control Analysis.. Each day that this procedure is performed, the Mohs surgeon checks the first slide of the day to make sure that the Hematoxylin and eosin stain is adequate. They will receive a quality form to fill out each day..." Review of quality control records revealed the Mohs Surgeon failed to document that the H&E stain was adequate each day the procedure was performed for approximately 22 days in March 2020. At approximately 2pm 4/22/21, the Histology Technician confirmed the Mohs Surgeon failed to document for the H& E stain each day of use in March 2020.</p>
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedures, review of patient and quality control records, and interview with the Histology technician 4/22/21, the laboratory failed to document the positive and negative control reactivity for the immunohistochemical stain each time of use. Findings: Review of the laboratory's Histopathology- Mohs Surgery procedure and interview with the Histology technician on 4/22/21 revealed the laboratory performs the Mart-1/Melan-A immunohistochemical stain procedure. The laboratory completes an "Immuno Checklist and QC" record and the Mohs surgeon checks and documents for the positive and negative control and stain quality for each patient that has the immunohistochemical stain procedure performed. Review of random "Immuno Checklist and QC" records revealed the positive and negative control reactivity of the immunohistochemical stain was not documented for the following: a. # 376291 on 8/21/19; b. # 379623 on 9/26/19; c. # 300639 on 9/30/19; d. # 379549 on 10/1/19. The Histology Technician confirmed at approximately 2:30pm that the positive and negative control reactivity was not documented for the 4 patients reviewed.