

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0860277	(X3) Date Survey Completed 06/04/2024
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
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> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2021, 2022, 2023, and 2024 quality control records, and interview with histotechnician #1 on 6/4/24, the laboratory failed to document the negative control for the Mart-1 immunohistochemical stain during a three-year period from 5/18/21-6/3/24. Approximately 729 patients were tested during this time. Findings: Review of the manufacturer's product insert for the Bio SB Mart-1/Melan-A antibody used to perform the Mart-1 immunohistochemical stain procedure revealed "... Product Limitations Due to inherent variability present in immunohistochemical procedures (including fixation of tissues, dilution factor of antibody, retrieval method utilized, and incubation time), optimal performance should be established through the use of positive and negative controls. ..." Review of 2021, 2022, 2023, and 2024 quality control records revealed the laboratory documented positive and negative controls for the Mart-1 stain from 4/22/21 (the date of the previous survey) to 5/13/21. On 5/18/21, the laboratory began using a different form to record quality control. The new form did not include a place to document results for the negative control, and only the positive control was documented. Approximately 729 patients were tested 5/18/21-6/3/24 when the negative control was not documented. During interview at approximately 2:30 p.m., the histotechnician confirmed that the current "Immuno Checklist and QC" form does not have a place to document the Mart-1 negative control.</p>