Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1096968	03/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Charlotte Dermatopathology	11301 Golf Links Drive North, Suite 205, Charlotte, 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
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, review of the manufacturer's instructions, review of QC(quality control) and patient records, and staff interview 3 /30/22, the laboratory failed to check and record negative reactivity each time of use for the MART-1 IHC(immunohistochemical) stain. Findings: The laboratory's "Positive and Negative Controls for Histopathology" procedure states, "..Normal skin specimens may be generated from excess tissue specimens that would normally be discarded and has been found to be negative for disease process on previous testing. These blocks would be negative controls for many studies..." The Bio-Care Medical MART-1 Cocktail product insert revealed, "limitations:...The clinical interpretation of any positive or negative staining should by complemented by morphological studies using proper positive and negative internal and external controls..." Review of MART-1 QC logs revealed slide quality documented for each day slides are read. Review of a computer-generated patient and QC log revealed documentation for each case where MART-1 stain was performed. Approximately 625 patients had MART-1 IHC stain performed from time of last survey in May 2019 to March 2022, a period of approximately 34 months. At approximately 11:40 a.m., the Histotechnologist confirmed they are staining a positive control each time of use. She stated the computer-generated patient and QC log showed that the positive control was stained

	correctly for each case performed. At approximately 12 p.m., the Laboratory Director confirmed they are only documenting the positive control reactivity for MART-1 IHC stain.