

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1089309	(X3) Date Survey Completed 07/22/2022
Name of Provider or Supplier Advanced Dermatology And Skin Cancer	Street Address, City, State 7658 Poplar Pike, Germantown, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, document request and interview with the laboratory director, the laboratory failed to monitor the storage temperature of stains/reagents used in histopathology procedures. The findings include: 1. Virtual observation of the laboratory on 07/22/2022 at 8:30 am revealed Mart-1 one reagents/stains used in histopathology MOHS procedure stored in the refrigerator. 2. Review of the manufacturer package insert revealed that the reagents/stains are to be stored at 2-8 degrees Celsius. 3. Request made to the lead histotech on 07/22/2022 at 9 am for records of temperature monitoring for the refrigerator where the reagents were stored revealed no records were available. 4. Interview with the laboratory director on 07/22/2022 at 11:00 am confirmed the laboratory does not monitor the temperature of the refrigerator where the Mart-1 reagents/stains are stored.</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</p>

reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer package insert, patient MOHS cases, document request, and interview with the laboratory director, the laboratory failed to document positive and negative control reactivity for three of three selected cases for use of the Mart-1 immunohistochemistry (IHC) stain in 2021 and 2022. The findings include: 1. Virtual observation of the laboratory on 07/22/2022 at 8:30 am revealed Mart-1 IHC reagents/stains used in histopathology MOHS procedures stored in the refrigerator. 2. Review of the manufacturer package insert revealed that "Positive and negative controls should be run simultaneously with patient specimens." 3. Review of randomly selected patient MOHS procedures where the Mart-1 immunohistochemical stain was used revealed patient testing done on the following dates: Case #21G8673-Performed on 04/13/2021 Case #21G8760-Performed on 06/01/2021 Case #22G9455-Performed on 06/28/2022 4. Request on 07/22/2022 at 10:30 am to the lead histotech for documentation of positive and negative control results for the selected cases revealed no documentation was present. 5. Virtual interview with the laboratory director on 07/22/2022 at 11:00 am confirmed the laboratory failed to document positive and negative reactivity for Mart-1 IHC stain for three of three selected dates/cases in 2021 and 2022.