

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1023695	(X3) Date Survey Completed 12/11/2023
Name of Provider or Supplier Dermatology And Skin Surgery Center, Plc	Street Address, City, State 111 N Nappanee St, Elkhart, IN	
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, record reviews, and interview, the laboratory failed to monitor and document humidity for one of one cryostat (Avantik QS 12) for 24 of 24 months (December 2021 to November 2023) and ten (PT#2-PT#11) of 11 patients reviewed. Findings Included: 1. A tour of the MOHS Microscopic Surgery (MOHS) Laboratory on 12/12/2023 at 10:53 am, revealed a cryostat used for MOHS testing, Avantik QS 12. 2. Review of the documents "Maintenance Record- Equipment Quality assessment and other" from December 2021 to November 2023 indicated there was no documentation for Humidity. 3. Review of the binder "CLIA regulations/manual", reviewed by Laboratory Director on 7/5/2023, revealed the procedure "Equipment Quality Control" required daily temperature checks and documentation, but did not require humidity check and documentation. 4. Review of the "Instruction Manual, The Avantik QS12 Cryostat", revision 2, page 14 "Technical Specifications " requires that air humidity to be lower than 60 percent up to 35 degrees Celsius. 5. Review of patient's records revealed the following patient had MOHS testing performed when humidity was not monitored: a) PT#2 tested on 1/4/2022 for MOHS. b) PT#3 tested on 7/15/2022 for MOHS. c) PT#4 tested on 12/15/2022 for MOHS. d) PT#5 tested on 2/23/2023 for MOHS. e) PT#6 tested on 8/24/2023 for MOHS. f) PT#7 tested on 11/21/2023 for MOHS. g) PT#8 tested on 8/19/2022 for MOHS. h) PT#9 tested on 10/25</p>

/2022 for MOHS. i) PT#10 tested on 5/23/2023 for MOHS. j) PT#11 tested on 9/15/2023 for MOHS. 6. On 12/11/2023 at 12:30 pm, Sp-1 (office manager) confirmed that humidity was not monitored or recorded. 7. Annual test volume for MOHS testing is 1,746.