Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2164056	01/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And Skin Cancer Surgery Center	731 Stirling Center Place #1931, Lake Mary, FL	

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
D0000	An on-site validation survey was conducted on January 29, 2026 with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory policies and procedures, and interview with the Testing Personnel (TP), the laboratory failed to have an established written policy and procedure to assess testing personnel and consultant competency for two of two years. Findings Included: 1. Review of the CMS Form 209 submitted revealed one TP and one Technical Supervisor (TS) listed for the laboratory. 2. Review of the laboratory's policy titled 'Dermatology and Skin Cancer Surgery Center-Staff Qualifications and Training' stated the following: "The Laboratory shall ensure that all personnel performing MMS (Mohs Micrographic Surgery) and related laboratory services possess appropriate qualifications, training, and experience as required ...". The policy did not include elements including procedures on staff competencies, how to perform competencies, and frequencies. 3. In an interview on January 29, 2026 at 9:17 AM in the laboratory, the TP confirmed the policy was approved and signed in January 2026, but did not include procedural elements related to competency for testing personnel and consultants.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions, laboratory policy and procedures, temperature records, and interview with the Testing Personnel (TP), the laboratory failed to define an acceptable temperature range for the Leica CM 1510 S Cryostat machine in accordance with manufacturer instructions for three of three months (Random Review October 2025 to December 2025). Findings Included: 1. During a laboratory tour at 8:50 AM, one Leica CM 1510 S Cryostat machine (Serial Number 043638460) was observed in use within the laboratory. 2. Review of the manufacturer's instructions titled 'Leica Microsystems Leica CM1510 S Cryostat Instructions Manual V1.4' stated the following temperature range requirements on page 33 of 56: "Skin with fat (-35 to -25 degrees Celsius). Skin without fat (-25 to -15 degrees Celsius)." 3. Review of the laboratory's policy titled 'Dermatology and Skin Cancer Surgery Center Quality Control' stated the following: "Principle Quality control activities are utilized to evaluate the uniformity of specific processes and basic functions to assure that they operate within acceptable parameters. The process include accessioning, processing, interpretation, reporting, and storage of submitted specimens. Quality control activities involve: Maintaining adequate lighting, water and drainage, and air conditioning in the laboratory. Routine checking and maintenance of cryostat. Maintaining temperature record of cryostat (-20 Celsius to -25 Celsius) ..." 4. Review of the laboratory's temperature records ranging from October 2025 to December 2025, titled 'Dermatology and Skin Cancer Surgery Center Mohs Equipment Check Log Lake Mary', revealed an acceptable temperature range of -26 to -22 degrees Celsius. 5. In an interview on January 29, 2026 at 9:43 AM in the laboratory, the TP confirmed the that the laboratory tested samples of skin with and without fat, and the acceptable temperature range was not defined in accordance with the manufacturer's instructions nor the laboratory's policy.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies and procedures,

	temperature records and corrective action documentation, the laboratory failed to document corrective actions taken when temperatures dropped below established ranges for the Leica CM 1510 S Cryostat machine for six of six days when testing was performed from October 2025 to December 2025 (Random Review). Findings Included: 1. During a laboratory tour at 8:50 AM, one Leica CM 1510 S Cryostat machine (Serial Number 043638460) was observed in use within the laboratory. 2. Review of the laboratory's policy titled 'Dermatology and Skin Cancer Surgery Center Quality Control' stated the following: "Principle Quality control activities are utilized to evaluate the uniformity of specific processes and basic functions to assure that they operate within acceptable parameters. The process include accessioning, processing, interpretation, reporting, and storage of submitted specimens. Quality control activities involve: Maintaining adequate lighting, water and drainage, and air conditioning in the laboratory. Routine checking and maintenance of cryostat. Maintaining temperature record of cryostat (-20 Celsius to -25 Celsius) ..." 3. Review of the laboratory's temperature records ranging from October 2025 to January 2026, titled 'Dermatology and Skin Cancer Surgery Center Mohs Equipment Check Log Lake Mary', revealed an acceptable temperature range of -26 to -22 degrees Celsius, with the following dates when temperatures were recorded below the acceptable range without corrective action documentation: a. 10/31/2025 Cryostat Temperature Recorded: -27 degrees Celsius b. 11/14/2025 Cryostat Temperature Recorded: -27 degrees Celsius c. 11/21/2025 Cryostat Temperature Recorded: -27 degrees Celsius d. 11/28/2025 Cryostat Temperature Recorded: -27 degrees Celsius e. 12/5/2025 Cryostat Temperature Recorded: -27 degrees Celsius f. 12/12/2025 Cryostat Temperature Recorded: -27 degrees Celsius 4. In an interview on January 29, 2026 at 9:43 AM in the laboratory, the TP confirmed the findings of temperatures being recorded below the acceptable range with no corrective action documentation.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, personnel records and interview with the Testing Personnel (TP), the Technical Supervisor (TS) failed to maintain testing personnel competency to perform test procedures and report test results promptly, accurately and proficiently for one of one TP. Findings Included: 1. Review of the laboratory's policy titled 'Dermatology and Skin Cancer Surgery Center-Staff Qualifications and Training' stated the following: "The Laboratory shall ensure that all personnel performing MMS and related laboratory services possess appropriate qualifications, training, and experience as required ..." 2. Review of the laboratory's personnel records titled 'Testing Personnel Competency and Evaluation Dermatology and Skin Cancer Survey Center - Lake Mary', revealed a cover sheet, dated January 12, 2026, with six required elements for competency assessment check-marked for the TP and signed by the TS, but no substantiating documentation provided of the competency assessment activities performed. 3. In an interview on January 29, 2026 at 9:17 AM in the laboratory, the TP confirmed she could not retrieve the documentation of patient slides, QC reviews, assessment of previously

	analyzed, blind samples, and more, of the six-element competency assessment requirements, that were specifically used to evaluate her competency as TP by the TS.