

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0680317	<b>(X3) Date Survey Completed</b>  12/01/2020
<b>Name of Provider or Supplier</b>  Associated Skin Care Specialists Pa -Coon Rapids	<b>Street Address, City, State</b>  3833 Coon Rapids Blvd Suite #280, Coon Rapids, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document instrument temperatures for a cryostat for two of three dates on which Mohs surgery was performed. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing as confirmed by the Nurse Manager (NM) during the entrance interview on 12/01/20 at 10:05 a.m. 2. A Leica model HM550 (S/N: 28140) and a Leica model HM550P (S/N: 53456) cryostat were observed as present and available for use during a tour of the lab. 3 A requirement to record the operating temperature of the cryostats each day of patient testing was established in the Procedure for Equipment / Daily Cryostat (MICROM), located in the Laboratory Manual. 4. During a review of the Cryostat Daily / Weekly / Monthly QA Log, cryostat temperature documentation was not found in laboratory records for two of three days on which Mohs surgery was performed during the timeframe reviewed, 08/20/18 through 12/01/20. Date of service: Mohs Case # performed: 9/12 /19 CM19-357 10/15/20 CM20-423 5. The laboratory was unable to provide the missing records upon request. 6. During an interview on 12/01/20 at 11:15 a.m., the NM confirmed the above findings. .</p>