

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1053093	(X3) Date Survey Completed 10/10/2018
Name of Provider or Supplier Hull Dermatology, Pa	Street Address, City, State 500 S 52nd Street, Rogers, AR	
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: Through a review of the "Frozen Section Procedure", a review of cryostat temperature log, MOHS surgery log and interviews with laboratory staff, it was determined the laboratory failed to monitor cryostat temperature to ensure reliable test system operation on two of nine days when MOHS surgery procedures were performed in September 2018. Survey findings include: A. The "Frozen Section Procedure" states, "Make sure the cryostat is at proper operating temperature -20 degrees Celsius to -30 degrees Celsius." B. Review of the cryostat temperature log for 2018 revealed that the cryostat operating temperature was not documented on September 4, 2018 and September 25, 2018. C. Review of the MOHS surgery log revealed that MOHS surgery was performed on the patient identified as number one on a separate patient identification logs on September 4, 2018 and on patient identified as number 2 on a separate patient identification log on September 25, 2018. D. In an interview at approximately 03:30 p.m. on 10/10/18, laboratory employee #2 (as listed on the Personnel Identification Worksheet) confirmed that cryostat temperature was not documented on September 4, 2018 and September 25, 2018.</p>