Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1076040	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Maryland Skin Cancer Specialists	75 Thomas Johnson Drive Suite H, Frederick, MD	

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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports and interview with the office manager, the final test report did not include the unique identifier assigned to the patient specimen by the laboratory and used throughout the testing process. Findings: 1. During the survey four patient charts were pulled to review the final report with the patients test results. Four of the four that were reviewed did not include the unique identifier/case number of the patient sample used during the testing process. 2. During the exit interview on 06/11/2019 at 11:45 AM the office manager confirmed that unique identifier/case number was not included on the final report.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of the quality control (QC) stain records and interview with the office manager, the laboratory director (LD) failed to ensure that the travel histotech who filled in when the routine testing person was unavailable had the proper education and training needed to perform high complexity testing. Findings: 1. The QC stain records for June 2019 through July 2017 were reviewed. 2. The records showed that on the following dates the regular histotech was not working in the laboratory: 08/30/17, 09/01/17, 11/17/17, 01/09/18, 02/09/18, 11/07 /18, 11/14/18, and 11/21/18. The records included the initials of five different histotechnologists. 3. When interviewed the laboratory manager stated that they contacted a company that provided traveling histotechnologists as needed. The company did not provide documentation showing that each of the five histotechnologists met the minimum qualifications of an associate degree in a laboratory science so that they could perform high complexity testing. 4. Review of the evaluation records for the testing personnel showed that there were no documentation showing that each of the five traveling histotechnologists received initial training that included review of the procedure manual; duties and responsibilities; maintenance, and orientation of the laboratory equipment. 5. During the exit interview on 06/11/2019 at 11:45 AM the office manager confirmed that the LD did not ensure that the traveling histotechnologists met the minimum qualifications of an associate degree in a laboratory science and provide initial training to ensure that the histotechnologists were capable of performing the testing per the specifics in the procedure manual for their laboratory.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on observation, review of the daily maintenance records and interview with the testing person, the testing person did not follow the laboratory's procedures for documenting the temperature of the cryostat that was being used each day of testing. Findings: 1. The laboratory has two cryostat available for use in the laboratory. The daily worksheets for May and June 2019 showed that the temperature of one cryostat is recorded each day of testing. 2. When interviewed the testing person stated that sometimes she may be using both of the cryostats but only records the temperature of one of the cryostats. 3. The testing person confirmed that she did not record the identity and temperature of both cryostats when both were in use. 4. During the exit interview on 06/11/2019 at 11:45 AM the testing person confirmed that the daily worksheets did not include the identity and temperature of both cryostats when both were in use.