

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D1027797	<b>(X3) Date Survey Completed</b>  03/28/2019
<b>Name of Provider or Supplier</b>  Maryland Skin Cancer Specialists Pa	<b>Street Address, City, State</b>  9711 Medical Center Drive #307, Rockville, MD	
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>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the patient final report and interview with the laboratory manager, the laboratory did not utilize a unique identifier nor a identification number on the patient report for positive identification. Findings: 1. Review of five patient reports from the year 2018 did not have a unique identifier nor a identification number on the final report. 2. The testing person stated that she was not aware that the final report needed a unique identifier or a identification number for positive patient identification. 3. The laboratory manager stated that the laboratory has never utilized a unique patient identifier nor a identification number on the final report.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:  
 Based on review of error log reports and interview with the testing person, the laboratory director (LD) failed to ensure that quality assessment procedures were established to maintain the quality of laboratory services when the laboratory employed travel techs to cover the lab when the testing person was unavailable. Findings: 1. The laboratory performs histopathology testing. 2. The testing person performs the inking of patient tissue once submitted in the laboratory by the director. 3. The testing person performs the maintenance procedures, maintains temperature records, slide preparation, and staining. 4. On January 18, 2018 and February 8, 2018 a travel tech was employed by the laboratory to perform the duties of the testing person. 5. On January 18, 2018 the travel tech mislabeled a patient slide and on February 8, 2018 the travel tech incorrectly assigned accession numbers on 8 patient slides. 6. The testing person documented the errors for 1/18/2018 and 2/8/2018 on the "lab error log" stating that she was the responsible person and a review was performed by the LD. 7. In the "future prevention" section on the "lab error log" was documentation that outlined steps to prevent the error from reoccurring. 8. The LD did not document a remedial training nor educate the travel tech who was responsible for making the errors.

**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 written procedure manual, interview with the testing person, and the laboratory manager, the laboratory director (LD) failed to ensure that the travel tech hired to work days when the testing person is unavailable had the proper education and training needed to perform high complex patient testing. Findings: 1. The laboratory performs histopathology testing. 2. The testing person performs the inking of patient tissue once submitted in the laboratory by the director. 3. The testing person performs the maintenance procedures, maintains temperature records, slide preparation, and staining. 4. On January 18 and February 8, 2018 a travel tech was employed by the laboratory to perform the duties of the testing person. 5. The LD did not maintain on file the name of the travel tech nor documentation of the maintenance procedures, temperature records, slide preparation, and staining performed by the travel tech. 6. The LD did not ensure that the travel tech had received the appropriate education to perform histopathology testing and a copy of the diploma was not not file in the laboratory. 7. The LD did not ensure that prior to performing laboratory testing the travel tech received the appropriate training, competent to perform the duties of histopathology testing , and read the laboratory standard operation procedures to perform the duties of the testing person. 8. Observations of competency skills were not documented by the LD such as inking and quality control of prepared slides. 9. The testing person stated that training and competency was not performed by the LD and the laboratory manager stated that education records were not on file.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, interview with the testing person, and the laboratory manager, the laboratory director (LD) failed to ensure that polices and procedures were established for monitoring travel techs who performs histopathology testing. Findings: 1. On January 18 and February 8, 2018 a travel tech was employed by the laboratory to perform the duties of the testing person. 2. The LD did not ensure that prior to performing laboratory testing the travel tech received the appropriate training, competent to perform the duties of histopathology testing , and read the laboratory standard operation procedures to perform the duties of the testing person. 3. On January 18, 2018 the travel tech mislabeled a patient slide and on February 8, 2018 the travel tech incorrectly assigned accession numbers on 8 patients slides. 4. The LD did not have procedures for performing and documenting remedial training to improve the skills of the travel tech. 5. The testing person stated that remedial training procedures were not performed by the LD.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual and interview with the testing person, the laboratory director did not specify in writing the duties and responsibilities of the travel tech. Finding: 1. The laboratory director did not have the duties and responsibilities of the travel tech who is responsible for working on days when the testing person is not available. 2. The testing person confirmed that duties and responsibilities of the travel tech who is responsible for working on days when she is not in the lab was not available.