

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2227667	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Warren Skin Care Center, Pa	Street Address, City, State 2597 Schoenersville Rd Room 303, Bethlehem, PA	
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient mohs microscopic examination maps and interview with the histotechnician, the laboratory failed to ensure each test requisition (mohs maps) solicits the address of the laboratory from August 2021 to the day of survey. Findings include: 1. The Mohs Maps list the following addresses: - 755 Memorial Parkway #204, Philipsburg, NJ 08865. - 2209 Lehigh Street, Easton, PA 18042. 2. On the day of survey, 11/10/2021, review of a sampling of Mohs maps (2 of 2) revealed, the laboratory mohs maps did not include the address of the laboratory where samples were collected (755 Schoenersville Road, Bethlehem, PA 18017). 3. During an interview on 11/10/2021 around 9:10 am, the histotechnician confirmed all mohs maps have not been updated to include the address of the laboratory at 755 Schoenersville Road, Bethlehem, PA 18017.</p>

<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure and interview with the histotechnician, the laboratory failed to have their laboratory procedure signed and dated by the current laboratory director (LD) from August 2021 to the day of survey. Findings include: 1. On the day of survey, 11/10/2021, a review of the laboratory procedure sheets revealed, the Mohs laboratory procedure in use was not signed and dated by the LD for the new laboratory location. 2. The histotechnician confirmed the finding above on 11/10/2021 around 8:35 am.</p>
<p>D5805</p>	<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 the review of a sampling of patient test reports and interview with the histotechnician, the laboratory failed to include on their test reports the exact location where mohs microscopic examinations were analyzed from August 2021 to the day of survey. Finding Include: 1. The Mohs final reports list the following addresses: - 755 Memorial Parkway #204, Philipsburg, NJ 08865. - 2209 Lehigh Street, Easton, PA 18042. - 755 Schoenersville Road, Bethlehem, PA 18017. 2. On the day of survey, 11 /10/2021, a review of a sampling of test reports (2 of 2) revealed, the mohs microscopic examination test reports did not state which one of the three laboratory addresses tests were reported from August 4, 2021 to November 10, 2021. 3. During the interview on 11/10/2021 around 8:45 am, the histotechnician confirmed neither the electronic medical record system or patient test reports state, which address mohs micrographic examinations were analyzed.</p>
<p>D6094</p>	<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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure and interview with the histotechnician,</p>

the laboratory director (LD) failed to ensure quality assessment (QA) programs were established to assess the quality of laboratory services provided from August 2021 to the day of survey. Findings Include: 1. On the day of survey, 10/06/2021, the laboratory could not provide a QA procedure to assess the laboratory's pre-analytic, analytic and post analytic phases of testing. 2. The laboratory could not provide documentation of periodic assessment of the laboratory from August 2021 to November 2021. 3. The histotechnician confirmed the findings above on 11/10/2021 around 9:20 am.