

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2091155	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Dermatology Ltd, Chadds Ford	Street Address, City, State 1788 Wilmington West Chester Pike, Glen Mills, 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
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory competency assesment records and interview with the Technical Supervisor #1 (TS), the TS #1 failed to evaluate the competency assessment of 1 of 1 Testing Personnel (TP) who performed Mohs microscopic examinations from 10/26/2018 to the day of survey. Findings include: 1. On the day of survey 04/16/2021, the TS could not provide competency assessment record for 1 of 1 TP who performed Mohs microscopic examinations from 10/26/2018 to the day of survey. 2. The TS#1 confirmed the finding above on 04/16/2021 at 11:25 a.m.</p>
D8103	<p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)</p>

(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with Testing Personnel #8 (TP8), The laboratory failed to provide Mohs microscopic examinations slides requested during the time of survey. Findings Include: 1. On the day of survey 04/16/2021, during the interview with TP 8, it was stated that the laboratory takes the slides to their other facility, located in Media, PA, after each day of patient testing for storage. 2. The laboratory could not retrieve Mohs Microscopic examinations slides upon request on 04/16/2021 at 12:00 p.m. 3. The TP#8 confirmed the findings above on 04/16/2021 at 12:30 p.m.