

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0916536	<b>(X3) Date Survey Completed</b>  09/02/2020
<b>Name of Provider or Supplier</b>  Dermatologic Surgi Center	<b>Street Address, City, State</b>  2221 Garrett Road, Drexel Hill, PA	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and interview with the histotechnologist (HT), the laboratory failed to establish a competency assessment policy to assess the competency for 2 of 3 personnel for their regulatory responsibilities from 2018 to the day of survey. Findings include: 1. On the day of survey, 09/02/2020, the HT could not provide a competency assessment policy for 2 of 3 personnel for their regulatory responsibilities (On the CMS 2019 Testing Personnel form, listed as a clinical consultants (CC) technical supervisors (TS) and general supervisors (GS)) in 2018, 2019 and 2020. 2. The HT could not provide documentation of regulatory competency for 2 of 3 CC, TS and GS from 2018, 2019 and 2020. 3. The HT confirmed the findings above on 09/02/2020 around 09:40 am.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on the review of the Mohs frozen section examinations procedure manual and interview with histotechnologist (HT), the laboratory failed to include, how physicians enter results into patient records for Mohs frozen sections examination procedure manual from 2018 to the day of survey. Findings Include: 1. On the date of survey, 09/02/2020, review of the Mohs frozen section examinations procedure manual revealed, how physicians enter results into patient records were not stated in the procedure manual from 02/09/2018 to 09/02/2020. 2. The HT confirmed the finding above on 09/02/2020 around 11:00 am.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the histotechnologist (HT), the LD failed to ensure a quality assessment (QA) policy was established to assess the quality of laboratory services provided from 2018 to the day of survey. Findings Include: 1. On the date of survey, 09/02/2020, the HT could not provide a QA policy that assessed the laboratory's pre-analytical, analytical, and post-analytical processes from 02/09/2018 to 09/02/2020. 2. The HT confirmed the finding above on 09/02/2020 around 10:10 am.