

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2130682	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier Nj Cd DbA Dedicated Dermatology	Street Address, City, State 281 N 12th St Suite 2b, Lehigh, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histotechnologist, quality manager and operations director, the laboratory failed to document expiration dates on 4 of 4 bottles of Davidson Tissue Marking Dyes prior to use on 1/15/2020. Findings include: 1. On the day of survey, 10/06/2021, observation of the laboratory revealed, the laboratory did not document expiration dates for 4 of 4 bottles of Davidson Tissue Marking Dyes (Blue, Red, Green and Yellow) that were received on 11/13/2019 and opened on 1/15/2020. 2. The laboratory was unable to provide a procedure for the handling of reagents without expiration dates. 3. The histotechnologist, quality manager and operations director confirmed the findings above on 10/06/2021 around 11:40 am.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities</p>

specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on lack of records and interview with the histotechnologist, quality manager and operations director, the laboratory failed to perform maintenance/function checks for 1 of 1 Olympus BX41 Microscope used to examine Mohs micrographic examinations from 2019 to the day of survey. Findings Include: 1. The MOHS procedure, VI. Maintenance, C. Annually states, "Have preventative maintenance services performed on the cryostat, linistain slide reader and the MOHS pathologist microscope". 2. On the day of survey, 11/06/2021, the laboratory could not provide annual preventative maintenance records for 1 of 1 Olympus BX41 Microscope used to examine Mohs micrographic examination from 10/06/2019 to 10/06/2021. 3. The histotechnologist, quality manager and operations director confirmed the findings above on 10/06/2021 around 11:20 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 quality assurance procedure and interview with the histotechnologist, quality manager and operations director, the laboratory director (LD) failed to ensure quality assessment (QA) programs were maintained in 2019 and 2020. Findings Include: 1. The quality assurance procedure states, "The LD or designee will audit each MOHS lab location periodically, at least annually..." 2. On the day of survey, 10/06/2021, the laboratory could not provide documentation of annual QA activities performed to assess the laboratory's pre-analytic, analytic and post analytic phases of testing in 2019 and 2020. 3. The histotechnologist, quality manager and operations director confirmed the findings above on 10/06/2021 around 11:20 am.