

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2019621	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Warren Skin Care Center, Pa	Street Address, City, State 2209 Lehigh Street, Easton, 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 tour of the laboratory, observation of reagents and interview with the histopathology technician, the laboratory failed to document all open and expiration dates of reagents prior to use from 03/30/2019 to 03/30/2021. Findings include: 1. On the day of survey, 03/30/2021, while on tour of the laboratory, it was discovered that the laboratory did not document the open and expiration dates of 1 of 1 bottle of Davidson Tissue Marking Dyes (Blue) Lot# 571-813270. 2. The histopathology technician confirmed the finding above on 03/30/2021 around 12:45 pm. **** Repeat Deficiency.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histopathology technician, the laboratory failed to perform the maintenance for 1 of 1 Olympus EX-</p>

41 microscope used to examine histology slides from 09/2019 to 03/30/2021. Findings include: 1. On the day of survey, 03/30/2021, observation of the laboratory revealed, 1 of 1 Olympus EX-41 microscope, Serial # 9E0947, maintenance sticker stated, "Due 9 /2019". 2. The laboratory was unable to provide documentation of maintenance performed on the Olympus EX-41 microscope after 09/2019. 3. The histopathology technician confirmed the findings above on 3/30/2021 around 12:45 pm.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

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

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, observation of the laboratory and interview with the histopathology technician, the laboratory failed to establish a maintenance policy to ensure 1 of 1 Baldr room temperature thermometer can monitor temperatures accurately from 03/30/2019 to 03/30/2021. Findings include: 1. On the day of survey, 03/30/2021, observation of the laboratory revealed, 1 of 1 Baldr room temperature thermometer was in use to monitor the temperature of the laboratory, the thermometer did not have maintenance sticker. 2. The laboratory was unable to provide documentation of the last maintenance performed on the Baldr room temperature thermometer from 03/30/2019 to 03/30/2021. 3. The laboratory was unable to provide a maintenance policy for thermometers, where function check protocols are not provided by the manufacturer. 4. The histopathology technician confirmed the findings above on 3/30/2021 around 12:45 pm.

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 histopathology technician, the laboratory director (LD) failed to ensure quality assessment (QA) programs were established to assure the quality of laboratory services provided from 2019 to the day of survey. Findings include: 1. On the date of survey, 03/30/2021, the laboratory could not provide a QA procedure or documentation of periodic evaluation of the laboratory assess its pre-analytical, analytical, and post-analytical processes from 03/30/2019 to 03/30/2021. 2. The histopathology technician confirmed the finding above on 03/30/2021 around 12:30 pm.