

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0987989	(X3) Date Survey Completed 06/16/2021
Name of Provider or Supplier Center For Skin Surgery Pc Lab,The	Street Address, City, State 1606 Carmody Court Blaymore I, Sewickley, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of peer review records and interview with the histotechnician (HT), the laboratory failed to perform twice annual verification of accuracy for tissue pathology microscopic examinations in 2019. Findings Include: 1. On the day of survey, 06/16/2021, the laboratory could not provide twice annual verification of accuracy performed for tissue pathology microscopic examinations in 2019. 2. The Laboratory could not provide a policy for the performance of twice annual verification of accuracy for tissue pathology microscopic examinations. 3. The HT confirmed the findings above on 6/16/2021 around 01:10 pm.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histotechnician (HT), the laboratory failed to ensure that 2 of 4 bottles of tissue marking dyes were not used beyond their expiration date. Finding Include: 1. On the day of survey, 06/16/2021, observation of the laboratory revealed, 2 of 4 Cancer Diagnostic Inc. (CDI) tissue</p>

marking dyes were expired: - Green CDI bottle, Batch Code: 4204 - Expired: 2016 /01. - Black CDI bottle, Lot# 7172 - Expired: 2018/09. 2. The HT confirmed the findings above on 06/16/2021 around 13:50 pm.

D5429

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

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.

This STANDARD is not met as evidenced by:

Based on observation, lack of documentation and interview with the histotechnician (HT), the laboratory failed to document maintenance for 1 of 1 room temperature thermometer from 05/12/2018 to 06/16/2021. Findings include: 1. On the day of survey, 06/16/2021, observation of the laboratory revealed, 1 of 1 Fisher Scientific Traceable min/max thermometer monitoring the room temperature, service sticker stated, "Due 05/12/2018". 2. The laboratory could not provide a maintenance procedure for the room temperature thermometer. 3. The HT confirmed the findings about on 06/16/2021 around 1:50 pm.