

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1077356	(X3) Date Survey Completed 12/08/2020
Name of Provider or Supplier Lance H Brown Md Pllc	Street Address, City, State 686 County Rd 39a, Southampton, NY	
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
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 surveyor's observation of the laboratory's testing area and an interview with the histotech, the laboratory used testing materials beyond manufacturer's expiration date. FINDINGS: Surveyor observed one Gallon bottle of Eosin lot # G156-19 expiration date 7/7/19 and one Gallon bottle of Hematoxylin lot # 069759 expiration date 4/1/2020. In-date container of Eosin and an in-date container of Hematoxylin were not available for use. Approximately 32 Mohs patient biopsy specimens were processed and test results released using the expired stain reagents.</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 surveyor review of laboratory equipment maintenance records and interview with the histotech, the laboratory failed to follow their established laboratory equipment maintenance policy and the manufacturer maintenance requirement, which require the laboratory to perform an annual preventative maintenance for the Microscope and for the Cryostat used for the histopathology slide reading.</p>

FINDINGS: The laboratory equipment maintenance policy and the manufacturer of the Microscope and the Cryostat require annual preventive maintenance of the Microscope and the Cryostat used for the histopathology slide reading. The records of preventive maintenance were not available at the time of the survey for the Microscope and for the Cryostat for calendar year 2019. Approximately 16 patient slides were read and reported for Mohs surgery during this time frame.