

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0960572	(X3) Date Survey Completed 12/07/2018
Name of Provider or Supplier Bruce E Katz, Md Pc	Street Address, City, State 60 East 56th Street, 2nd Floor, New York, 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
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 a lack of proficiency test verification records and an interview with the practice manager, the laboratory failed to verify the accuracy of the histopathology slides. Findings Include: On December 7, 2018, at approximately 10:45 AM the practice manager confirmed that the laboratory failed to perform twice annual verification for histopathology slide procedure performed for the year 2017. Approximately 1544 patient specimens were tested and results reported for histopathology slides.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor review of cryostat temperature records and an interview with the practice manager, the laboratory failed to monitor and document the cryostat</p>

temperature on the following days of patient testing: Findings Include: On November 7, 2018 at approximately 11:00 am, the practice manager confirmed that the Moh's processors failed to monitor and document the cryostat temperature from the date of the last survey (November 22, 2016) through the date of this survey. Approximately 306 patient specimens were tested and reported for Mohs surgery when cryostat temperatures were not monitored.

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 a review of procedures and an interview with the practice manager, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5217 and D5413