

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0861298	(X3) Date Survey Completed 06/24/2021
Name of Provider or Supplier Gary Karakashian Md Pa	Street Address, City, State 2640 Route 70, Manasquan, NJ	
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 surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the Calendar year 2019. The LD confirmed on 6/24/21 at 9:45 am that the laboratory did not verify the accuracy of Histopathology testing.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from 9/13/18 to the date of survey. The LD confirmed on 6/24/21 at 9:45 am that a BA procedure was not established.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Temperature Charts (TC) and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature on each day of Mohs testing from 9/13/18 to the date of the survey. The finding includes: 1. Review of TC revealed that the laboratory did not monitor and record room temperature from 9/13/18 to the date of the survey on days patient testing was performed. 2. The LD confirmed on 6/24/21 at 9:30 am that the room temperature was not monitored and recorded each day of Mohs testing.