Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0861298	08/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gary Karakashian Md Pa	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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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 Operators Manual (OM) for the Zeiss Axioskop microscope, review of the Temperature Logs and interview with the Testing Personnel (TP) the laboratory failed to monitor and document the humidity range where the Professional Component (PC) for Histopathology tests are performed from 6/24/21 to the date of the survey. The finding include: 1. The OM defined the operating environment maximum relative humidity as 80% for the Zeiss Axioskop microscope. 2. The TP confirmed on 8/28/23 at 2:35 pm the laboratory failed to monitor and document the humidity where the PC for Histopathology tests are performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, a lack of a Reagent Tracking Log and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system from 6/24/21 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure for tracking reagents used in Histopathology testing. 2. The TP confirmed on 8/28/23 at 2:15 pm that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.