Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2142530	04/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
New Jersey Podiatric Physicians	4645 Highway 9 North, Howell, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of Biannual Assessment (BA) records, Procedure Manual (PM) and interview with the Laboratory Consultant (LC) the laboratory failed to follow its "Proficiency Testing" procedure to verify the accuracy and reliability of Histopathology tests from 7/1/22 to 4/2/24. The findings include: 1. The procedure for Proficiency Testing states " if a significant difference of opinion is identified an expert opinion will be obtained for final diagnosis." 2. Case Number NJG22880 was marked as significant disagreement between the reviewing and referring pathologist. 3. There was no documented evidence the expert opinion of a third pathologist was obtained for final diagnosis of the case. 4. The LC confirmed on 4/2/24 at 10:30 am that the laboratory failed to follow its Proficiency Testing procedure.
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 Users Manual (UM) for the Olympus BX40 microscope, the lack of temperature logs and interview with the Laboratory Consultant (LC), the laboratory failed to monitor and document room temperature and humidity where the Professional component (PC) for Histopathology tests were performed from 8/23/22 to the date 4/2/24. The findings include: 1. The UM defined the operating environment ambient temperature as 5 to 40C (41 to 104 F). 2. The UM defined the operating environment of a maximum relative humidity as 80%. 3. There was no record of temperature or humidity in the office where the PC was being performed. 4. The LC confirmed on 4/2/24 at 10:35 am the laboratory failed to monitor and document room temperature and humidity where the PC was being performed.