Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0147714	08/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ocean Parkway Pediatric Practice Pc	515 Avenue I, Brooklyn, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the review of the Cobas Liat manufacturer's requirements, the absence of temperature monitoring, lack of temperature and relative humidity (RH) records, and interviews with the laboratory director and testing person, the laboratory failed to monitor and document the temperatures and RH for the area where patient testing and reagent storage occurred. Findings: 1. The Cobas Liat manufacturer's requirements indicated temperature range of 15C - 32C (59F - 89.6F) and RH range of 15% - 80%. 2. The OSOM reagent manufacturer's requirements indicated temperature range of 15C - 30C (59F - 86F). 3. Approximately 500 patients were tested each year during which the temperatures and RH were not monitored and documented. 4. Confirmed the findings by interview with the testing person and laboratory director on August 17, 2023, at 11:00 A.M.
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 the review of Hardy Diagnostics SSA plate manufacturer's requirements, the laboratory procedure manual, lack of temperature records, and interviews with the laboratory director and testing person, the laboratory failed to document temperatures of the refrigerator where SSA plates were stored. Findings: 1. The Hardy Diagnostics SSA plate manufacturer's requirements indicated storage temperature range of 2C - 8C (35.6F - 46.4F). 2. Although a refrigerator thermometer was present, no temperatures were documented for 2021, 2022, and 2023. 3. Approximately 500 patients were tested each year during which the temperatures were not documented. 4. Confirmed the findings by interview with the testing person and laboratory director on August 17, 2023, at 11:00 A.M.