Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0072037	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Greater Lowell Pediatrics Inc	33 Bartlett St Ste 305, Lowell, MA	

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
D0000	A CLIA recertification survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documenation to verify that validation studies had been performed for all performance characteristics prior to reporting out patient testing results as evidenced by the following: Abbott Cell Dyn Emerald: a) A review of validation studies for the Abbott Cell Dyn Emerald hematology analyzer revealed that there was no documentation of accuracy as well as day to day precision studies being performed. b) The technical consultant confirmed in an interview on 9/21/21 at 10:20 AM that the studies had been performed by the technical representative who set up the analyzer but could not provide the documentation during the time of the survey. The laboratory performs 7,722 complete blood counts annually. .
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, the laboratory director failed to provide a safe environment in which employees are protected from potential physical hazards as evidenced by the following: * On the day of the survey at 9:59 AM it was observed that a space heater was on the floor in the general traffic area of the laboratory creating a potential tripping hazard. .
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to fulfill the responsibility for verification of the laboratory's test performance characteristics as evidenced by the following: a) Documentation was not available to verify that the technical consultant reviewed and approved validation studies for the hematology analyzer prior to implementing the analyzer for patient testing and reporting for within run precision as well linearity (reportable range) studies. b) At the time of the survey documenation was not available to verify that accuracy as well as day to day precision studies were performed for the hematology analyzer prior to implementing the analyzer for patient testing and reporting (refer to D5421) c) The technical consultant confirmed in an interview on 9/21/21 at 10:15 AM that the documenation for accuracy as well as day to day precision studies had been performed but was unable to find the documentation to confirm this. The technical consultant also confirmed not documenting a review of the within run and linearity studies. .