Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0720637	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Merrimack Valley Pediatrics	1 Meetinghouse Road, Suite 8, Chelmsford, 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 Merrimack Valley Pediatrics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to maintain a copy of all proficiency testing records as evidenced by the following: A review of proficiency testing records for calendar years 2016, 2017, and 2018 (6 testing events) revealed the fact that the program report forms and the attestation statements provided by the proficiency testing program were not available for one (1) of the six (6) testing events reviewed (American Associateion of Bioanalysts (AAB) proficiency testing program report form and attestation statement for the second testing events of 2018). The medical assistant interviewed on 10/10/18 at 10:30 AM confirmed that the program report and attestation statement for the above event were not available. .
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 demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for a newly introduced test system as evidenced by the following: Sysmex Cell-Dyn Emerald hematology analyzer Accuracy: a) In October of 2016 the laboratory put into place a new hematology analyzer for the performance of complete blood counts (CBC). A review of the validation studies revealed no documentation that accuracy studies had been performed. Reportable range: b) The laboratory had linearity studies performed to determine the reportable range for the hematology analyzer. A review of the documentation revealed that only the raw data was available. There was no documentation available of the compiled data to calculate the reportable range for the measured parameters of the CBC (white blood count, red blood count, hemoglobin, and platelet count). Day to day precision: c) The laboratory had performed ten (10) days of quality control testing to determine the the day to day precision for the measured parameters of the CBC. A review of the study revealed that only the raw data was available for each day of testing. There were no coefficients of variation (CV's) calculated to determine whether the precision data met or exceeded manufacturer's specifications for day to day precision. The laboratory technologist interviewed on 10/10/18 at 11:42 AM confirmed that the technician who installed the analyzer and had performed some of the installation validation had told her that the analyzer was all set. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review, and confirmed through an interview with the laboratory technologist on 10/10/18, the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy and precision and other pertinent performance characteristics of new test methods as evidenced by the following: Sysmex Cell-Dyn Emerald hematology analyzer Accuracy: a) In October of 2016 the laboratory put into place a new hematology analyzer for the performance of complete blood counts (CBC). A review of the validation studies revealed no

	documentation that accuracy studies had been performed. Reportable range: b) The laboratory had linearity studies performed to determine the reportable range for the hematology analyzer. A review of the documentation revealed that only the raw data was available. There was no documentation available of the compiled data to calculate the reportable range for the measured parameters of the CBC (white blood count, red blood count, hemoglobin, and platelet count). Day to day precision: c) The laboratory had performed ten (10) days of quality control testing to determine the the day to day precision for the measured parameters of the CBC. A review of the study revealed that only the raw data was available for each day of testing. There were no coefficients of variation (CV's) calculated to determine whether the precision data met or exceeded manufacturer's specifications for day to day precision. .
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: Sysmex Cell-Dyn Emerald hematology analyzer Accuracy: a) In October of 2016 the laboratory put into place a new hematology analyzer for the performance of complete blood counts (CBC). A review of the validation studies revealed no documentation that accuracy studies had been performed. Reportable range: b) The laboratory had linearity studies performed to determine the reportable range for the hematology analyzer. A review of the documentation revealed that only the raw data was available. There was no documentation available of the compiled data to calculate the reportable range for the measured parameters of the CBC (white blood count, red blood count, hemoglobin, and platelet count). Day to day precision: c) The laboratory had performed ten (10) days of quality control testing to determine the the day to day precision for the measured parameters of the CBC. A review of the study revealed that only the raw data was available for each day of testing. There were no coefficients of variation (CV's) calculated to determine whether the precision data met or exceeded manufacturer's specifications for day to day precision. The laboratory technologist interviewed on 10/10/18 at 11:42 AM confirmed that the technician who installed the analyzer and had performed some of the installation validation had told her that the analyzer was all set.