Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1077523	11/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric And Young Adult Medicine	1610 Maxwell Drive, Suite 245, Hudson, WI	

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
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the clinic administrator, the laboratory director did not ensure an approved corrective action plan was created and followed for two hematology events in 2017 with unacceptable scores. Findings include: 1. Review of hematology proficiency testing events from 2017 show: Event one included unacceptable hematocrit and red cell count results for sample HEM-01. A corrective action plan was not present in the record. Test / Submitted Result / Expected Result Hematocrit / 33 / 34 - 39 Red Cell Count / 3.74 / 3.86 - 4.36 Event three included an unacceptable result for the differential Monocyte/Mid % on sample HEM-12. A corrective action plan was not present in the record. Test / Submitted Result / Expected Result: Monocyte/Mid % / 5.9 / 3.1 - 5.6 2. Interview with the clinic administrator on November 5, 2018 at 12:45 PM confirmed corrective action plans were not developed or followed for the unacceptable hematology results in 2017 events one and three.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory procedures, corrective action logs, quality control records, the Laboratory Personnel Report (CLIA), and personnel records, and interview with the clinic administrator, the technical consultant, who is also the laboratory director, did not provide technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The technical consultant did not ensure the quality control program was maintained. See D 6042. 2. The technical consultant did not identify and resolve technical problems with the Monocyte/Mid % portion of the automated differential. See D 6043. 3. The technical consultant did not ensure performance of all testing personnel was evaluated and documented in 2017. See D 6054.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) procedures and Corrective Action Logs and interview with the clinic administrator, the technical consultant did not ensure the hematology quality control program, which requires three levels of acceptable controls each day of patient testing, was maintained. Findings include: 1. Review of the laboratory's hematology quality control procedures showed for each day of patient testing the laboratory requires three levels of quality control (low, normal and high) and requires that all results are in acceptable ranges before patient samples are tested. 2. Review of the Corrective Action Log for the Emerald hematology analyzer from November 2017 showed the differential Monocyte/Mid % results for LQC (low QC) were above the acceptable range on November 27, 2017. The entry for November 27 notes the LQC (low QC) was repeated and was still above the acceptable range. No further corrective action is documented. Review of the Corrective Action Log for March 2018 shows the LQC was above the acceptable range on March 19, 2018. The entry notes the control was repeated and a backflush performed with the LQC result still above the acceptable range. No further corrective action is documented. The logs are both initialed by the laboratory director as having been reviewed. No documentation is present to show any further actions were taken by the director who is also the technical consultant. 3. Interview with the clinic administrator on November 5, 2018 at 2:45 PM confirmed the procedure states all three levels of control must be in range to be acceptable. Further interview confirmed staff did not follow procedures and the technical consultant did not ensure the quality control program was maintained as established.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems

	and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) results, quality control (QC) records, and interview with the clinic administrator, the technical consultant, who is also the laboratory director, did not identify and resolve problems with the Monocyte /Mid% result in the automated differential. Findings include: 1. Review of PT records from 2017 event three tested on November 16, 2017 showed the submitted result (5.9) for sample HEM-12 was above the expected range (3.1-5.6) for the Monocyte/Mid% component of the automated differential. No evaluation of this unacceptable result was present in the record. See D6019. Review of records for the next PT event, 2018 event one tested on March 20, 2018, showed three of five submitted results for Monocyte/Mid% were above the expected range. The laboratory's review of the unsuccessful performance indicated Quality Control results were acceptable. Sample / Submitted Result / Expected Result HEM-01 / 10.3* / 1.1 - 8.2 HEM-02 / 5.9* / 2.1 - 5.6 HEM-03 / 4.1 / 2.0 - 4.2 HEM-04 / 6.5* / 2.2 - 6.2 HEM-05 / 5.5 / 3.1 - 6.6 * indicates an unacceptable result 2. Review of the Corrective Action Log from November 2017 showed the Monocyte/Mid% values were unacceptably high and required corrective action on seven days (November 1, 3, 10, 13, 15, 16, 27). Review of the log from March 2018 shows the Monocyte/Mid% values were high and required corrective action on four days. Both logs are initialed by the laboratory director as having been reviewed. Review of the Quality Control Report for the low level control from March 2 through March 30, 2018 shows the assayed (expected) value is 6.0%, all the values obtained by the laboratory were above the assayed value. The average result obtained by the laboratory was 11.1%. The report showed no indication the shift in results was noted or evaluated. 3. Interview with the clinic administrator on November 5, 2018 at 2:45 PM confirmed the records showed no indication that the shift in QC results was identified or evaluated by the technical consultant.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Personnel Report (CLIA) and competency evaluation records and interview with the clinic administrator, the technical consultant did not evaluate and document the performance of two of three testing personnel in 2017. Findings include: 1. Review of the CMS (Centers for Medicare and Medicaid Services) Form 209, Laboratory Personnel Report (CLIA) signed by the laboratory director on November 1, 2018 showed three testing personnel are employed by the laboratory. 2. Competency evaluation records include a letter signed by the laboratory director in January 2017, documenting evaluation of the performance of staff A. No records showing evaluation of performance during 2017 are available for staff B or staff C. 3. Interview with the clinic administrator on November 5, 2018 at 2:45 PM confirmed evaluations of the performance of two testing personnel were not completed in 2017.