Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366207	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Consultants Of Troy	633 E South Blvd, Rochester Hills, MI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain the Medonic hematology analyzer daily patient log for 25 (July 1 -23 and August 1 - 14) of 62 calendar days in 2017 for two years. Findings include: 1. On January 24, 2018 at 2:30 p.m., record review of the Medonic daily patient logs revealed for 25 of 62 calendar days in 2017 the laboratory did not retain the patient's complete blood cell count (CBC) records for two years. 2. During the interview on January 24, 2018 at 2:30 p. m., testing personnel #1 as listed on the CMS-209 confirmed the daily patient logs were not retained for two years.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure written competency policies were implemented for one (#10) of 12 testing personnel in performing the hematology complete blood cell count testing in 2017. Findings include: 1. On January 24, 2018 at 10:05 a.m., record review for one of 12 testing

	personnel revealed the initial competency assessment was not performed and documented in 2017. 2. During the interview on January 24, 2018 at 10:05 a.m., testing personnel #1 and #5 confirmed the initial competency assessment was not completed. ***Repeat Deficiency from June 26, 2014 survey***
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform the hematology calibration procedures at least every six months for one (2017) of two years reviewed. Findings include: 1. On January 24, 2018 at 11:30 a.m., review of the calibration data for the Medonic hematology analyzer revealed the laboratory did not perform and document the calibration procedure every six months for one of two years. 2. On January 24, 2018 at 11:30 a.m. when queried, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor with the documentation to demonstrate the calibrations had been performed every six months in 2017 for the complete blood cell count. 3. During the interview on January 24, 2018 at 11:30 a.m., testing personnel #1 confirmed the calibrations for the hematology analyzer were not performed and documented every six months in 2017.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to maintain a record system that included the identity of the testing personnel for one (#8) of ten patient charts audited for the hematology complete blood cell count (CBC) testing in 2016 and 2017. Findings include: 1. On January 24, 2018 at 2:15 p.m., record review for one of ten patient charts audited revealed the laboratory did not have a record system in place that included the identity of the testing personnel who performed and

	documented the hematology testing. 2. During the interview on January 24, 2018 at 2: 15 p.m., testing personnel #1 as listed on the CMS-209 confirmed the testing personnel identity was not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to provide 1) the hematology complete blood cell count (CBC) units of measurement on the final report in the patients electronic medical records (EMR) for seven (July 2017 to January 24, 2018) of seven months and 2) the final paper report for one (#4) of ten charts audited in the patient's paper chart. Findings include: 1. On January 24, 2018 at 10:37 a.m., record review for seven of seven months the patient's final CBC result in the EMR system revealed the units of measurement were not included in the final report. 2. On January 24, 2018 at 2:00 p.m., record review revealed for one of ten patient charts audited the laboratory did not have a copy of the final report in the patient's paper chart. 3. During the interview on January 24, 2018 at 10:37 a.m. and 2:00 p.m., with testing personnel #1 and #5 as listed on the CMS-209 confirmed the units of measurement for each parameter of the CBC were not reported on the patient's final report in the EMR system and the final paper report was not in the patient's paper chart .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to review and evaluate the hematology complete blood cell count (CBC) results on the Medical Laboratory Evaluation (MLE) proficiency testing final graded report for four (M3 in 2016 and M1-M3 in 2017) of six events reviewed in 2016 and 2017. Findings include: 1. On January 24, 2018 at 11:00 a.m., document review of the MLE proficiency testing final graded reports revealed for four of six events reviewed in 2016 and 2017 there was no documentation to show the laboratory reviewed or evaluated the results.

	2. During the interview on January 24, 2018 at 11:00 a.m., testing personnel #1 and #5 confirmed there was no documentation to show the laboratory reviewed or evaluated the final proficiency testing reports. ***Repeat Deficiency from January 20, 2016 survey***