Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1034340	12/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Consultants Of Troy	50720 Schoenherr Road, Shelby Township, 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 original instrument patient printouts for the Medonic M-Series hematology analyzer for two (#5 and #6) of ten patient charts audited. Findings include: 1. On December 20, 2018 at 12:25 PM, record review for patient charts audited revealed the laboratory did not retain the Medonic M-series hematology instrument printout with the patient's results for two years. 2. During the interview on December 20, 2018 at 12:25 PM, testing personnel #1 as listed on the CMS-209 confirmed patient results from the hematology instrument were not retained for two years.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish a system to ensure the manually entered hematology testing was entered into the patient's electronic medical records (EMR) correctly for two (#6 and #10) of ten patient charts audited. Findings include: 1. On December 20, 2018 at 12:25 PM, record review of patient charts audited revealed the final results in the patient's EMR file did not match the monthly log printed with patient results as follows: a. #6 - the absolute counts for the lymphocytes, monocytes, and the granulocytes were switched with the percent count values. b. #6 - the percent counts for the lymphocytes, monocytes, and the granulocytes were switched with the absolute count values. c. #10 - the white blood cell count, granulocyte absolute, red blood cell count, hemoglobin, hematocrit, RDW%, and the platelet count had values not listed on the monthly log. 2. On December 20, 2018 at 12:25 PM, testing personnel #1 as listed on the CMS-209 confirmed the laboratory did not have a measure in place to ensure the correct results are entered into the EMR system. .
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to detect an incorrect laboratory test result reported out for one (#6) of ten patient charts audited. Findings include: 1. On December 20, 2018 at 12:25 PM, record review revealed for one patient chart audited the final result enetered in the electronic medical records (EMR) system did not match the results on the monthly patient log from the hematology Medonic M-series instrument as follows: a. #6 - the absolute counts for the lymphocytes, monocytes, and the granulocytes were switched with the percent count values. b. #6 - the percent counts for the lymphocytes, monocytes, and the granulocytes were switched with the absolute count values. 2. During the interview on December 20, 2018 at 12:25 PM, testing personnel #1 as listed on the CMS-209 confirmed incorrect results were entered into the patient's EMR.
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 record review and interview, the laboratory director failed to ensure the final Medical Laboratory Evaluation (MLE) hematology proficiency testing reports were reviewed by the appropriate staff for three (3rd event in 2017 and 2nd-3rd events in 2018) of seven events reviewed. Findings include: 1. On December 20, 2018 at 10: 05 AM, record review of the MLE proficiency testing reports revealed there was no documentation to show the testing personnel reviewed the final graded proficiency testing reports to evaluate the laboratory's performance and identify any problems that would require corrective action as follows: a. 2017 - 3rd event b. 2018 - 2nd and 3rd events 2. During the interview on December 20, 2018 at 10:05 AM, testing personnel #1 as listed on the CMS-209 confirmed the appropriate staff did not review the final graded proficiency testing reports. ***Repeat Deficiency from the July 17, 2014 survey***