Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366207	03/11/2020
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: . A. Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to retain the hematology maintenance logs for 12 (May to December 2018 and January to April 2019) of 24 months reviewed. Findings include: 1. Record review of the M-series Medonic hematology analyzer maintenance log revealed a lack of documentation of the monthly maintenance for 12 (May to December 2018 and January to April 2019) of 24 months reviewed. 2. When queried on 3/11/2020 at 11: 41 am, TP1 stated the maintenance was completed but the documentation was not retained. 3. During the interview on 3/11/202 at 11:41 am, TP1 confirmed the laboratory did not retain the monthly maintenance log for 2 years. B. Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to retain the hematology calibration documents for 2 (April and October 2018) of 4 calibrations performed in 2018 and 2019. 1. Record review of the M-series Medonic hematology calibration documents revealed the laboratory did not retain 2 (April and October in 2018) of 4 calibrations performed in 2 years. 2. When queried on 3/11/2020 at 1:16 pm, TP1 stated the calibrations were performed and the documents were not retained. 3. During the interview on 3/11/2020 at 1:16 pm, TP1 confirmed the calibration documents were not retained for 2 years.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must

	meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to meet the requirements for the specialty in Hematology. Findings include: 1. The laboratory failed to establish a system to ensure the manually transcribed hematology complete blood cell count (CBC) test values were accurately reported from point of entry to the final report. Refer to D5801. 2. The laboratory failed to document the specimen collection date and time for the hematology complete blood cell count (CBC) result in the electronic medical record (EMR). Refer to D5805.
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 document review and interview with Testing Personnel (TP) #1, the laboratory failed to establish a system to ensure the manually transcribed hematology complete blood cell count (CBC) test values were accurately reported from point of entry to the final report in the electronic medical record (EMR) system for 1 (#9) of 13 patient charts audited. Findings include: 1. Record review revealed for 1 (#9) of 13 patient charts audited the manually transcribed results for the CBC did not match the instrument generated report as follows: a. white blood cell count i. instrument report = 2.6 ii. manually transcribed = 4.6 b. granulocytes i. instrument report = 1.3 ii. manually transcribed = 2.3 c. red blood cell count i. instrument report = 1.69 ii. manually transcribed = 4.69 d. hemoglobin i. instrument report = 5.1 ii. manually transcribed = 15.0 e. hematocrit i. instrument report = 14.5 ii. manually transcribed = 44.5 f. red blood cell distribution width % i. instrument report = 10.6 ii. manually transcribed - 35.1 g. platelet i. instrument report = 105 ii. manually transcribed = 155 2. On 3/11/2020 at approximately 1:30 pm when requested, TP1 was unable to provide documentation to show the transcribed manual results entered into the EMR system were valid as no repeat testing was available. 3. During the interview on 3/11 /2020 at approximately 1:30 pm, TP1 confirmed the transcribed results in the EMR did not match the results generated from the analyzer and no repeat testing or redraw of the specimen was 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 with Testing Personnel (TP) #1, the laboratory failed to document the specimen collection date and time for the hematology complete blood cell count (CBC) result in the electronic medical record (EMR) for 8 (2, 4-5, 7-9, 11, and 13) of 13 patient charts audited. Findings include: 1. Record review for 8 (2, 4-5, 7-9, 11, and 13) of 13 patient charts audited the collection date and time was not manually entered into the EMR final transcribed result. 2. On 3/11/2020 at approximately 1:40 pm when queried, TP1 acknowledged the collection date and time was not manually entered into the EMR system. 2. During the interview on 3/11/2020 at approximately 1:40 pm, TP1 confirmed the collection date and time was not documented in the EMR system for the manually transcribed CBC results.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP)#1, the laboratory failed to provide the educational requirements for 1 (#7) of 11 testing personnel who perform the moderately complex hematology testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to ensure that all testing personnel met the educational requirements at 493.1423 for 1 (#7) of 11 testing personnel as listed on the CMS-209 performing moderately complex hematology testing. Findings include: 1. On 3/11/2020 at 9:00

	AM, record review for 1 of 11 testing personnel credentials revealed the educational requirements for performing moderately complex hematology testing was not met. 2. During the interview on 3/11/2020 at 9:00 AM, TP1 as listed on the CMS-209 confirmed the educational requirements were not met. 3. On 3/11/2020 at 9:00 am, the laboratory was given 7 additional days to supply the necessary educational documents. The documents were not received.