Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1034340	10/09/2024
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
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 with Testing Personnel #6, the laboratory failed to establish a competency assessment policy to assess its laboratory employees for two (October 2022 to October 2024) of two years reviewed. Findings include: 1. A review of the laboratory's competency assessment documentation revealed a lack of competency assessments for Technical Consultant #2. 2. The surveyor requested the competency assessments for Technical Consultant #2 and the laboratory's competency assessment policy on 10/9/24 at 10:58 am and they were not made available. 3. An interview on 10/9/24 at 10:58 am with Testing Personnel #6 confirmed the laboratory had not established a competency assessment policy.
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 observation, record review, and interviews, the laboratory failed to include patient last names on test reports for three (Patient #2, Patient #3, and Patient #11) of eleven patient test reports reviewed. Findings include: 1. The surveyor observed Testing Personnel #2 collect Patient #11's specimen and perform Complete Blood Count (CBC) testing on 10/9/24 at 9:05 am. Prior to sampling the patient's specimen into the CBC analyzer, Testing Personnel #2 entered the patient's identification number and first name into the analyzer manually. When the test report was generated after testing, the patient identifiers only included the identification number and first name. Shortly after the report was printed, Testing Personnel #2 initialed the report, and the ordering provider reviewed and signed the report. 2. An interview on 10/9/24 at 9:15 am with Testing Personnel #2 confirmed it was laboratory practice to include only the first name and patient identification number on the test report initially. About twice a day, the printed reports from that day have stickers including the full patient's name, date of birth, and identification number affixed to the report and are scanned into the appropriate patient charts. 3. A review of patient test reports revealed the following patient test reports did not include the sticker with the full name, date of birth, and identification number: a. Patient #2 with CBC testing performed on 6/12/24. b. Patient #3 with CBC testing performed on 5/10/24. 4. A review of patient test reports revealed the following patient test reports with incorrect patient identification numbers manually entered into the instrument and generated on the test report: a. Patient #7 with CBC testing performed on 7/18/23. b. Patient #8 with CBC testing performed on 6/13/23. 5. An interview on 10/9/24 at 9:45 am with Testing Personnel #6 confirmed providers review test reports before stickers with additional patient information are added to patient test reports. Discrepancies in patient identification numbers would be discovered when stickers are generated at the time reports are scanned into the chart. Corrective action for patients with incorrect identification numbers is performed by using the patient's first name.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #6, the Laboratory Director failed to ensure testing personnel had demonstrated they could perform patient testing reliably and accurately prior to performing patient testing for one (Testing Personnel #8) of eight testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed Testing Personnel #8 had started employment in May 2024 and had a lack of documentation of competency or training to perform Complete Blood Count (CBC) testing. 2. An

	interview on 10/9/24 at 10:36 am with Testing Personnel #6 confirmed Testing Personnel #8 had performed patient CBC testing since about June 2024 and no documentation of completion of training or competency assessments were available.