Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366207	11/20/2023
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview, the laboratory failed to follow its Bayer & Bayer Contour glucometer manufacturer's instructions for 1 of 1 patient test observed. Findings include: 1. The surveyor observed Testing Personnel #6 on 11 /20/23 at 2:05 pm collect and perform Complete Blood Count (CBC) testing using a capillary puncture specimen collected in an EDTA, lavender-top microtainer tube. Once the CBC testing concluded, Testing Personnel #6 looked in the cabinets near the CBC analyzer and Testing Personnel #7 gave the Bayer & Bayer Contour glucometer to Testing Personnel #6. Testing Personnel #6 proceeded to perform a blood glucose test using the glucometer and the patient's EDTA capillary blood specimen. 2. The surveyor requested the laboratory's Bayer & Bayer Contour glucometer manufacturer's instructions on 11/20/23 at 2:05 pm and it was not made available. 3. A review of the laboratory's "Controls and Testing for Glucose" policy revealed a section titled "TESTING" stating, "Wipe first drop of blood off and use second drop for testing." 4. A review of the Bayer & Bayer Contour Blood Glucose Monitoring System manufacturer's instructions revealed a lack of specification for using EDTA anticoagulated blood samples in glucose testing. 5. An interview on 11/20/23 at 4:05 pm with Technical Consultant #2 and Testing Personnel #7 that Testing Personnel #6 had not followed manufacturer's instructions when performing patient testing using the Bayer & Bayer Contour glucometer.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2, the laboratory failed to have the individual testing the proficiency testing samples and the Laboratory Director attest to the integration of samples into the patient workload using the laboratory's methods for 4 (2022 Event 3, 2023 Events 1-3) of 5 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Association of Bioanalysis and Medical Laboratory Evaluation proficiency testing records revealed a lack of attestation statement from the testing personnel and Laboratory Director attesting to the integration of samples into the patient workload using the laboratory's methods for the following testing events: a. 2022 Event 3 b. 2023 Event 1 c. 2023 Event 2 d. 2023 Event 3 2. An interview on 11/20/23 at 2:55 pm with Technical Consultant #2 confirmed the laboratory had not attested to the integration of samples into the patient workload using the laboratory's methods for the testing events listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, record review, and interview, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview, the Laboratory Director failed to ensure testing personnel were competent, could provide accurate test results, and were assuring compliance. Refer to D1001.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2, the Technical Consultant failed to evaluate testing personnel at least semiannually in their first year of testing for 1 (Testing Personnel #4) of 2 new testing personnel hired since the previous survey. Findings include: 1. A review of testing personnel competency assessments revealed Testing Personnel #4 was hired 11/1/22 and had their competency assessed for Complete Blood Count testing on 10/11/23. 2. An interview on 11/20/23 at 3:59 pm with Technical Consultant #2 confirmed Testing Personnel #4 had not been assessed at least semiannually during their first year of testing patient specimens.
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 record review and interview with Technical Consultant #2, the laboratory failed to evaluate testing personnel at least annually for 2 (Testing Personnel #1 and #7) of 7 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel competency assessments for Complete Blood Count testing revealed the following personnel had not been assessed in over one year: a. Testing Personnel #1 was last assessed on 8/12/22. b. Testing Personnel #7 was last assessed on 2/23/22. 2. An interview on 11/20/23 at 4:02 pm with Technical Consultant #2 confirmed the testing personnel listed above had not had their competency assessed at least annually.