

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0366207	(X3) Date Survey Completed 02/24/2026
Name of Provider or Supplier Pediatric Consultants Of Troy	Street Address, City, State 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
D0000	A recertification survey was performed on February 24, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiency: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with technical consultant #2, the laboratory failed to test proficiency testing samples the same number of times it routinely tests patient samples for three (Testing event Nonchemistry M3 2024, Testing event Nonchemistry M1 2025, and Testing event Nonchemistry M1 2026) of three proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "MLE Checklist" proficiency testing policy revealed a section stating, "Once blood has been out for 30 minutes, run MLE. Run each tube two times." 2. The surveyor observed testing personnel #2 collect and perform Complete Blood Count (CBC) testing for one patient on 2/24/26 at 9:15 am. Testing personnel #2 ran the specimen one time. 3. A review of the laboratory's proficiency testing records revealed the following events included two runs per proficiency testing specimen: a. Nonchemistry M3 2024 b. Nonchemistry M1 2025 c. Nonchemistry M1 2026 4. An interview on 2 /24/26 at 11:43 am with technical consultant #2 confirmed each proficiency testing sample is ran twice while it is not routine to run all patients twice.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p>

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the practice manager, the laboratory failed to perform and document its daily probe cleaning maintenance for the Medonic M-Series Hematology analyzer for four (10/14/24, 8/7/25, 9/2/25, and 9/26/25) testing dates between February 2024 to February 2026. Findings include: 1. A review of the laboratory's "Medonic M-Series Analyzer Daily Quality Control and Maintenance" log revealed "Clean Probe(s) w/alcohol" was listed under the tasks to be performed daily and there was a lack of documentation of the probe cleaning for the following dates: a. 10/14/24 b. 8/7/25 c. 9/2/25 d. 9/26/25 2. A review of patient testing records revealed patients were tested on dates when probe cleaning was not performed and documented: a. 10/14/24, a total of 17 patients tested. b. 8/7/25, a total of 14 patients tested. c. 9/2/25, a total of 20 patients tested. d. 9/26/25, a total of 20 patients tested. 3. An interview on 2/24/26 at 12:42 pm with the practice manager confirmed the above findings.

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 interviews, testing personnel #9 failed to have documentation of Complete Blood Count (CBC) training prior to analyzing patient specimens. Refer to D6066.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
- (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
- (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (b)(6)(ii)(E) A working knowledge of reagent stability and storage;
- (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
- (b)(6)(ii)(G) An awareness of the factors that influence test results; and
- (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based on record review and interviews, testing personnel #9 failed to have documentation of Complete Blood Count (CBC) training prior to analyzing patient specimens for seven (July 2025 to February 2026) of seven months since the testing personnel started patient testing. Findings include: 1. A review of the laboratory's personnel records revealed testing personnel #9 had a high school diploma and a hire date of 7/14/25. No documentation of training was present. One competency assessment was completed on 1/5/26. 2. An interview on 2/24/26 at 10:03 am with technical consultant #2 revealed testing personnel #9 started patient CBC testing sometime in July 2025. 3. An interview on 2/24/26 at 10:10 am with the office manager confirmed documentation of laboratory training was not available for testing personnel #9.