

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0870804	(X3) Date Survey Completed 01/16/2025
Name of Provider or Supplier Edgewood Center Pediatrics	Street Address, City, State 8896 Commerce Rd Ste 5, Commerce Twp, 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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinical Supervisor, the laboratory failed to establish a system to ensure that patient specific data was accurately reported from point of entry to the final report for 1 (P5) of 10 patient records reviewed. Findings include: 1. A record review of the patient log dated 06/26/2023 revealed P5's date of birth (DOB) as 6/21/2020. Review of P5's test report dated 06/26/2023 revealed P5's DOB was documented as 03/22/2021. 2. The interview conducted with the Clinical Supervisor on 1/16/2025 at 12:09 pm confirmed the test report was inaccurate as the patient dob should have been documented as 6/21/2020.</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview with the Clinical Supervisor, the laboratory failed to document and review post analytic systems quality assessment activities for 24 (January 2023 - December 2024) of 24 months reviewed. Findings include: 1. A record review of the laboratory's quality assessment documentation revealed the reviewer's and laboratory director's signature line were not completed on quality assurance review checklists dated January 2023 through December 2023 and July 2024 through December 2024. Additionally, quality assurance review checklists for January 2024, February 2024, March 2024, April 2024, May 2024, June 2024 were not present. 2. An interview with the Clinical Supervisor on 1/16/2025 at 11:38 am confirmed documentation of post analytic systems quality assessment activities for January 2024 - June 2024 was missing and signatures for reviewer and laboratory director were not present. 3. A review of the laboratory's Quality Assessment Policy revealed that the "QUALITY SYSTEMS (QA) ... will be reviewed on an on-going basis (every six months) ...".