

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0870804	<b>(X3) Date Survey Completed</b>  07/14/2021
<b>Name of Provider or Supplier</b>  Edgewood Center Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM) and Testing Personnel (TP) #2, the laboratory director failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for 4 (event 3 in 2019, event 1 and 2 in 2020, and event 1 in 2021) of 5 events reviewed. Findings include: 1. Record review of the American Proficiency Institute (API) testing documents, the Laboratory Director (LD) failed to sign the attestation statement sheet as follows: a. event 3 in 2019 - not signed by the LD a. event 1 in 2020 - not signed by the LD b. event 2 in 2020 - signed by the testing personnel c. event 1 in 2021 - not signed by the LD 2. During the interview on 7/14/2021 at 10:50 AM, the OM and TP2 confirmed the LD did not sign the attestation statement sheet for the events listed above.</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on lack of documentation and interview with the Office Manager (OM) and Testing Personnel (TP) #2, the laboratory failed to perform and document the function checks as required for the room temperature for 7 months (January - July 2021) of 2 years reviewed. Findings include: 1. A record review revealed lack of documentation of the room temperature for the proper operation of the laboratory instrumentation for 7 months (January - July 2021) of 2 years. 2. An interview on 7/14/2021 at 11:41 AM, the OM and TP2 were unable to provide the surveyor the documentation requested.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager (OM) and Testing Personnel (TP) #2, the Technical Consultant (TC) failed to evaluate the competency of testing personnel performing the hematology testing for 11 (TP1 - TP11) of 11 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of testing personnel competency assessments revealed testing personnel competencies were assessed by a "reviewer" TP1 and TP2 who are not qualified or credentialed as a Technical Consultant to perform this task as follows: a. TP1 assessed by TP2 - assessment dates of 8/16/2019 and 8/22/2020 b. TP2 assessed by TP1, assessment dates of 8/24/2019 and 8/14/2020 c. TP3 assessed by TP2, assessment dates of 7/30/2020 due now d. TP4 assessed by TP2, assessment dates of 5/20/2019, 5/27/2020, and 6/9/2021 e. TP5 assessed by TP2, assessment dates of 9/09/2020 and 12/30/2020 f. TP6 assessed by TP2, assessment dates of 8/05/2019, 2/21/2021, and 2/02/2021 g. TP7 assessed by TP2, assessment dates of 9/28/2020 and 2/15/2021 h. TP8 assessed by TP2, assessment dates of 7/01/2021 i. TP9 assessed by TP2, assessment dates of 7/01/2021 j. TP10 assessed by TP2, assessment dates of 7/01/2021 k. TP11 assessed by TP2, assessment dates of 5/04/2020 and 11/02/2020 2. An interview on 7/14/2021 at 9:55 AM, the OM and TP2 confirmed the TC did not perform the competency assessments and the OM and TP2 were not qualified as a TC and not listed on the CMS-209 form as a TC. \*\*\*Repeat Deficiency from 11/17/2016 survey\*\*\*