

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0870804	<b>(X3) Date Survey Completed</b>  12/21/2022
<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>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review, lack of documentation, and interview with Testing Personnel (TP) #2, the laboratory failed to follow written policies and procedures to perform the semi-annual quality assurance (QA) checklist for 2 (January and July of 2022) of 3 semi-annual checks reviewed in 2021 and 2022. Findings include: 1. Review of the "Quality Assessment Policy" states "The Quality Systems (QA) for Edgewood Center Pediatrics will be reviewed on an on-going basis (every six months) to monitor, assess and when indicated, corrected. Problems identified in the laboratory's quality systems". The quality systems include the general laboratory system, pre-analytic quality system, analytic quality system, and the post analytic quality systems. 2. When queried on 12/21/2022 at 12:06 pm, TP2 was unable to provide the surveyor documentation to show the QA checklist had been performed for 2 of 3 semi-annual checks for 2021 and 2022. 3. During the interview on 12/21/2022 at 12:06 pm, TP2 confirmed the QA checks had not been performed semi-annually in 2022 as written in the policy.</p>