

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0870804	(X3) Date Survey Completed 05/23/2019
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 and #3 (TP1 and TP3), the laboratory failed to retain the hematology monthly maintenance log for 1 (August 2018) of 24 months reviewed. Findings include: 1. Record review of the monthly hematology "XP-300 Maintenance Log" revealed the laboratory did not retain August 2018 log for 2 years. 2. During the interview on May 23, 2019 at 10:30 AM, TP1 and TP3 confirmed the monthly maintenance log was not retained.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 and #3 (TP1 and TP3), the laboratory failed to have a written request for patient testing for the routine bacteriology and hematology testing for 2 (#8 and #11) of 18 patient charts audited. Findings include: 1. Record review conducted on 18 patient charts audited revealed the laboratory did not have a written request or standing order for the routine testing as follows: a. #8 - 2/18/19 throat culture b. #11 - 2/21/18 complete blood cell count 2. During the interview on May 23, 2019 at 11:47 AM and 12:25 PM, TP1 and TP3</p>

	<p>confirmed the patient chart did not contain a written and/or standing order for the laboratory testing performed.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 and #3 (TP1 and TP3), the laboratory failed to perform and document the required hematology instrument maintenance for 17 (2018 and 2019) of 24 months reviewed. Findings include: 1. The Sysmex "XP-300 Maintenance Log" listed weekly, monthly, and quarterly maintenance. There was no documentation to show the maintenance was performed as follows: a. weekly 1. three of four weeks in May and June 2018 2. three of four weeks in March and April 2019 b. monthly 1. April, July, and October in 2018 2. April 2019 c. quarterly (or every 4500 samples) - no documentation in 2018 and 2019 2. During the interview on May 23, 2019 at 10:30 AM, TP1 and TP3 confirmed the maintenance had not been documented as required.</p>
<p>D5791</p>	<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 policy review, record review, and interview with testing personnel #1 and #3 (TP1 and TP3), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified in 493.1251 through 493.1283 in the analytic laboratory systems for 4 (2017 and 2018) of 5 every six month assessment. Findings include: 1. Review of the "Quality Assessment Policy" revealed the lab was to review the quality assessment monitors every six month. 2. Record review revealed the laboratory did not perform and document patient chart reviews every six months in 2017 and 2018. 4. On May 23, 2019 at approximately 12:45 PM, TP1 and TP3 confirmed the quality assessment policy had not been followed.</p>
<p>D5803</p>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 and #3 (TP1 and</p>

TP3), the laboratory failed to have the final bacteriology report maintained as part of the patient's chart or medical record for 1 (#8) of 18 patient charts audited. Findings include: 1. Record review revealed for 1 of 18 patient charts audited, the final bacteriology throat culture report was not maintained in the patient's paper chart. 2. On May 23, 2019 at 11:47 AM, TP1 and TP3 confirmed the final throat culture test result was not included in the patient's paper chart as part of their medical records.