

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2151501	<b>(X3) Date Survey Completed</b>  10/17/2019
<b>Name of Provider or Supplier</b>  Eml Group Llc	<b>Street Address, City, State</b>  3706 Crondall Lane Suite 105, Owings Mills, MD	
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>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure and interview with the technical supervisor (TS), the laboratory did not perform analytic systems quality assessment procedures when performing toxicology testing. Findings: 1. The laboratory did not perform quality assessment procedures to ensure the quality of laboratory services provided when performing toxicology testing. 2. The laboratory modified the spin time of patient samples during processing from 15 minutes to 30 minutes. 3. The spin time was modified for better sample performance when testing is done with the LCMS. 4. The TS did not perform a quality assessment with other members of the laboratory and did not document the events that lead to the sample processing spin time change.</p>
<b>D6116</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(3)</p> <p>The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documents and interview with the technical supervisor (TS), the TS did not enroll in CMS approved toxicology PT</p>

program prior to performing patient testing. Findings: 1. The laboratory began testing patient samples in December 2018. 2. The TS failed to enroll in an approved PT program for performing toxicology testing. 3. The TS stated that once she realized that the lab was not enrolled in PT split samples were performed with passing grades. 4. The TS confirmed that the lab was not enrolled in PT prior to performing patient testing and has since enrolled in August 2019 and requested off cycle PT.