

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D1033316	<b>(X3) Date Survey Completed</b> 12/11/2019
<b>Name of Provider or Supplier</b> St Elizabeth Diagnostic Laboratory	<b>Street Address, City, State</b> One Elizabeth Place 2nd Floor, Dayton, OH	
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>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to report the correct glucose and sodium normal range values for one out of one patient test reports reviewed. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings include: 1. Review of the laboratory's policy and procedure titled "Piccolo Xpress-BMP SED-300", approved by the laboratory director on 07/18/19 revealed the following ranges for male and female adults: Analyte Common Units Glucose 73-118 mg/dL Sodium 128-145 mmol/L 2. Review of one male chemistry test report found the following normal ranges listed: Test Results Units Glucose 65-115 mg/dL Sodium 132-145 mmol/L 3. An interview with the GS, confirmed the glucose and sodium normal ranges listed on the test reports were wrong. The interview occurred 12/11/2019 at 12:00 PM. mg/dL = milligrams per deciliter mmol/L = millimoles per liter</p>
<b>D6107</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test</p>

results.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the General Supervisor (GS), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities of seven out of seven testing personnel (TP) and the general supervisor listed on the Form CMS-209. All patients tested at this laboratory have the potential to be affected by this deficient practice. Findings include: 1. Review of the laboratory's form CMS-209 Personnel Report (CLIA) found seven individuals listed as TP and one individual listed as GS. 2. Review of the policy and procedure manual titled, "ST. Elizabeth Diagnostic Clinical Laboratory, One Elizabeth Place Dayton, Ohio 45417" approved by the LD on 7/18/19 failed to find evidence of the written duties and responsibilities for each TP and the GS delegated by the LD. 3. An interview with the GS confirmed the LD failed to specify in writing the duties and responsibilities of the TP and the GS. The interview occurred on 12/11/2019 at 10:23 AM.