

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0912551	<b>(X3) Date Survey Completed</b>  11/25/2019
<b>Name of Provider or Supplier</b>  Belleville Health Care Pc	<b>Street Address, City, State</b>  265 Main Street Suite B, Belleville, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy at least twice annually for 1 (2018) of two years reviewed. Findings include: 1. A record review of the laboratory's "Split Specimen Analysis Reports" revealed the following analytes did not have verification of accuracy performed in 2018: a. Buprenorphine b. Cannabinoid c. Creatinine d. pH 2. A record review of the laboratory's established "Proficiency Testing (PT) and Split-Specimen Testing" procedure revealed a section stating, "Split-Specimen testing is required on five specimens twice each year for all unregulated analytes not enrolled in PT." 3. An interview on 11/25/19 at 9:47 am with the TC confirmed the laboratory did not perform verification of accuracy for the analytes listed above.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure expired calibration materials were not used for the current lot in use. Findings include: 1. An observation by the surveyor on 11/25/19 at 9:18 am revealed cannabinoid calibration</p>

materials with the lot number 73207055 and expiration date of August 2019 in use. 2. An interview on 11/25/19 at 9:18 am with Testing Personnel #1 revealed the last cannabinoid calibration took place on 11/20/19. 3. An interview on 11/25/19 at 9:18 am with the Technical Consultant confirmed calibration materials had exceeded the expiration date.