

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D1080846	<b>(X3) Date Survey Completed</b> 02/06/2020
<b>Name of Provider or Supplier</b> Db Biologics, Llc	<b>Street Address, City, State</b> 2933 North 7th Street, Harrisburg, PA	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the center manager and the center quality manager, the laboratory director failed to sign the standard operating procedures (SOPs) used by the laboratory (6 of 6 reviewed). Findings include: 1. On the day of survey, 02/06/2020, a review of SOPs (6 of 6 reviewed) provided by the laboratory revealed they were not signed by the current CLIA laboratory director. 2. The center manager and the center quality manager confirmed the findings above on 02/06/2020 around 10:00 am.</p>
<b>D6051</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records, the american association of bioanalysts proficiency testing (PT) records and interview with the center manager and the center quality manager, the technical consultant (laboratory director) failed to assess the competency of 14 of 17 TP who performed total protein testing in 2018 and 2019 through internal blind testing samples or external PT samples. Findings Include: 1. On the day of survey, 02/06/2020, a review of AAB PT</p>

records revealed 3 of 17 TP participated in PT for total protein in 2018 and 2019. 2. The laboratory could not provide documentation for the assessment of test performance for 14 of 17 TP who participated in the PT program or in internal blind testing samples in 2018 and 2019. 3. The center manager and the center quality manager confirmed the findings above on 02/06/2020 around 10:05 am.