

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2015997	<b>(X3) Date Survey Completed</b>  09/14/2023
<b>Name of Provider or Supplier</b>  Beacon Pain Clinic	<b>Street Address, City, State</b>  115 W Main St Ste 201, Boise, ID	
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>D6013</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the Siemens Viva ProE instrument verification and an interview with testing personnel 1 on 9/14/2023, the laboratory director failed to ensure that the instrument verification was adequate before patient testing began. The findings include: 1. A record review of the new instrument verification for the Siemens Viva ProE, used for toxicology testing, identified that the laboratory director failed to review and approve performance specification verification results to ensure that they were adequate before patient testing began on 6/27/2023. 2. An interview with testing personnel 1 on 9/14/2023 at 2:18 pm confirmed that the laboratory director failed to review and approve instrument performance specification verifications before patient testing began. 3. The laboratory reports performing 15,000 toxicology tests annually.</p>