

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2015997	(X3) Date Survey Completed 12/06/2021
Name of Provider or Supplier Beacon Pain Clinic	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records, manufacturers package inserts and an interview with the laboratory supervisor on 12/6/21, the laboratory failed to store reagents and quality control (QC) material for toxicology testing within the manufacturers temperature requirements. The findings include: 1. A review of the package inserts for the Mindray toxicology reagents and package inserts for the Thermo Scientific MAS DOA Total controls identified storage requirements of 2-8 C. 2. A review of the laboratory "thermometer temperature record" for the refrigerator identified a temperature range of 5-9 C. The laboratory failed to store reagents and QC within the manufacturers requirements two (2) of 18 days in July 2020, seven (7) of 20 days in October 2020, three (3) of 14 days in November 2020, six (6) of 17 days in January 2021, eight (8) of 17 days in February 2021, seven (7) of 18 days in March 2021, three (3) of 21 days in April, two (2) of 21 days in May 2021 and three (3) of 23 days in June 2021. 3. An interview with the laboratory supervisor on 12/6/2021 at 2: 21 pm confirmed the above findings. 4. The laboratory reports performing 15,000 toxicology tests annually.</p>