

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2034422	(X3) Date Survey Completed 11/03/2022
Name of Provider or Supplier Gammawest Brachytherapy	Street Address, City, State 5475 South 500 East, Ogden, UT	
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 direct observation, record review, and interview with laboratory director (LD) the laboratory failed to follow the laboratory's procedure to document the temperature and humidity of the laboratory space and laboratory refrigerator. The laboratory performed approximately 1,500 prostate-specific antigen tests on Qualigen FastPack IP System. Findings include: 1. The laboratory had posted a Daily Environmental Log that stated "Take Refrigerator and Room Temperature along with Relative Humidity readings daily." 2. Record review revealed that refrigerator temperature, room temperature, and relative humidity were only documented 6 of 31 days the month of October 2022 3. In an interview on 11/03/2022 at approximately 2:30 PM, the LD confirmed refrigerator temperature, room temperature, and relative humidity were not documented daily.</p>