

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2034426	(X3) Date Survey Completed 09/03/2019
Name of Provider or Supplier Gammawest Brachytherapy	Street Address, City, State 700 West 800 North, Ste 140, Orem, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing and patient test records review as well as an interview with the laboratory director, the laboratory failed to ensure proficiency testing was performed by personnel who routinely perform patient testing for 4 of 4 American Proficiency Institute (API) testing from 2017 to 2019. Findings include: 1. Patient test records review included documentation one (test person A) of ten testing personnel performed Prostate Specific Antigen (PSA) for 4 biannual API testing events performed from the second event of 2017 through the first event of 2019. 2. Review of patient testing records revealed at least 4 testing personnel routinely performed patient testing for 10 patient test reports reviewed for tests performed on: 09/14/2017 by test person A, 10/12/2017 by test person B, 12/14/2017 by test person A, 03/01/2018 by test person B, 06/28/2018 by test person B, 08/21/2018 by test person A, 12/17/2018 by test person C, 02/11/2019 by test person A, 05/22/2019 by test person A, and on 08/19/2019 by test person D. 3. In an interview conducted on 09/03/2019 at approximately 3:40 P.M. the director confirmed all PSA proficiency testing was performed by one of ten testing personnel routinely performing patient PSA tests.</p>