

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0108387	(X3) Date Survey Completed 12/19/2023
Name of Provider or Supplier Regional Cancer Care Associates	Street Address, City, State 1 Clara Maass Drive, Belleville, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records the lack of attestation statements and interview with the Testing Personnel (TP), the laboratory failed to ensure that all attestation statements provided by the American Association of Bioanalysts (AAB) for Hematology 1st, 2nd and 3rd events in calendar year 2023 were signed by TP and the Laboratory Director (LD) . The TP #1 as listed on the CMS-209 form confirmed on 12/19/23 at 11:00 am that the attestation statements for the aforementioned events were not signed by the LD and TP.</p>