

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1018141	<b>(X3) Date Survey Completed</b>  03/13/2024
<b>Name of Provider or Supplier</b>  Regional Cancer Care Associates	<b>Street Address, City, State</b>  210 Woodport Road, Sparta, NJ	
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>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Instrument Correlation Records (ICR) and interview with the Testing Personnel (TP), the laboratory failed to define the relationship between Hematology test results performed on the Two Horiba ABX Micros analyzers from 2/9/23 to 3/13/24. The finding includes: 1. The "Hematology Instrument Correlation Procedure" states "review the data by the established correlation criteria in relation to the target values and approve or disapprove the correlation." 2. The procedure failed to have written criteria for acceptable differences in test values or state what the established correlation criteria was for the Horiba ABX Micros analyzer. 3. The TP # 1 as listed on the CMS form 209, confirmed on 3/13/24 at 11:00 AM that the laboratory failed to have written criteria for acceptable differences in test values for correlation studies performed on the two Horiba ABX Micros 60 analyzers. B) Based on surveyor review of the Procedure Manual (PM), ICR and interview with the Testing Personnel (TP), the laboratory failed to review instrument correlation data performed on the Two Horiba ABX Micros analyzers from 2/9/23 to 3/13/24. The finding includes: 1. There was no documented evidence the ICR test values performed on 2/9/23, 10/17/23, and 2/27/24 were reviewed and if the ICR were approved or disapproved. 2. The above mentioned ICR were not signed by the Laboratory Director or designee. 3. The TP # 1 as listed</p>

on the CMS form 209, confirmed on 3/13/24 at 11:10 AM that the laboratory failed to have documented evidence of review for ICR performed on the two Horiba ABX Micros 60 analyzers.