

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1044568	<b>(X3) Date Survey Completed</b>  03/03/2026
<b>Name of Provider or Supplier</b>  New Jersey Hematology Oncology Associates Llc	<b>Street Address, City, State</b>  508 Lakehurst Road Suite 1b, Toms River, 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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of analyzer calibration records, review of the Manufacture Operator Manual (OM) and interview with the Techincal Consultant (TC), the laboratory failed to follow the OM for Hematology testing performed on the Beckman Coulter DXH-520 analyzer in the calendar years 2024 and 2025. The findings include: 1. The OM Chapter 11 "Quality Assurance" states to follow "repeatability" and "carryover" procedures after Calibration is completed. 2. There was no documented evidence that repeatability" and "carryover" was performed after Calibration. 3. The TC confirmed on 3/3/26 at 10:40 am the laboratory failed to follow the OM.</p>