

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0662345	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Birmingham Hematology / Oncology	Street Address, City, State 100 Pilot Medical Drive Suite 175, Birmingham, AL	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, laboratory policy, and an interview with Testing Personnel #1 (TP1), the laboratory failed to label XN-L Check Hematology Quality Control (QC) material with revised expiration dates for 3 of 3 control vials reviewed in January 2026. Findings Included: 1. During a tour of the facility on 01/14/2026 at 8:42 AM, surveyor observation revealed all 3 levels of XN-L Check Hematology controls for the Sysmex XN-330 analyzer were currently in use with no new open and expiration dates written on the vials. 2. Review of the manufacturer's instructions revealed, "...Storage and shelf life after first opening... which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 C after being re-capped." 3. Further review of the laboratory policy revealed, "Quality Assurance Program- Quality Control...are stored as directed by manufacturer. All outdated materials are discarded..." 4. During the exit conference on 01/14/2026 at 11:49 PM, the Office Manager and TP1 confirmed the laboratory failed to label the Hematology QC (Quality Control) material with revised expiration dates.</p>