

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0991726	<b>(X3) Date Survey Completed</b>  02/06/2024
<b>Name of Provider or Supplier</b>  Hematology - Oncology Of Alabama	<b>Street Address, City, State</b>  513 Brookwood Boulevard Suite 275, Homewood, AL	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP-300 Hematology Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to use acceptable in-date QC material. This was noted for two days of patient testing and affected 151 patient Complete Blood Count (CBC) tests. The findings include: 1. A review of the Hematology QC records revealed lot #31640710 expired on 9/20/2023. 2. A review of Hematology QC records revealed the laboratory continued to use lot #31640710 after expiration on two days of patient testing, as follows: a) 9/21/2023; 61 patient CBC tests were performed. b) 9/22/2023; 90 patient CBC tests were performed. 3. During an interview on 2/6/2024 at 11:04 AM, Testing Personnel #1 confirmed the above findings. ----- Based on a review of the Sysmex XP-300 Hematology Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to use acceptable in date QC material. This was noted for two days of patient testing and 151 patient Complete Blood Count (CBC) tests were affected. The findings include: 1. A review of the Hematology QC records revealed lot #31640710 expired on 9/20/2023. 2. A review of Hematology QC records also revealed lot #31640710 was ran on the following days: a) 9/21/2023; 61 patient CBC tests were performed. b) 9/22/2023; 90 patient CBC tests were performed. 3. During an interview on 2/6/2024 at 11:04 AM, Testing Personnel #1 confirmed the above findings.</p>
<b>D6054</b>	<b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

PLEASE EDIT--NEEDS CLARIFICATION Based on a review of the personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate annual competency documentation for Testing Personnel performing moderate complex patient testing. This was noted for three of three testing personnel in 2023. The findings include: 1. A review of the personnel records revealed no evidence of Technical Consultant's evaluation on the 2023 annual competency documentation for Testing Personnel #1, 2, and 3. [WHAT DOES THIS MEAN? THERE WERE NO 2023 COMPETENCY ASSESSMENTS?OR COMPETENCY ASSESSMENTS WERE PERFORMED, WITHOUT DOC. THE TC DID THE EVALUATION ( NO SIGNATURE)? WAS A COMPETENCY PERFORMED BY AN UNQUALIFIED PERSON, OR JUST NOT SIGNED AT ALL?] 2. During an interview on 2/6/2024 at 9:32 AM, Testing Personnel #1 confirmed the above findings.