

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0993254	(X3) Date Survey Completed 09/27/2024
Name of Provider or Supplier Auerbach Hematology Oncology Assoc Pc	Street Address, City, State 5233 King Avenue, #308, Baltimore, MD	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have signed attestation statements for staff performing proficiency testing for event 1 of 2024. Findings: 1. The staff performing proficiency testing for event 1 of 2024 did not sign attestation statements showing that the staff performed the testing in the same manner as patient testing. 2. This was confirmed with testing person #4 at 12:00 pm on 9/20/2024. 3. This deficient practice was corrected during the survey on 9/27/2024.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not ensure that the laboratory director reviewed and provided corrective actions, if needed, for the proficiency results evaluated by the proficiency test provider. Findings: 1. The review of proficiency results obtained for the first event of 2024 were not signed off for review by the laboratory director. 2. The laboratory did not investigate and document corrective actions for event #2 of 2024 when the laboratory obtained automated differential scores of 60% for lymphocytes, 20% for monocytes and 60% for</p>

neutrophils. 3. The laboratory did not investigate and document corrective actions for event #3 of 2023 when the laboratory obtained a score of 0% for hematocrit. 4. This was confirmed with testing person #4 on 9/20/2024 at 12:00 pm.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory did not observe and document humidity records for the room where hematology testing was performed. Findings: 1. The laboratory did not document humidity records for the room where hematology testing was performed throughout 2024 (for 20 of 20 days of testing reviewed), and testing person # 4 confirmed on 9/20/2024 at 12:00 pm the humidity was not monitored for this space. 2. This deficient practice was corrected during the survey on 9/27/2024.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant was not able to ensure that competency checks for documenting quality control testing were monitored for testing staff as the quality control records were missing the quality control operator identification (initials) for 17 of 31 days reviewed in January 2024 for the low level of quality control reagent. This was confirmed with testing person #4 at 12:00 pm on 9/20/2024.