

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040017	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier University Health System	Street Address, City, State 1130 Middle Creek Rd, Suite 160, Sevierville, TN	
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 a review of the laboratory's College of American Pathologists (CAP) proficiency testing records and an interview with the laboratory lead, the laboratory testing personnel and laboratory director/designee failed to sign two of six attestation statements from 2023 and 2024. The findings include: 1. A review of the laboratory's 2023 and 2024 CAP proficiency testing attestation statements revealed the testing personnel and laboratory director/designee failed to sign the attestation statements for the following: - Hematology 2023 third event - Hematology 2024 second event 2. An interview with the laboratory lead on 11.07.2024 at 11:00 a.m. confirmed the above survey findings.</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 a review of the laboratory's College of American Pathologists (CAP) proficiency testing records and an interview with the laboratory lead, the laboratory failed to review proficiency testing and evaluate the laboratory's results for three of six events reviewed from 2023 and 2024. The findings include: 1. A review of the</p>

laboratory's 2023 and 2024 CAP proficiency testing results revealed the laboratory had not reviewed the following events: - Hematology 2023 third event - Hematology 2024 first event - Hematology 2024 third event 2. An interview with the laboratory lead on 11.07.2024 at 11 a.m. confirmed the above survey findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
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:
Based on observation of the laboratory, review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (Form CMS-209), review of personnel records, and staff interview, the technical consultant failed to perform annual competency assessments for two of three testing personnel who performed complete blood count (CBC) patient testing in 2023. The findings include: 1. Observation of the laboratory on 11.07.2024 at 9:30 a.m. revealed a Sysmex XS-1000i (serial # 69129) in use for patient testing. 2. A review of Form CMS-209 revealed three testing personnel (TP1, TP2, TP3) who perform moderately complex patient testing. 3. A review of personnel records revealed no documentation of annual competency assessment for two of three testing personnel (TP1 and TP2) in 2023. 4. An interview with the laboratory lead on 11.07.2024 at 10:00 a.m. confirmed the above survey findings.