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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>44D2130677                  | <b>(X3) Date Survey Completed</b><br>01/24/2024 |
| <b>Name of Provider or Supplier</b><br>University Health System  | <b>Street Address, City, State</b><br>5779 Creekwood Park Blvd Ste 140, Lenoir City, TN |   |
| 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>  |
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| <b>D2009</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>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:<br/>Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory liaison, the laboratory director and testing person failed to sign one of three PT attestation statements in 2023. The findings include: 1. Review of the laboratory's proficiency testing records revealed the attestation statement for hematology 2023 event three was not signed by the laboratory director or testing personnel. 2. Interview with the laboratory liaison on 01.24.2024 at 12:45 p.m. confirmed the laboratory director and testing person failed to sign the attestation statement for one of three PT events in 2023.</p> |
| <b>D2127</b>              | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation of the laboratory, review of College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory liaison, the laboratory failed to return proficiency testing results to the proficiency testing</p>  |

program before the due date resulting in a score of 0% for hematology 2022 Event 2. The findings include: 1. Observation of the laboratory on 01.24.2024 at 7:15 a.m. revealed a Sysmex XS-1000i (serial number 75474) hematology analyzer in use for complete blood count patient testing. 2. Review of hematology 2022 Event 2 CAP PT records revealed "exception code [40] Results for this kit were not received" and test scores of 0% for cell identification/differential, red blood cell count, hematocrit, hemoglobin, white blood cell count, and platelet count. 3. Interview with the laboratory liaison on 01.24.2024 at 12:45 p.m. confirmed the laboratory failed to return proficiency testing results to CAP for hematology 2022 Event 2 before the due date specified by the program resulting in a score of 0% for the testing event. Word Key: % = percent

**D3031**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of laboratory records and interview with the laboratory liaison, the laboratory failed to retain Complete Blood Count (CBC) quality control (QC) records for two of seven lots reviewed in 2023. The findings include: 1. Observation of the laboratory on 01.24.2024 at 7:15 a.m. revealed a Sysmex XS-1000i (serial number 75474) hematology analyzer in use for CBC patient testing. 2. Review of QC records for the Sysmex XS-1000i CBC analyzer revealed no retention of Level 1, 2, and 3 quality control data for lots 3149 and 3205 to include daily QC performance as compared with expected ranges or daily quality control graphed on the Levy-Jennings plot. 3. Interview with the laboratory liaison on 01.24.2024 at 12:45 p.m. confirmed the above findings.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Citation One Based on review of the laboratory procedure manual, review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and phone interview with the office manager, the laboratory failed to follow its' own policy for review/evaluation of proficiency testing results for five of five events reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance" revealed the following under the section titled "Proficiency Testing": "We forward the results of our proficiency testing (PT) to the laboratory director within one week of the return from the PT program. The director will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort to identify the cause of the failure". 2. Review of the laboratory's CAP proficiency testing result records revealed no documentation of

laboratory director review/evaluation for five of five events (2022 events two and three and 2023 events one, two, and three) reviewed. 3. Phone interview with the office manager on 01.24.2024 at 2:15 p.m. confirmed the laboratory failed to follow its' own policy for review/evaluation of proficiency testing results for five of five events reviewed in 2022 and 2023. Citation Two Based on review of the laboratory's Proficiency Testing Policy, review of proficiency testing records, request for documented corrective action, and staff interview, the laboratory failed to follow the proficiency testing policy for corrective action of unsatisfactory proficiency testing results in 2022. The findings include: 1. Review of the laboratory's Proficiency Testing policy under the section titled "Proficiency Testing Survey Policies" revealed the following statements: "12. When the evaluated results have been received the testing personnel will review the results for any unsatisfactory test results. 13. If unsatisfactory test results are found, the lab director will be notified immediately, and an investigation worksheet will be completed. Findings will be reported back to the lab director and any corrective actions documented and approved". 2. Review of the laboratory's proficiency testing records revealed 2022 hematology Event 2 scores of 0% for all analytes (Cell identification/differential, red blood cell count, hematocrit, hemoglobin, white blood cell count, and platelet count). 3. Request of laboratory's documented corrective action for 2022 hematology proficiency testing event 2 revealed no corrective action for surveyor review. 4. Interview with the laboratory liaison on 01.24.2024 at 12:45 p.m. confirmed the laboratory failed to follow its' own proficiency testing policy for corrective action of unsatisfactory proficiency testing results in 2022. Word Key: % = percent