Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2130677	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
University Health System	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: ========== Based on review of the laboratory's procedure manual and upon interview with the Laboratory Director, determined the laboratory manual failed to include panic or alert values for the Complete Blood Count (CBC) test since 2020. The findings include: 1. A review of the laboratory's procedure manual revealed no panic or alert values included for CBC testing. 2. An interview at approximately 1:00 p.m. on 09.15.2022 with the Laboratory Director confirmed there were no panic or alert values included in the procedure manual for CBC testing. ==========

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 observation of the laboratory, review of the Sysmex XS-1000i manufacturer instructions for use, document request, and interview with the laboratory director, the laboratory did not monitor the humidity for operation of the Sysmex XS-1000i complete blood count (CBC) instrument in 2020, 2021, or 2022. The findings include: 1. Observation of the laboratory on 09.15.2022 at 8:30 a.m. revealed the Sysmex XS-1000i in use for patient testing for complete blood count (CBC). 2. Review of the Sysmex XS-1000i manufacturer instructions for use revealed the instrument has an operating humidity range of 30%-85%. 3. Request on 09.15.2022 at 9:30 a.m. to the lead laboratory personnel for humidity monitoring records revealed no records were available. 4. Interview on 09.15.2022 at 1:00 p.m. with the laboratory director confirmed the laboratory did not monitor the humidity in the area where the Sysmex XS-1000i CBC instrument was being used in 2020, 2021 and 2022. ==========