Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2130677	05/17/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: ========== Review of 2018 Proficiency Testing (PT) records and interview with the laboratory supervisor determined the testing personnel and laboratory director/designee failed to sign attestation sheets. The findings include: 1. Review of 2018 PT records revealed attestation sheets were not signed by testing personnel or laboratory director/designee. 2. Interview with the laboratory supervisor at approximately 12:00 p.m. May 17, 2019 confirmed the 2018 Proficiency Testing attestation sheets were failed to be signed by testing personnel or laboratory director/designee. ==========
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: ========== Upon review of Complete Blood Count (CBC) quality control (QC) records for 2018 and interview with the laboratory supervisor, determined QC records had not been retained for lot number 8016, dates 1 /24/18 to 4/8/18. The findings include: 1. Upon review of CBC quality control records

	for 2018, it was discovered that QC records for lot number 8016, dates 1/24/18 to 4/8 /18 were not available for review. 2. Interview with laboratory supervisor at approximately 12:00 p.m. May 17, 2019 confirmed that CBC quality control records, lot number 8016, for dates 1/24/18 to 4/8/18 were not available for review. ==========
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: ========== Based on review of five patient Complete Blood Count (CBC) reports for dates 1/28/19, 3/28/19, 11/28/18, 8/1/18 and 4/10/18 with no testing personnel identification and upon interview with the laboratory supervisor, determined the laboratory failed to document identity of testing personnel on CBC reports for 2018 and 2019. The findings include: 1. Review of five patient CBC reports for 1/28/19, 3/28/19, 11/28/18, 8/1/18 and 4/10/18 revealed no testing personnel identification. 2. Interview with laboratory supervisor at approximately 12:00 p.m. May 17, 2019 confirmed five patient reports reviewed for dates in 2018 and 2019 failed to have the identity of the testing person documented. ==========