Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0691588	12/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Utah State University Student Health & Wellness	850 E 1200 N, Logan, UT	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to run proficiency testing (PT) samples using the laboratory's routine methods by not having all testing personnel (TP) perform PT. The laboratory performs approximately 11,664 hematology tests a year. Findings include: 1. Review of CMS-209 Laboratory Personnel Form showed the laboratory had ten TP that performed hematology testing. 2. PT record review revealed that TP #1 performed PT for three out of three API Hematology events in 2022. 3. In an interview on 12/15/2022 at 11: 30 AM, the laboratory director confirmed that not all laboratory personnel were performing PT.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and interview with testing personnel (TP), the laboratory failed to ensure that serum separator tubes (SST) were not used past their expiration date. The laboratory performs approximately 42 serum human chorionic gonadotropin

	(hCG) tests annually. Findings include: 1. Direct observation of SST lot number 1326275 on 12/15/2022 at 9:47 AM revealed that the SST had an expiration date of 11 /30/2022. 2. Interview with TP #1 on 12/15/2022 at 9:50 AM confirmed the SST were being utilized for serum hCG patient testing past their expiration date.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient test reports, laboratory procedure manual, and an interview with the laboratory director, the laboratory failed to include the correct normal ranges for complete blood counts (CBC) on nine out of ten values. Findings include: 1. Review of the patient reports revealed nine of the ten reference ranges did not correctly match those reference ranges for the CBC test in the procedure manual. 2. The procedure manual showed: Parameter Reference Range White Blood Count (WBC) 4.5 - 10.50 Red Blood Count (RBC) 4.00 - 6.00 Hemoglobin (HGB) 11.0 - 18.0 Hematocrit (HCT) 35.0 - 60.0 Mean Corpuscular Volume (MCV) 80.0 - 99.9 Mean Corpuscular Hemoglobin (MCH) 27.0 - 31.0 Mean Corpuscular Hemoglobin Concentration (MCHC) 33.0 - 37.0 Red Blood Cell Distribution Width (RDW) 22.6 - 13.7 Platelet Count (PLT) 150 - 450 3. The patient report showed: Parameter Reference Range White Blood Count (WBC) 4.5 - 11.5 Red Blood Count (RBC) 4.00 - 5.20 Hemoglobin (HGB) 12.0 - 16.0 Hematocrit (HCT) 36.0 - 46.0 Mean Corpuscular Volume (MCV) 80.0 - 100.0 Mean Corpuscular Hemoglobin (MCH) 26.0 - 34.0 Mean Corpuscular Hemoglobin Concentration (MCHC) 32.0 - 36.0 Red Blood Cell Distribution Width (RDW) 11.3 - 15.6 Platelet Count (PLT) 150 - 400 4. In an interview on 12/15/2022 at 1:26 PM, the laboratory director confirmed the lab failed to provide the correct normal ranges on the test report.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the Laboratory Director failed to ensure a quality assessment plan was established to assure quality of laboratory services through the pre-analytical, analytical, and post-analytical phases. The laboratory performs approximately 12,145 tests annually. Findings include: 1. The document review of the procedure manual failed to include a written Quality Assessment (QA) plan. 2. Laboratory Director confirmed during an interview on 12/15 /2022 at approximately 12:45 PM, the laboratory did not have a written QA plan.