Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0691588	02/05/2018
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
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 temperature records review and interview with staff, the laboratory failed to define the acceptable storage and operating temperatures for complete blood cell count (CBC) and serum pregnancy test controls, the instrument operating ambient temperature range, reference laboratory specimen storage temperature ranges, and humidity range for CBC testing. The laboratory performed approximately 1 to 5 CBC tests per day, 1 serum pregnancy test per month, and 2 to 5 tests collected for referral per day. Findings include: 1. The laboratory temperature record reviewed failed to include the acceptable ranges for storage refrigerator, freezer, room temperature and per cent humidity. 2. In an interview conducted on 02/05/2018 at approximately 4:30 P.M. staff confirmed the temperature ranges were not posted for testing personnel to use in determining the recorded temperature met the test and storage temperature requirements for CBC and serum pregnancy testing performed on site and for specimens referred for testing.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures

	that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records review, lack of documentation and confirmation by staff, the laboratory failed to monitor complete blood count (CBC) testing over time for accuracy and precision for 2 of 2 years of quality control testing reviewed, January 2016 to January 2018. The laboratory performed approximately 1 to 5 CBC tests per day. Findings include: 1. Quality control testing records reviewed failed to include documentation the laboratory had an established method to evaluate CBC quality control performance over time for 3 levels of QC performed. 2. In an interview conducted on 02/05/2018 at approximately 4:40 P.M., staff confirmed they did not have a process to evaluate QC for shifts and trends or influences of changes in test system performance and environmental conditions or variance in operator performance.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on personnel competency evaluations review, lack of documentation, and interview with staff, the technical consultant failed to ensure new testing personnel were evaluated semi-annually the first year of testing for 1 of 1 new primary testing person from October 2016 to October 2017. Findings include: 1. Personnel competency evaluations failed to include semi-annual documentation for 1 new testing person performing moderate complexity complete blood count (CBC), serum pregnancy (hCG) microscopic urinalysis, vaginal wet prep and potassium hydroxide testing the first year the person performed testing. 2. In an interview conducted on 02 /205/2018 at approximately 4:30 P.M. staff stated competency evaluations were not documented semi-annually the first year testing was performed for one new test person who is the primary laboratory staff person. The laboratory performs approximately 1 to 5 CBC tests per day, 1 serum pregnancy tests per month, and 1 microscopic test per day.
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 personnel competency evaluations review, lack of documentation, and interview with staff, the technical consultant failed to ensure 5 of 5 established testing personnel were evaluated annually for 2 of 2 years of testing reviewed January 2016 to January 2018. Findings include: 1. Personnel competency evaluations failed to include annual documentation for 5 established testing personnel (A, B, C, D, E, and F) performing moderate complexity complete blood count (CBC), serum pregnancy (hCG) microscopic urinalysis, vaginal wet prep and potassium hydroxide testing after the first year the person performed testing. 2. In an interview conducted on 02/205 /2018 at approximately 4:30 P.M. staff stated competency evaluations were not documented annually after the first year of testing for staff members who performed microscopic KOH and Wet prep testing and performed CBC and pregnancy testing when the primary test person was not available. The laboratory performs approximately 1 to 5 CBC tests per day, 1 serum pregnancy tests per month, and 1 microscopic test per day.