Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0859649	12/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Campus Health Service	Arizona State Universty Health Services, Tempe, AZ	

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: Based on review of proficiency testing (PT) records from 2018 and interview with the facility personnel, the laboratory director failed to sign the PT attestation statement. Findings include: 1. The laboratory participates in PT for testing performed in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology. 2. The PT attestation statements presented for review for the second and third events of 2018 lacked the director's signature. 3. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of verification activities for Measles testing and interview with the facility personnel, the laboratory failed to provide documentation showing the verification activities were performed by the laboratory and acceptable. Findings include: 1. The laboratory performs Measles testing on the Mini-Vidas analyzer. It is the practice of the laboratory to send 5 samples at least twice annually to another laboratory to verify the accuracy of the test. 2. No documentation was provided for review during the survey conducted on December 20, 2018 to indicate the laboratory

	verified the accuracy of the Measles test performed on the Mini-Vidas analyzer during 2017 and 2018. During the survey, the laboratory presented a spread sheet for review for each year which contained the test results of the 5 samples tested on the Mini-Vidas and the test results from the reference laboratory, but failed to retain the instrument printouts from either laboratory indicating the samples were tested by the laboratory and the reference laboratory. 3. No documentation was provided for review to indicate the laboratory evaluated the verification results referenced above for acceptability. 4. The facility personnel confirmed that the laboratory failed to retain the analyzer printouts/reference lab reports and evaluate the verification results for acceptability for Measles testing during 2017 and 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory performs serum hCG testing using the Henry Schein combo pregnancy test kit under the sub-specialty of Endocrinology.. On the date of the survey, December 20, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once each month and/or each new lot of test kit. 2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. 3. During the survey, review of QC records from January 1, 2016 through December 20, 2018 indicated the laboratory performed and documented QC with the number and frequency as described in their policy above, and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test kit. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the serum pregnancy test. 5. The number of patients tested during the time period indicated above could not be determined at the time of the survey.