Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050874	05/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Osu University Health Services	1202 West Farm Road, Stillwater, OK	

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
D0000	The recertification survey was performed on 05/28/19. The laboratory was found in compliance with the CLIA conditions with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
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 a review of records and interview with the laboratory director, the laboratory director and testing person failed to sign the statement attesting proficiency testing samples were analyzed in the same manner as patient specimens. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory performed KOH (Potassium Hydroxide) fungal prep examinations; (2) The surveyor reviewed Microbiology proficiency testing records for the Third 2017 Event; the First, Second, and Third 2018 Events; and the First 2019 Event. From the review, the surveyor identified in 1 of the 5 events reviewed (Third 2018 Event), the attestation statement had not been signed by laboratory director and had not been signed by the testing person who performed the proficiency testing; (3) The surveyor reviewed the findings with the laboratory director, who stated to the surveyor, the laboratory director and the testing person who performed the proficiency testing, had not signed the statement attesting the proficiency samples were tested as patient testing using the laboratory's routine methods.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)

	(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to maintain proficiency testing records for a minimum of two years. Findings include: (1) At the beginning of the survey, the surveyor reviewed Hematology proficiency testing records for the Third 2017 Event; the First, Second, and Third 2018 Events; and the First 2019 Event. The surveyor could not locate the analyzer printouts from 1 of the 5 events reviewed. The analyzer printouts for proficiency samples XE-11, XE-12, XE-13, XE-14, and XE-15 from the Third 2017 Event could not be located; (2) The surveyor asked the laboratory director if the printouts from the Third 2017 Event were available. The laboratory director could not locate the printouts and stated to the surveyor the laboratory failed to maintain proficiency testing records for the Third 2017 Event as required for at least 2 years.
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: Based on a review of records and interview with the laboratory director, the laboratory failed to retain patient records for at least 2 years. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g., WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.). In addition, the laboratory director stated the the laboratory replaced the Sysmex XS-1000i hematology analyzer on 03/08/18 with the Sysmex XN-550; (2) The surveyor requested analyzer printouts from testing performed on the Sysmex XS-1000i analyzer during 2 randomly selected months (September 2017 and January 2018) for review to verify the laboratory followed the manufacturer's instructions and laboratory policy, for patient CBC results which obtained morphologic flags (e.g., Blasts?, Left Shift?, Atypical Lymph?, etc.); (3) The laboratory director provided patient test result reports from the LIS (Laboratory Information System), but the surveyor was unable to verify that all patient results which obtained flags and messages in the months requested, had been addressed following the manufacturer's instructions; (4) The laboratory director located a thumb drive and a computer disc on which patient test results performed on the Sysmex XS-1000i analyzer had been stored, but the laboratory director could not retrieve the information without the Sysmex XS-1000i analyzer to utilize its software; (5) The surveyor explained to the laboratory director

	the laboratory must retain quality control and patient test records, including instrument printout, and records documenting all analytic systems activities for at least 2 years.