Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0670093	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic - Owasso	10512 N 110th East Ave, Suite 300, Owasso, 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 findings were reviewed with the technical consultant at the conclusion of the survey.
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 technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director and analyst. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified for 1 of 24 proficiency testing events: (a) 2016 Immunology 3rd Event - The attestation statement had not been signed and dated by the laboratory director and analyst. (2) The surveyors reviewed the records with the technical consultant, who stated the attestation statement, as indicated above, had not been signed and dated by the laboratory director and the analyst.
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 technical consultant, the laboratory failed to maintain records of lot numbers and expiration dates of media used for patient testing. Findings include: (1) At the beginning of the survey, the technical consultant stated that the laboratory performed throat culture testing (reported as presumptive for Streptococcus A) using SSA (Strep Select Agar) plates and Bacitracin discs; (2) Surveyor #2 then reviewed quality control records for testing performed from January through December 2017. There was no documentation in the records which included the lot numbers and expiration dates of media used during the review period; (3) The technical consultant stated that the laboratory did not have a method in place to maintain records of lot numbers of media used in the laboratory.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the technical consultant, written policies and procedures had not been approved by the current laboratory director. Findings include: (1) At the beginning of the survey, the technical consultant stated to surveyors the following testing was performed: (a) CBC (Complete Blood Count) testing using the Boule Medonic M Series analyzer (2) The technical consultant stated to the surveyors the instrument was put into use for patient testing on 07/05/17; (3) Surveyor #2 reviewed the procedure manual for the above testing. It had not been approved, signed, and dated by the current laboratory director; (4) The surveyors then reviewed the procedure manual with the technical consultant, who stated it had not been approved, signed, and dated by the current laboratory director.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (b) The analyzer was put into use on 07/05/17 to replace the Beckman Coulter AcT Diff 2 analyzer. (2) Later

	during the survey, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for maintenance were as follows: (a) Daily Cleaning (b) Monthly Cleaning (3) Surveyor #1 then reviewed maintenance records for 6 months (July 2017 through December 2017). It was identified for 4 of 6 months, that maintenance procedures had been documented on Beckman Coulter AcT Diff 2 analyzer logs. The AcT Diff 2 analyzer had different maintenance requirements, therefore, surveyor #1 could not determine if the required maintenance had been performed on the Medonic M-Series analyzer as follows: (a) Daily Cleaning (i) July - Days 05,06,07,10,11,12,13,14,17,18,19,20,21,24,25,26,27,28,31 (ii) August - Days 01,02,03,04,07,08,09,10,11,14,15,16,17,18,21,22,23,24,25,28,29,30,31 (iii) September - Days 01,05,06,07,08,11,12,13,14,15,18,19,20,21,22,25,26,27,28,29 (iv) October - Days 02,03,04,05,06,09,10,11,12,13,16,17,18,19,20,23,24,25,26,27,30,31 (b) Monthly - Not performed 4 of 6 months (July, August, September, October) (4) Surveyor #1 reviewed the records with the technical consultant who stated the incorrect maintenance logs had been used, and there was no documentation to prove the maintenance procedures had been performed for the 4 months.