Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1057665	10/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic Broken Arrow North	1551 N 9th Street, Broken Arrow, 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 10/14/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records 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 retain proficiency testing records for at least 2 years. Findings include: (1) At the beginning of the survey, the surveyor reviewed Hematology and Microbiology proficiency testing records from 2018 and 2019. The attestation statement for 1 of the 7 events reviewed (Microbiology 2nd 2018 Event) could not be located; (2) The surveyor asked the technical consultant if the attestation statement for the event was available. The technical consultant reviewed the documents but could not locate the attestation statement; (3) The surveyor explained to the technical consultant that all proficiency testing records must be retained for at least 2 years.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate verification data prior to implementing a new test system. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory began using a replacement Beckman Coulter AcT Diff2 analyzer to perform CBC (Complete Blood Count) testing on 06/26 /19; (2) The surveyor reviewed the validation records for the test system. There was no evidence the data had been reviewed and evaluated as acceptable by the laboratory director before the analyzer was put into use for patient testing; (3) The surveyor reviewed the records with the technical consultant, who stated although the laboratory director had reviewed and evaluated the data and approved the test system as acceptable, it was not documented. (NOTE: The interpretive guidelines at 493.1253(b) (1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the clients' needs, as determined by the laboratory director and clinical consultant." In addition, it states, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")
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 a review of records and interview with the technical consultant, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) The laboratory used the Beckman Coulter AcT Diff2 hematology analyzer to perform CBC (WBC-White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing (On 06/26/19, a replacement Beckman Coulter AcT Diff2 analyzer was put into use); (b) Three levels (Low, Normal, and High) of Beckman Coulter 4C-ES Cell Control QC (Quality Control) materials were tested each day of patient testing. (2) The surveyor reviewed QC records from the old analyzer between 11/27/17 and 06 /25/19 and the surveyor identified 15 QC lot numbers were used during the review period. For 6 of the 15 lot numbers used during the review period, there were no records (i.e., Levey-Jennings (LJ) graphs, statistical reports, etc.) proving the control results had been monitored for variances (i.e. shifts and trends). The specific lot

	numbers were as follows: (a) Used from 11/27/17-03/09/18: Low, Lot #068500; Normal, Lot #078500; and High, Lot #088550 (b) Used from 03/27/18-07/06/18: Low, Lot #069500; Normal, Lot #079500; and High, Lot #089500 (3) The surveyor asked the technical consultant for QC records for the dates listed above. The technical consultant explained the quality control data management system (DAQ) of the analyzer's computer stopped functioning in February 2018 and the LJ records could not be printed until the DAQ was installed in July 2018; (4) The surveyor asked the technical consultant if the QC results had been monitored for immediate errors and if the laboratory had monitored over time the accuracy and precision of test performance for variances during the time the DAQ was not functioning. The technical consultant stated to the surveyor, the daily QC results were reviewed and determined to be acceptable each day of patient testing, but since the LJ graphs could not be printed, the QC data had not been monitored for variances that might occur over time.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview the technical consultant, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to review and evaluate verification data prior to implementing a new test system. Refer to D5421; (b) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441.