Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2020809	04/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cpn West Clinic	781 Grand Casino Blvd, Suite 134 Lab, Shawnee, 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.
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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) On the first day of the survey, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex 1000i analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from March 2017 through March 2018 which verified the humidity readings were less than 30% for 6 of 13 months as follows: (a) March 2017 - 5 of 31 humidity readings were documented as less than 30% (days 1,2,3,8,15); (b) May 2017 - 1 of 31 humidity readings was documented as less than 30% (day 11); (c) September 2017 - 1 of 30 humidity readings was documented as less than 30% (day 22); (d) October 2017 - 2 of 31 humidity readings were documented as less than 30% (days 27,31); (g) December

	2017 - 12 of 31 humidity readings were documented as less than 30% (days 6,7,8,11,12,13,14,15,26,27,28,29); (h) January 2018 - 14 of 31 humidity readings were documented as less than 30% (days 3,4,5,8,12,15,16,17,18,19,25,29,30,31); (i) February 2018 - 12 of 28 days humidity readings were documented as less than 30% (days 1,2,5,6,7,8,9,12,13,22,23,26); (j) March 2018 - 8 of 31 humidity readings were documented as less than 30% (days 6,7,8,12,13,14,15,22) (4) The surveyor reviewed the records with the technical consultant who stated the humidity of the laboratory had been maintained below 30% as indicated above.
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, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure equipment maintenace was performed as required by the manufacturer. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor microalbumin and creatinine testing were performed on the DCA Vantage analyzer; (2) The surveyor reviewed the 2017 (12 months) manufacturer's maintenance logs for the analyzer. The surveyor identified the following: (a) Weekly - Clean Barcode Window and Clean Exterior Window had not been documented as performed between: (i) 01/03/17 and 02/01/17 (ii) 03/01/17 and 04/03/17 (iii) 05/01/17 and 06/01/17 (iv) 07/03/17 and 08/01/17 (v) 09/01/17 and 10/02/17 (vi) 11/01/17 and 12/01/17 (3) The surveyor reviewed the records with the technical consultant who stated there was no evidence the above maintenance had been performed as required.
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 would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance; and failed to have control procedures that monitored the accuracy and precision of the testing process. Findings include: (1) On the first day of the survey, the technical consutlant verified the following to the surveyor: (a) CBC

	(Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (b) Three levels (low, normal, and high) of Sysmex e-check XS quality control materials were tested each day that patient testing was performed. (2) On the second day of the survey, the surveyor reviewed quality control records. The records verified that low control (lot #80160804), normal control (lot #80160805), and high control (lot #80160806) had been put into use on 3/28/18 and were currently in use. It appeared that the laboratory had failed to establish a target value for the lower limit of acceptability and utilized the low default setting of 0.0. In addition, the upper limit that had been entered was beyond the manufacturer's expected guideline ranges as follows: (a) Low Control (i) RBC (Red Blood Cell) - A target value of 2.34 and a control range of 0.0-4.68 was used. The manufacturer's guideline range was 2.23-2.47; (iii) Hemoglobin - A target value of 5.5 and a control range of 0.0-11.0 was used. The manufacturer's guideline range was 5.3-5.9; (iv) Hematocrit - A target value of 17.0 and a control range of 0.0-34.0 was used. The manufacturer's guideline range was 16.0-18.4; (b) Normal Control (i) WBC - A target value of 7.34 and a control range of 0.0-14.68 was used. The manufacturer's guideline range was 6.59-7.89; (vi) Platelet - A target value of 210 and a control range of 0.0-420.0 was used. The manufacturer's guideline range was 201-255. (c) High Control (i) RBC (Red Blood Cell) - A target value of 5.26 and a control range of 0.0-10.52 was used. The manufacturer's guideline range was 5.09-5.51; (iii) Hemoglobin - A target value of 16.3 and a control range of 0.0-32.6 was used. The manufacturer's guideline range was 15.8-17.2; (iv) Hematocrit - A target value of 47.7 and a control range of 0.0-95.4 was used. The manufacturer's guideline range was 44.9-50.7. (3) The records were reviewed with the technical consutlant. The technical consultant did not know where the above ranges came from, but stated they were not ranges that would not detect immediate error.