Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0929197	03/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Conrad Pearson Clinic (The)	1325 Wolf Park Dr, #102, Germantown, TN	

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 the laboratory's 2016 American Proficiency Institute (API) Chemistry Group 2 proficiency testing attestation statements for events one, two, and three and interview with testing personnel number one, the testing personnel failed to sign the attestation statement for one of three proficiency testing events, and the laboratory director failed to sign the attestation statement for three of three proficiency testing events in 2016. The findings include: 1. Review of the laboratory's 2016 API proficiency testing attestation statements revealed that testing personnel did not sign the attestation statement for 2016 Chemistry Group 2 event one. 2. Review of the laboratory's 2016 API proficiency testing attestation statements revealed that the laboratory director did not sign the attestation statements for 2016 Chemistry Group 2 events one, two, and three. 3. Interview with testing personnel number one on March 22, 2018 at 9:45 am confirmed that testing personnel failed to sign one of three attestation statements in 2016 and the laboratory director failed to sign three of three proficiency testing attestation statements in 2016.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the calibrator package inserts for testosterone, SHBG, and PSA, calibration verification records and interview with testing personnel number one, the laboratory failed to verify calibration at least every six months for testosterone, sex-hormone binding globulin (SHBG), prostate specific antigen (PSA) in 2017. The findings include: 1. Observation of the laboratory on March 22, 2018 at 8:30 am revealed the Roche Cobas e411 in use for patient testing for testosterone, SHBG, and PSA. 2. Review of the calibrator package inserts for testosterone, SHBG, and PSA revealed only two calibrator levels for each of the assays. 3. Review of the calibration verification records for 2017 revealed that calibration verification was performed on January 4, 2017 with the next calibration verification performed on November 3, 2017 for each of the assays. 4. Interview with testing personnel number one on March 22, 2018 at 11:00 am confirmed that the laboratory's calibration for the testosterone, SHBG, and PSA only includes two levels of calibrator and the laboratory failed to perform calibration verification at least every six months in 2017.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Food and Drug Administration (FDA) website for test complexity, and interview with testing personnel number one, the laboratory failed to compare results between urinalysis instruments twice a year in 2016, 2017 and 2018. 1. Observation of the laboratory on March 22, 2018 at 8:30 am revealed three Siemens Clinitek Status Advantus instruments in use for patient testing for dipstick urinalysis. 2. Review of the FDA website revealed the Clinitek Status Advantus instrument has a complexity status of moderate. 3. Interview with testing personnel number one on March 22, 2018 at 10:45 am confirmed that the laboratory

	uses three moderately complex instruments for patient testing for dipstick urinalysis and did not compare results between instruments twice a year in 2016, 2017, and 2018.