Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0929197	06/21/2023
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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure manual for the Roche Cobas e411 and interview with the lab supervisor, the laboratory's procedures for the Testosterone, Prostate Specific Antigen (PSA) and Sex Hormone Binding Globulin (SHBG) failed to include calibration verification requirements or procedures. The findings include: 1. Observation of the laboratory on 06/21/23 at 8:15 am revealed the Roche Cobas e411 (serial # 1246-29) in use for performing patient testing for Testosterone, PSA, and SHBG. 2. Review of the laboratory's procedure manual revealed calibration verification was not included in the procedures. 3.

	Interview with the lab supervisor on 06/21/23 at 3:00 pm confirmed the laboratory performs calibration verification, but calibration verification is not included in the laboratory's procedures for Testosterone, PSA and SHBG.
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: Citation Number One: Based on observation of the laboratory, review of manufacturer environmental operating conditions, lack of records and interview with the laboratory supervisor, the laboratory failed to ensure the temperature and humidity were monitored in the area where urinalysis dipstick testing was being performed and reagent strips were being stored in 2021, 2022, and 2023. The findings include: 1. Observation of the urinalysis testing area on 06/21/23 at 8:15 am revealed four non-waived Siemens Clinitek Advantus instruments in use for performing urine dipstick testing. Also observed were urinalysis reagent strips with a storage range of 15 - 30 degrees Celsius on the bottle label. 2. Review of the manufacturer environmental operating conditions revealed the following: Ambient operating temperature of 18 degrees Celsius to 30 degrees Celsius. It also stated that at temperatures under 22 degrees Celsius urobilinogen and leukocyte results may be decreased, and at temperatures above 26 degrees Celsius, increased. Relative humidity of 20% to 80%. The optimum operating temperature was defined as 22 degrees Celsius to 26 degrees Celsius and an optimum relative humidity of 35% to 55%. 3. There were no records documenting room temperature or humidity in the area where the urinalysis testing was being performed and urinalysis reagent strips were being stored. 4. Interview with the laboratory supervisor on 06/21/23 at 3:00 pm confirmed there were no records for monitoring of room temperature or humidity for 2021, 2022 or 2023. This confirmed the survey findings. Citation Number Two: Based on observation of the laboratory, review of laboratory temperature records, and staff interview, the laboratory failed to ensure monitoring of the frost proof freezer where chemistry calibration verification products were stored in 2021, 2022, and 2023. The findings include: 1. Observation of the freezer in the chemistry lab on 06/21/23 at 8:15 am revealed the following: Storage of Validate chemistry calibration verification materials. The observed temperature storage range on the box was -10 to -25 degrees Celsius. The label in the freezer indicated it was frost proof. 2. Review of laboratory temperature records revealed no monitoring of minimum and maximum temperatures was occurring. 3. Interview with the previous lab supervisor on 06/21/23 at 10:30 am confirmed the laboratory uses a frost proof freezer for storage of chemistry calibration verification materials and did not monitor the minimum and maximum temperatures.
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 observation of the laboratory, lack of records, review of urinalysis dipstick quality control (QC) records, and staff interview, the laboratory failed to verify the performance specifications for the Siemens Clinitek Advantus urinalysis instrument before use for patient testing in 2022. The findings include: 1. Observation of the laboratory on 06/21/23 at 8:15 am revealed four non-waived Siemens Clinitek Advantus instruments in use for patient testing for urinalysis dipstick testing (serial #s 606122, 495720, 296617, and 452820). Serial number 606122 was a new instrument since the last survey date. 2. There were no records of verification of performance specifications for the new instrument (606122). 3. Review of urinalysis QC records revealed instrument serial number 606122 on printouts beginning 09/16/22. 4. Interview with the previous lab supervisor on 06/21/23 at 10:00 am revealed the following: The instrument was moved from their north location sometime between 06 /21/22 and 12/30/22. Instrument validation was not performed after the move to the new location. This confirmed the survey findings.
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 observation of the laboratory, review of quality control records, and staff interview, the laboratory failed to have a process in place to monitor controls for accuracy and precison over time in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 06/21/23 at 8:15 am revealed the Roche Cobas e411 (serial # 1246-29) in use for performing patient testing for Testosterone, PSA, and SHBG. 2. Review of quality control records for the analytes performed on the Roche Cobas e411 for the months of October 2021, May 2022, and March 2023 revealed no evidence that the laboratory had a process in place to monitor for shifts and trends over time. 3. Interview with the previous lab supervisor on 06/21/23 at 10:30 am revealed the following: The laboratory only prints the daily quality control for review to ensure it is within range. The laboratory does not print Levy Jennings graphs and does not have another process in place to monitor for shifts and trends. This confirmed the survey findings.

D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, review of job descriptions and staff interview, the technical consultant failed to review the validation studies performed for the revised Prostate Specific Antigen (PSA) test in 2021, and the revised Testosterone method in 2022. The findings include: 1. Observation of the laboratory on 06/21/23 at 8:15 am revealed the Roche Cobas e411 (serial # 1246-29) in use for performing patient testing for PSA, Testosterone, and Sex Hormone Binding Globulin (SHBG). 2. Review of laboratory records revealed validations for revised methods for PSA (performed on 01/21/21) and Testosterone (performed on 07/14/22). Neither of the validations had been reviewed by the technical consultant. 3. Review of the technical consultant job description revealed "Verification of the test procedures performed and the establishment of test performance characteristics, including the precision and accuracy." 4. Interview with the previous laboratory supervisor on 06/21/23 at 1:00 pm confirmed the technical consultant failed to review or approve the validations performed for the revised PSA and Testosterone methods in 2021 and 2022.