Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0929197	07/31/2024
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
D0000	During a recertification survey completed on July 31, 2024, the laboratory was found OUT OF COMPLIANCE with the following conditions: 493.1210 Condition: Routine chemistry 493.1212 Condition: Endocrinology 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
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 the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview, the laboratory director failed to sign the attestation statements for two of the nine PT events reviewed. The findings include: 1. A review of the laboratory's API PT records revealed the laboratory director failed to sign the PT attestation statements for 2024 Hematology Event One and 2024 Hematology Event Two. 2. Testing Person One (TP #1) confirmed the survey findings during an interview on 07/26/24 at 4:00 p.m.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210

	If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration verification records, lack of records, observation of the Roche Cobas e411 quality control (QC) files, staff interviews, electronic mail (email) communication, review of QC data, review of patient test reports, and review of the Form CMS-116, the laboratory failed to follow the calibration verification procedure (Refer to D5401 Citation One), failed to follow the procedure for printing and evaluating Levy Jennings QC graphs (Refer to D5401 Citation Two), failed to ensure the manufacturer QC ranges were verified for QC lot numbers 699257 and 699260, and failed to ensure the laboratory performed and evaluated QC data using the correct QC lots in the correct QC files for the Prostate Specific Antigen (PSA) (Refer to D5469).
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration verification records, lack of records, observation of the Roche Cobas e411 quality control (QC) files, staff interviews, electronic mail (email) communication, review of QC data, review of patient test reports, and review of the Form CMS-116, the laboratory failed to follow the calibration verification procedure (Refer to D5401 Citation One), failed to follow the procedure for printing and evaluating Levy Jennings QC graphs, (Refer to D5401 Citation Two), failed to ensure the manufacturer QC ranges were verified for QC lot numbers 699257 and 699260, and failed to ensure the laboratory performed and evaluated QC data using the correct QC lots in the correct QC files for the Sex Hormone Binding Globulin (SHBG) and Testosterone analytes (Refer to D5469).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual and staff interview, the laboratory policy for testing personnel training and competency was not in compliance with the requirements in Subpart M. The findings include: 1. Observation of the laboratory on 07/26/24 at 8:30 a.m. revealed the

	following non-waived test systems used for patient testing: Roche Cobas e411 instrument (serial # 1246-29) used for patient testing for Prostate Specific Antigen (PSA), Testosterone, and Sex Hormone Binding Globulin (SHBG) Siemens Clinitek Advantus instruments used for Urinalysis dipstick testing Microscopes used for microscopic examination of urine sediment 2. A review of the laboratory policy titled "Quality Assessment Plan Summary" under the section titled "Personnel Assessment" revealed the personnel policy did not include the following: Elements required in the training of testing personnel. A requirement for re-assessment of competency if test methodology or instrument changes. The six criteria required for competency assessment: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of the performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem-solving skills. 3. TP #1 confirmed the survey findings during an interview on 07/26/24 at 4:00 p.m.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's API PT records, lack of documentation, and staff interview, the laboratory's corrective action for unacceptable PT scores was ineffective when it did not include staff communication or a process in place to prevent future errors for one of one PT events with unacceptable PT scores. The findings include: 1. A review of the laboratory's Miscellaneous Chemistry 2024 Event One API PT records revealed a score of 0% for Free Testosterone calculation (Samples numbers SHB-01, SHB-02, and SHB-03 scored as unacceptable) and an unacceptable result for Testosterone (SHB) for sample SHB-03. The laboratory determined that the cause of the unacceptable results for the Free Testosterone was incorrect calculations. The laboratory determined the cause of the unacceptable result for sample SHB-03 for Testosterone was clerical. 2. The laboratory failed to provide documentation of staff communication, retraining, or processes implemented to prevent future errors with proficiency testing. 3. TP #1 confirmed the survey findings during interview on 07/26/24 at 4 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: CITATION NUMBER ONE: Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration verification records, and staff interview, the laboratory failed to follow the procedure for six-month calibration verification for the tests performed on the Roche Cobas e411 (four of six calibration verifications due since the last survey date.) The findings include: 1. Observation of the laboratory on 07/26/24 at 8:30 a.m. revealed the Roche Cobas e411 instrument (serial # 1246-29) used for patient testing for Prostate Specific Antigen (PSA), Testosterone, and Sex Hormone Binding Globulin (SHBG). 2. A review of the Cobas e411 Calibration Verification procedure revealed that "Calibration Verification must be performed: 1) Every 6 months." The analytes listed that required calibration verification were PSA, Testosterone, and Sex Hormone Binding Globulin (SHBG). 3. A review of the laboratory's calibration verification records revealed that the six-month calibration verification was not performed when due in December 2023 for the SHBG analyte, May 2024, when PSA and Testosterone were due, or by July 2, 2024, for the Sex Hormone-Binding Globulin. 4. Testing Person One (TP #1) confirmed during an interview on 07/26/24 at 3:30 p.m. that the laboratory failed to perform calibration verification every six months as required by laboratory procedure for tests performed on the Roche Cobas e411 instrument. CITATION NUMBER TWO: Based on laboratory observation, a review of the laboratory procedure manual, a review of patient test reports, a lack of documentation, and an electronic interview, the laboratory failed to follow the procedure for printing Levy-Jennings graphs for data review and evaluation from March 2024 until June 2024 for the tests performed on the Roche Cobas e411 instrument. 1. Observation of the laboratory on 07/26/24 at 8:30 a.m. revealed the Roche Cobas e411 instrument (serial # 1246-29) used for patient testing for Prostate Specific Antigen (PSA), Testosterone, and Sex Hormone Binding Globulin (SHBG). 2. A review of the laboratory procedure titled "The Evaluation and Printing of Levy Jennings graphs on the Cobas e411" revealed the following policy statement: "Levy Jennings graphs will be printed and evaluated each month on the Cobas e411." 3. A review of patient test reports revealed PSA and Testosterone reported on 03/07/24 for patient 191068. PSA, Testosterone, and SHBG were reported on 06/03/24 for patient number 188589. 4. There was no documentation that the laboratory printed and reviewed the Cobas e411 Levy Jennings data for March 2024, or June 2024. 5. An email communication with TP #1 on 08/01/24 at 12:37 p.m. confirmed that February 2024 was the last month the Levy Jennings were printed for review and evaluation. This confirmed that the laboratory failed to follow the procedure for monthly printing and evaluation of Levy Jennings graphs for March, April, May, and June of 2024.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, observation of the Roche Cobas e411 quality control (QC) files, staff interviews, electronic mail (email) communication, review of QC data, review of patient test reports, and review of the Form CMS-116, the laboratory failed to ensure the manufacturer QC ranges were verified for QC lot numbers 699257 and 699260 performed from 06/20/24 until the date of the survey on 07/26/24 and failed to ensure the laboratory performed and evaluated quality control data using correct QC files and subsequent QC ranges from sometime in May 2024 to the date of the survey on 07/26/24 with potentially 4,304 patient test results reported during the period. The findings include: 1. Observation of the laboratory on 07/26/24 at 8:30 a.m. revealed the Roche Cobas e411 used for performing patient testing for Prostate Specific Antigen (PSA), Testosterone, and Sex Hormone Binding Globulin (SHBG). 2. Observation on 07/26/24 at 2:45 p.m. of the Roche Cobas e411 QC files programmed in the instrument revealed the following: The control files used for daily quality control management were listed under IMMUNO 1 (QC Lot number 00675491) and IMMUNO 2 (QC Lot number 00675493) and assigned positions of 50-1 and 50-2. The QC lots observed in the QC rack at positions 50-1 and 50-2 were labeled as 699257 and 699260. Additional control files were set up as PC U1 (QC Lot 699257) and PC U2 (QC Lot 699260) and assigned positions of 50-3 and 50-4. The received date observed on the control box containing lot numbers 699260 and 699257 was 07/15/24. 3. Staff interviews with TP #1 and TP #2 on 07/26/24 at 3:00 p.m. revealed the following: The racks are programmed specifically to match QC file configuration. IMMUNO 1 (QC Lot 00675491) and IMMUNO 2 (QC Lot 00675493) were programmed to run in Rack 50 positions one and two, respectively. TP#2 stated she ran the controls daily under the rack positions assigned to IMMUNO 1 and IMMUNO 2 and then moved the controls to the positions for PC U1 and PC U2 programmed for rack positions 50-3 and 50-4 and repeated them. The staff was asked how long the laboratory had been running lot numbers 699260 and 699257 in the control files for lots 675491 (IMMUNO 1) and 675493 (IMMUNO 2) and evaluating the QC against incorrect ranges. The staff replied they were unsure. TP #1 stated he had the staff set up the new lot numbers (699260 and 699257) under control files PC U1 and PC U2 on 06/20/24, and the lab had been running those daily since that date but did not use that data for daily acceptable QC determination. 4. Post survey email communication with TP #1 on 07/30/24 at 3:33 p.m. revealed the following: The new lots (00699260 and 00699257) were shipped to the laboratory on 05/06/24 and were potentially performed and evaluated under the ranges of the old lot numbers (00675491 and 00675493) from the date received (which is unclear) until the date of the onsite survey (07/26/24). 5. A desk review of QC data completed on 07/31/24 revealed the QC ranges that were set in the instrument QC files for PC U1 (Lot 699257) and PC U2 (Lot 699260) did not match the manufacturer's package insert as follows: SHBG PC U1 - Lot 699257 Package Insert target and 1SD = 50.3 / 3.52 Lab target and 1 SD = 50.7 / 3.55 PC U2 - Lot 699260 Package insert target and 1SD= 17.3 / 1.21 Lab target and 1 SD = 17.4 / 1.22 Testosterone PC U1 - Lot 699257 Package Insert target and 1SD = 620 / 62 Lab target and 1 SD = 607 / 60.7 PC U2 - Lot 699260 Package insert target and 1SD 264 / 26.4 Lab target and 1 SD = 252 / 25.2 PSA PC U1 - Lot 699257 Package Insert target and 1SD = .97 / .07 Lab target and 1 SD = .99 / .07 PC U2 - Lot 699260 Package insert target and 1SD = 43.2 / 3.02 Lab target and 1 SD = 41 / 2.87 6. A review of patient test reports revealed PSA, Testosterone, and SHBG were reported on 06/03/24 for patient number 188589 during the period when the QC ranges for 699260 and 699257 were entered incorrectly in the

	files for PCU1 and PCU2 and when lot numbers 699260 and 699257 were run in the QC files for lots 675491 and 675493 and thus evaluated against the incorrect QC ranges. 7. A review of Form CMS-116 revealed an average annual test volume of 25,827 for tests performed on the Roche Cobas e411, resulting in a potential of 4,304 patient test results reported during the approximately two-month period the laboratory used incorrect QC ranges.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Aspen Web 116 database, review of a patient test report, lack of documentation, and staff interview, the laboratory director failed to maintain compliance with the requirement at 493.51 that requires laboratories to notify HHS or its designee within six months of change in specialties. The findings include: 1. Laboratory observation on 07/26/24 at 8:30 a.m. revealed microscopes on the counter used for patient testing. TP #1 stated the laboratory used the microscopes to examine urine sediment. When asked if the laboratory performed semen analysis, he stated they did not. 2. An Aspen Web 116 database review revealed hematology listed as a specialty. 3. Review of a patient test report revealed the last patient reported for post-vasectomy semen analysis was patient 181985, reported on 10/31/23. 4. The laboratory failed to provide documentation that the State Agency had been notified of the change in specialties. 5. An interview with TP #1 on 07/26/24 at 4 p.m. confirmed the survey findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of testing personnel competency assessment records and staff interview, personnel performing technical consultant duties were not qualified (Refer to D6035) and the technical consult of record failed to perform testing personnel competency assessments (Refer to D6046).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

	(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of testing personnel records, lack of documentation, and staff interview, the three persons that performed three of five competency assessments in 2024 were not qualified to perform technical consultant duties. The findings include: 1. A review of testing personnel records revealed the following: TP #1 - Initial Competency Assessment dated 06/28/24 The validator's initials for the non-waived Clinitek Advantus, Cobas e411, and Urine Microscopy test systems were those of TP #2. The Director of Clinical Operations finalized the form. TP #3- Annual Competency dated 7/1/24- completed by TP #1. TP #5 - Initial Competency Assessment dated 05/20/24 TP #2 initialed as the validator for the non-waived Clinitek Advantus and Urine Microscopy test systems. TP #1 finalized the form. 2. The personnel records did not contain education and experience documentation that qualified TP #1, TP #2 or the Director of Clinical Operations to perform the technical consultant duty of testing personnel competency assessment. 3. Phone interview with the technical consultant of record on 08/01/24 at 3:05 p.m. confirmed that persons performing testing personnel competency assessments did not have the required education and/or experience to perform technical consultant duties.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records and staff interview, the technical consultant failed to perform three of five testing personnel competency assessments in 2024. The findings include: 1. Review of testing personnel competency assessment records revealed that the technical consultant did not perform three of five assessments completed in 2024 (TP #1 initial competency dated 06/28/24, TP #3 annual competency dated 07/01/24, and TP #5 initial competency dated 05/20/24). 2. The technical consultant confirmed the survey findings during a phone interview on 08/01/24 at 3 p.m.