Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0929197	05/06/2026
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 05/06/26, the laboratory was found out of compliance with the following conditions: D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry; D5018 - 42 C.F.R. 493.1211 Condition: Urinalysis; D5020 - 42 C. F.R. 493.1212 Condition: Endocrinology; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), a review of proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that personnel who routinely performed patient testing performed proficiency testing when five of six PT events for the urine microscopy and urine dipstick on the Clinitek Advantus were performed by the lead testing person in 2024, 2025, and 2026. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for the following test systems: Urine microscopy, dipstick urinalysis on the Clinitek Advantus (backup system), the Roche Cobas e411 used for Prostate Specific Antigen (PSA), Sex Hormone Binding Globulin (SHBG), and Testosterone, and the Beckman Coulter DxC 700 AU used for automated urinalysis/urine chemistry. During observations, the lead testing person stated that she performed testing on all platforms, and the other testing personnel performed urine microscopy and urine dipstick testing on the Clinitek Advantus. 2. A review of the FORM CMS-209 revealed six testing personnel listed who performed moderately complex patient testing. 3. A review of the laboratory's PT records

	revealed that the urine microscopy and urinalysis (performed on the Clinitek Advantus) PT surveys were performed by the lead testing person (testing person three as listed on FORM CMS-209) for 2024 event three, 2025 event one, 2025 event two, 2025 event three, and 2026 event one (five of six events reviewed). 4. The interim technical consultant confirmed the survey findings during an interview on 05/05/26 at approximately 2:10 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 laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's calibration verification records, laboratory communication, review of quality control records, review of patient test reports, review of analytic records, review of the laboratory's quality assessment plan, review of staff communications, and staff interview, the laboratory failed to follow the procedure for performing calibration verification every six months for the PSA analyte (Refer to D5401), failed to verify the quality control ranges used for urine chemistry analytes on the Beckman Coulter DxC 700 AU (Refer to D5469), and failed to ensure the quality assessment procedure for review of analytic records was followed (Refer to D5791).
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, 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 laboratory observations, a review of the manufacturer reagent package insert, a review of the manufacturer calibrator package insert, a review of calibration records, patient test reports, observation of instrument calibration configuration, a review of quality control records, a review of laboratory records, a review of the quality assessment plan, staff communications and staff interview, the laboratory failed to perform daily calibration of the urine hemoglobin analyte in 2024, 2025, and 2026 (Refer to D5437), the laboratory failed to verify the quality control ranges used for monitoring urinalysis analytes on the Beckman Coulter DxC 700 AU were consistent with the manufacturer package insert (refer to D5469), and failed to follow the quality assessment procedure for review of analytic records (Refer to D5791).
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 laboratory observations, a review of the laboratory procedure manual, a review of the laboratory's calibration verification records, laboratory communication, review of the laboratory's analytic records, review of the laboratory's quality assessment plan, and staff interview, the laboratory failed to follow the procedure for performing calibration verification every six months for the Sex Hormone Binding Globulin (SHBG) and Testosterone analytes (Refer to D5401), and failed to follow the quality assessment procedure for review of analytic records (Refer to D5791).
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 laboratory observation, review of testing personnel records, review of the laboratory's testing personnel policy, and staff interview, the laboratory failed to follow the policy for training of testing personnel for one of five new testing persons. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a. m. revealed moderately complex patient testing for the following test systems: Urine microscopy, urinalysis on the Clinitek Advantus (backup system), the Roche Cobas e411 used for PSA, SHBG, and Testosterone analytes, and the Beckman Coulter DxC 700 AU used for automated urinalysis and urine chemistry. 2. A review of testing personnel records revealed no documentation of training for performance of urinalysis on the Clinitek Advantus for testing person six, with a date of hire listed as 01/12/26. 3. A review of the Testing Personnel section of the policy titled "Quality Management System" revealed that "all testing personnel are properly trained and are competent prior to performing patient specimens." The procedure listed the training requirements for each non-waived test system. 4. The technical consultant confirmed the survey findings during an interview on 05/05/26 at approximately 12:50 p.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's procedure manual, alternative assessment proficiency testing (PT) records, and staff interview, the laboratory failed to follow the policy for performing corrective action for unacceptable alternative PT assessment scores for three of three alternative PT events reviewed from 2025 and 2026. The findings include: 1. Laboratory observation on 05 /05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for automated urinalysis and urine chemistry performed on the Beckman Coulter DxC

	700 AU using Sciteck AutoUA reagents. 2. A review of the policy titled "GEN-01 Quality Management System" revealed the following under the section titled "PROFICIENCY TESTING": "We will carefully evaluate all results in a timely manner. Any unacceptable, unsatisfactory, or unsuccessful grade will result in an investigation to determine the cause and corrective action if indicated." 3. A review of the alternative proficiency testing records for the automated urinalysis and urine chemistry analytes revealed the following: 2025 AutoUA Survey Alternative Assessment Event A The raw value results were unacceptable for hemoglobin for samples AUA-3 and AUA-5, for albumin for sample AUA-1, and for urobilinogen for samples AUA-1 and AUA-2. The creatinine-normalized results were unacceptable for hemoglobin for sample AUA-05, and for Leukocyte for sample AUA-5. The technical consultant reviewed the results as "passed," with no corrective action taken for the unacceptable results. 2025 AutoUA Survey Alternative Assessment Event B The raw value results were unacceptable for glucose for sample AUA-10, for hemoglobin for sample AUA-06, for total protein for sample AUA-06, and for albumin for sample AUA-07. The creatinine-normalized results were unacceptable for hemoglobin for samples AUA-06, AUA-07, and AUA-10, and for total protein for sample AUA-06. The results were received on 10/03/25. They had not been reviewed, and corrective action had not been taken for the unacceptable results. 2026 AutoUA Survey Alternative Assessment Event A The raw value results were unacceptable for hemoglobin for sample AUA-1, for ketone for sample AUA-1, for leukocyte for sample AUA-5, and for urobilinogen for sample AUA-5. The creatinine-normalized results were unacceptable for hemoglobin for samples AUA-2 and AUA-5, for Ketone for AUA-1, for leukocyte for AUA-5, and urobilinogen for sample AUA-5. Corrective action had not been performed. 4. The interim technical consultant confirmed the survey findings during an interview on 05/05/26 at approximately 2:10 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: Based on laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's calibration verification records, laboratory communication, and staff interview, the laboratory failed to follow the procedure for performing calibration verification every six months for the PSA, SHBG, and Testosterone analytes performed on the Roche Cobas e411 instrument when due in 2025 (two of two). This was cited on the previous survey conducted on 07/31/24, and compliance was not maintained. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed the Roche Cobas e411 used for PSA, SHBG, and Testosterone patient testing. 2. A review of the procedure titled "Cobas E411 Calibration Verification" revealed a statement that calibration verification must be performed every six months for all three methods performed on the Cobas e411. 3. A review of the laboratory's calibration verification documents for the Cobas e411 revealed that the calibration verification due on 03/18/25 was not performed until 06 /18/25; the calibration verification due on 12/18/25 was not performed until 01/07/26. 4. A review of a document provided by the director of operations on 05/05/26 at approximately 4:03 p.m. revealed that approximately 4,871 PSA, 1,528 Testosterone,

	and 463 SHBG tests were reported during the gap in calibration verification from 03 /18/25 to 06/17/25, and approximately 744 PSA, 184 Testosterone, and 73 SHBG tests were reported during the gap in calibration verification from 12/18/25 to 01/06 /26. 5. The interim technical consultant confirmed the survey findings on 05/05/26 at 2:30 p.m.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer reagent package insert, a review of the manufacturer calibrator package insert, a review of calibration records, patient test reports, observation of the hemoglobin test configuration in the DxC 700 AU instrument, inter-office electronic mail communication, and staff interview, the laboratory failed to perform hemoglobin analyte calibration according to the manufacturer's recommendations in 2024, 2025, and 2026, with approximately 42,441 urine hemoglobin analytes reported annually. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for automated urinalysis/urine chemistry performed on the Beckman Coulter DxC 700 AU using Sciteck AutoUA reagents. During observation, the lead testing person stated that all urine analytes on the Beckman Coulter DxC 700 AU are calibrated daily. 2. A review of the Sciteck AutoUA reagent package insert revealed the following: "Sciteck recommends daily calibration for all the AutoUA assays." "For each assay, use Sciteck Diagnostics, Inc. calibrators to provide accuracy over the entire assay range." 3. A review of the Sciteck AutoUA calibrator package insert revealed that calibration of the urine hemoglobin analyte is performed using calibrators Level One, Level Four, and Level Five. 4. A random audit of the laboratory's calibration records for the urine hemoglobin analyte performed on the Beckman Coulter DxC 700 AU revealed that calibration was not performed using the Sciteck calibrators on 03/06/25, 09/10/25, and 02/10/26. Further review revealed the following: Calibration of the urine hemoglobin analyte was performed on 07/12/24 (prior to completing validations) using the three calibrator levels; hemoglobin calibration using the three calibrator levels was not documented in the daily calibration reports on 08/14/24, 09/12/24, 11/12/24, 11/26/24, 12/17/24, or 05/04/26 (the day prior to the survey). 5. A review of patient test reports revealed that patient testing began on 11/21/24 with patient number 202897. A random audit revealed that the following patients were tested on dates when the urine hemoglobin analyte was not calibrated according to the manufacturer's instructions: patient number 91571, performed on 03/06/25; patient order number PR0849336, performed on 09/10/25; and patient number 154994, performed on 02/10/26. 6. Observation of the urine

	hemoglobin calibration configuration in the Beckman Coulter DxC 700 AU on 05/06 /26 at 2:37 p.m. revealed a screen without three calibration points. During the observation, the laboratory lead (testing person three) contacted technical support and corrected the hemoglobin calibration configuration in the instrument. 7. A review of an electronic interoffice mail communication revealed that approximately 42,441 hemoglobin analytes were performed annually on the Beckman Coulter DxC 700 AU instrument. 8. The current technical consultant confirmed the survey findings during an interview on 05/06/26 at approximately 5:00 p.m.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on laboratory observations, review of quality control records, patient test reports, review of an interoffice electronic mail communication, and staff interviews, the laboratory failed to verify that the automated urinalysis/urine chemistry quality control (QC) ranges were consistent with manufacturer's ranges when QC lot numbers changed, resulting in the use of incorrect QC limits from 08/11/25 through 09/21/25, and 01/12/26 to the date of the survey on 05/06/26, with approximately 42,441 urinalysis panels reported annually with twelve analytes reported on each panel. 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for automated urinalysis/urine chemistry on the Beckman Coulter DxC 700 AU using Sciteck AutoUA reagents. 2. During an observation of the automated urinalysis QC limits in the Beckman Coulter DxC 700 AU instrument and an interview on 05/06/26 at approximately 2:37 p.m., the lead testing person stated that the lab used the manufacturer's QC ranges, and that the quality control ranges were not updated in the Beckman Coulter DxC 700 AU when the QC lot numbers changed. She stated that she understood that the QC targets and ranges did not change from lot to lot. 3. A review of Sciteck AutoUA QC package inserts and QC ranges used by the laboratory revealed the following: QC Lot numbers 102025 (level 1), 102125 (level 2), 102225 (level 3), 102325 (level 4), and 101525 (level 5) were put into use on 01/12/26 and were in use on the survey date. Albumin QC was performed on Levels 3, 4, and 5 Bilirubin QC was performed on Levels 3, 4, and 5 Creatinine QC was performed on Levels 3, 4, and 5 Hemoglobin QC was performed on Levels 1, 2, and 5 Ketone QC was performed on Levels 3, 4, and 5 Leukocyte was performed on Levels 3, 4, and 5 Nitrite QC was performed on Levels 1, 2, and 3 pH QC was performed on Levels 2, 3, and 5 Protein QC was performed on Levels 3, 4, and 5 Specific Gravity QC was performed on Levels 1, 4, and 5 Urobilinogen QC was performed on Levels 3, 4, and 5 The QC ranges used did not match the package insert as follows: Albumin: (measured in mg/dL) Level 3 Package insert target = 35, with a range of 7.0 - 70 (calculated range of values = 63), and a calculated 1 SD of 10.5. BC DxC 700 AU setting: target = 42, range = 60, 1 SD = 15, resulting in an acceptable

range of 12 - 72. Level 4 Package insert target = 18, with a range of 5.0 - 30 (calculated range of values = 25), and a calculated 1 SD of 4.2. BC DxC 700 AU setting: target = 14, range = 17, 1 SD = 4.25, resulting in an acceptable range of 5.5 - 22.5. Level 5 Package insert target = 0, with a range of -999.9 - 15 (calculated range of values = 1014.9), and a calculated 1 SD of 170. BC DxC 700 AU setting: target = 0, range = 1014.9, 1 SD = 253.725, resulting in an acceptable range of -507.45 - 507.45. Bilirubin (measured in mg/dL) Level 3 Package insert target = 0.5, with a range of 0.1 - 3.0 (calculated range of values = 2.9), and a calculated 1 SD of .48. BC DxC 700 AU setting: target = 0.5, range = 2.9, 1 SD = .725, resulting in an acceptable range of -.95 - 1.95. Level 4 Package insert target = 1.0, with a range of 0.2 - 5.0 (calculated range of values = 4.8), and a calculated 1 SD of 0.8. BC DxC 700 AU setting: target = 1.3, range = 4.7, 1 SD = 1.175, resulting in an acceptable range of -1.05 - 3.65. Level 5 Package insert target = 0, with a range of -999.9 - 3 (calculated range of values = 1002.9), and a calculated 1 SD of 167.15. BC DxC 700 AU setting: target = 0, range = 1002.9, 1 SD = 250.725, resulting in an acceptable range of -501.45 - 501.45. Creatinine (measured in mg/dL) Level 3 Package insert target = 150, with a range of 50 - 290 (calculated range of values = 240), and a calculated 1 SD of 40. BC DxC 700 AU setting: target = 190, range = 240, 1 SD = 60, resulting in an acceptable range of 70 - 310. Level 4 Package insert target = 290, with a range of 100 - 550 (calculated range of values = 450), and a calculated 1 SD of 75. BC DxC 700 AU setting: target = 400, range = 420, 1 SD = 105, resulting in an acceptable range of 190 - 610. Level 5 Package insert target = 0, with a range of -999.9 - 20 (calculated range of values = 1019.9), and a calculated 1 SD of 169.98. BC DxC 700 AU setting: target = 0, range = 1019.9, 1 SD = 254.975, resulting in an acceptable range of -509.95 - 509.95. Glucose (measured in mg/dL) Level 3 Package insert target = 150, with a range of 50 - 255 (calculated range of values = 205), and a calculated 1 SD of 34.2. BC DxC 700 AU setting: target = 155, range = 205, 1 SD = 51.25, resulting in an acceptable range of 52.5 - 257.5. Level 4 Package insert target = 405, with a range of 200 - 600 (calculated range of values = 400), and a calculated 1 SD of 67.7. BC DxC 700 AU setting: target = 390, range = 400, 1 SD = 100, resulting in an acceptable range of 190 - 590. Level 5 Package insert target = 0, with a range of -999.9 - 20 (calculated range of values = 1019.9), and a calculated 1 SD of 169.98. BC DxC 700 U setting: target = 0, range = 1019.9, 1 SD = 254.975, resulting in an acceptable range of -509.95 - 509.95. Hemoglobin (measured in ug/dL) Level 1 Package insert target = 600, with a range of 100 - 2000 (calculated range of values = 1900), and a calculated 1 SD of 316.7 BC DxC 700 AU setting: target = 880, range = 1800, 1 SD = 450, resulting in an acceptable range of -20 - 1780. Level 2 Package insert target = 1500, with a range of 500 - 4500 (calculated range of values = 4000), and a calculated 1 SD of 666.67. BC DxC 700 AU setting: target = 2000, range = 3800, 1 SD = 950, resulting in an acceptable range of 100 - 3900. Level 5 Package insert target = 0, with a range of -999.9 - 250 (calculated range of values = 1249.9), and a calculated 1 SD of 208.3. BC DxC 700 AU setting: target = 0, range = 1249.9, 1 SD = 312.475, resulting in an acceptable range of -624.95 - 624.95. Ketones (measured in mg/dL) Level 3 Package insert target = 25, with a range of 10 - 40 (calculated range of values = 30), and a calculated 1 SD of 5. BC DxC 700 AU setting: target = 20, range = 25, 1 SD = 6.25, resulting in an acceptable range of 7.5 - 32.5. Level 4 Package insert target = 11, with a range of 2 - 26 (calculated range of values = 24), and a calculated 1 SD of 4. BC DxC 700 AU setting: target = 14, range = 16, resulting in an acceptable range of 6 - 22. Level 5 Package insert target = 0, with a range of -999.9 - 5.0 (calculated range of values = 1004.9), and a calculated 1 SD of 167.48. BC DxC 700 AU setting: target = 0, 1 SD = 251.225, resulting in an acceptable range of -502.45 to 502.45. Leukocyte (measured in EUA/L) Level 3 Package insert target = 23, with a range of 8.0 - 75 (calculated range of values = 67),

and a calculated 1 SD of 11.2. BC DxC 700 AU setting: target = 30, range = 65, 1SD = 16.25, resulting in an acceptable range of -2.5 - 62.5. Level 4 Package insert target = 62, with a range of 5 - 95 (calculated range of values = 90), and a calculated 1SD of 15. BC DxC 700 AU setting: target = 55, range = 80, 1SD = 20, resulting in an acceptable range of 15 - 95. Level 5 Package insert target = 0, with a range of -999.9 - 6.0 (calculated range of values = 1005.9), and a calculated 1 SD of 167.65. BC DxC 700 AU setting: target = 0, 1 SD = 251.475, resulting in an acceptable range of -502.95 - 502.95. Nitrite (measured in mg/dL) Level 1 Package insert target = 0.1 , with a range of .03 - 0.20 (calculated range of values = .17), and a calculated 1 SD of . 028. BC DxC 700 AU setting: target = .110, range = .17, 1 SD = .0425, resulting in an acceptable range of .025 - .195. Level 2 Package insert target = 0.55, with a range of 0.2 - .75 (calculated range of values = 0.55), and a calculated 1 SD of .091. BC DxC 700 AU setting: 1 SD = .1375, resulting in an acceptable range of 0.275 - .825. Level 5 Package insert target = 0, with a range of -999.9 - .06 (calculated range of values = 999.96), and a calculated 1 SD of 166.66. BC DxC 700 AU setting: target = 0, range = 999.95, 1 SD = 249.9875, resulting in an acceptable range of -499.975 - 499.975. pH Level 2 Package insert target = 7.7, with a range of 5.8 - 10 (calculated range of values = 4.2), and a calculated 1 SD of 0.7. BC DxC 700 AU setting: target = 7.8 range = 4, 1 SD = 1.0, resulting in an acceptable range of 5.8 - 9.8. Level 3 Package insert target = 5.5, with a range of 4.0 - 8.0 (calculated range of values = 4), and a calculated 1 SD of .667. BC DxC 700 AU setting: target = 5.7, 1 SD = 1.0, resulting in an acceptable range of 3.7 - 7.7. Level 5 Package insert target = 3.1, with a range of 1.5 - 5.5 (calculated range of values = 4), and a calculated 1 SD of .667. BC DxC 700 AU setting: target = 3.1, 1 SD = 1.0, resulting in an acceptable range of 1.1 - 5.1. Protein (measured in mg/dL) Level 3 Package insert target = 35, with a range of 18.0 - 62.0 (calculated range of values = 44), and a calculated 1 SD of 7.3. BC DxC 700 AU setting: target = 40, range = 44, 1 SD = 11.0, resulting in an acceptable range of 18 - 62. Level 4 Package insert target = 14, with a range of 1.0 - 25.0 (calculated range of values = 24), and a calculated 1 SD of 4. BC DxC 700 AU setting: target = 9.0, range = 19, 1 SD = 4.75, resulting in an acceptable range of -0.5 - 18.5. Level 5 Package insert target = 0.0, with a range of -999.9 - 10.0 (calculated range of values = 1009.9), and a calculated 1 SD of 168.32. BC DxC 700 AU setting: target = 0.0, 1 SD = 252.475, resulting in an acceptable range of -504.95 - 504.95. Specific Gravity Level 1 Package insert target = 1.023, with a range of 1.010 - 1.042 (calculated range of values = .032), and a calculated 1 SD of .005. BC DxC 700 AU setting: target = 1.023, 1 SD = .008, resulting in an acceptable range of 1.007 - 1.039. Level 4 Package insert target = 1.050, with a range of 1.022 - 1.070 (calculated range of values = .048), and a calculated 1 SD of .008. BC DxC 700 AU setting: target = 1.050, range = .048, 1 SD = .012, resulting in an acceptable range of 1.026 - 1.074. Level 5 Package insert target = 1.000, with a range of .800 - 1.006 (calculated range of values = .206), and a calculated 1 SD of .034. BC DxC 700 AU setting: target = 1.000, range = .206, 1 SD = .0515, resulting in an acceptable range of .897 - 1.103. Urobilinogen (measured in mg/dL) Level 3 Package insert target = 3.0, with a range of 0.5 - 13.0 (calculated range of values = 12.5), and a calculated 1 SD of 2.08. BC DxC 700 AU setting: target = 4.2, range = 11, 1 SD = 2.75, resulting in an acceptable range of -1.3 - 9.7. Level 4 Package insert target = 10, with a range of 1.5 - 25.0 (calculated range of values = 23.5), and a calculated 1 SD of 3.9. BC DxC 700 AU setting: target = 13.6, range = 22, 1 SD = 5.5, resulting in an acceptable range of 2.6 - 24.6. Level 5 Package insert target = 0.0, with a range of -999.9 - 5.0 (calculated range of values = 1004.9), and a calculated 1 SD of 167.48. BC DxC 700 AU setting: target = 0, 1 SD = 251.225, resulting in an acceptable range of -502.45 - 502.45. 4. A review of the QC records for March 2025 revealed the same settings in the BC DxC 700 AU instrument as observed on the day of the survey. The lot numbers and corresponding ranges could

not be determined from the documentation provided during the survey. 5. A review of QC records revealed the following for September 2025: QC lot numbers 062525, 050825, 051425, 050125, and 042925 were put into use on 08/11/25 and were used through 09/21/25. The same instrument setting for QC as observed in finding three were noted for the month of September 2025 for all analytes. The package insert ranges and settings in the BC DxC 700 AU are detailed below: Albumin: (measured in mg/dL) Level 3 Package insert target = 35, with a range of 7.0 - 70 (calculated range of values = 63), and a calculated 1 SD of 10.5 BC DxC 700 AU setting: target = 42, range of values = 60, 1 SD = 15, resulting in an acceptable range of 12 - 72. Level 4 Package insert target = 18, with a range of 5.0 - 30 (calculated range of values = 25), and a calculated 1 SD of 4.2. BC DxC 700 AU setting: target = 14, range of values = 17, 1 SD = 4.25, resulting in an acceptable range of 5.5 - 22.5. Level 5 Package insert target = 0, with a range of -999.9 - 15 (calculated range of values = 1014.9), and a calculated 1 SD of 170. BC DxC 700 AU setting: target = 0, 1 SD = 253.725, range = 1014.9, resulting in an acceptable range of -507.45 - 507.45. Bilirubin (measured in mg/dL) Package insert target = 0.5, with a range of 0.1 - 3.0 (calculated range of values = 2.9), and a calculated 1 SD of .48. BC DxC 700 AU setting: target = 0.5, range = 2.9, 1 SD = .725, resulting in an acceptable range of -.95 - 1.95. Level 4 Package insert target = 1.0, with a range of 0.2 -5.0 (calculated range of values = 4.8), and a calculated 1 SD of 0.8. BC DxC 700 AU setting: target = 1.3, range = 4.7, 1 SD = 1.175, resulting in an acceptable range of -1.05 - 3.65. Level 5 Package insert target = 0, with a range of -999.9 -3 (calculated range of values = 1002.9), and a calculated 1 SD of 167.15. BC DxC 700 AU setting: 0, range = 1002.9, 1 SD = 250.725, resulting in an acceptable range of -501.45 - 501.45. Creatinine (measured in mg/dL) Level 3 Package insert target = 150, with a range of 50 - 290 (calculated range of values = 240), and a calculated 1 SD of 40. BC DxC 700 AU setting: target = 190, range = 240, 1 SD = 60, resulting in an acceptable range of 70 - 310. Level 4 Package insert target = 290, with a range of 100 - 550 (calculated range of values = 450), and a calculated 1 SD of 75. BC DxC 700 AU setting: target = 400, range = 420, 1 SD = 105, resulting in an acceptable range of 190 - 610. Level 5 Package insert target = 0, with a range of -999.9 - 20 (calculated range of values = 1019.9), and a calculated 1 SD of 169.98. BC DxC 700 AU setting: target = 0, range = 1019.9, 1 SD = 254.975, resulting in an acceptable range of -509.95 - 509.95. Glucose (measured in mg/dL) Level 3 Package insert target = 150, with a range of 50 - 255 (calculated range of values = 205), and a calculated 1 SD of 34.2. BC DxC 700 AU setting: target = 155, range = 205, 1 SD = 51.25, resulting in an acceptable range of 52.5 - 257.5. Level 4 Package insert target = 405, with a range of 200 - 600 (calculated range of values = 400), and a calculated 1 SD of 67.7. BC DxC 700 AU setting: target = 390, range = 400, 1 SD = 100, resulting in an acceptable range of 190 - 590. Level 5 Package insert target = 0, with a range of -999.9 - 20 (calculated range of values = 1019.9), and a calculated 1 SD of 169.98. BC DxC 700 AU setting: target = 0, range= 1019.9, 1 SD = 254.975, resulting in an acceptable range of -509.95 - 509.95. Hemoglobin (measured in ug/dL) Level 1 Package insert target = 600, with a range of 100 - 2000 (calculated range of values = 1900), and a calculated 1 SD of 316.7. BC DxC 700 AU setting: target = 880, range = 1800, 1 SD = 450, resulting in an acceptable range of -20 - 1780. Level 2 Package insert target = 1500, with a range of 500-4500 (calculated range of values = 4000), and a calculated 1 SD of 666.67. BC DxC 700 AU setting: target = 2000, range = 3800, 1 SD = 950, resulting in an acceptable range of 100 - 3900. Level 5 Package insert target = 0, with a range of -999.9 - 250 (calculated range of values = 1249.9), and a calculated 1 SD of 208.3. BC DxC 700 AU setting = 0, range = 1249.9, 1 SD = 312.475, resulting in an acceptable range of -624.95 - 624.95. Ketones (measured in mg/dL) Level 3 Package insert target = 27, with a range of 10 - 35 (calculated range of values = 25), and a calculated 1 SD of 4.2. BC DxC 700 AU setting: target = 20,

range = 25, 1SD = 6.25, resulting in an acceptable range of 7.5 - 32.5. Level 4 Package insert target = 13, with a range of 2 - 22 (calculated range of values = 20), and a calculated 1 SD of 3.3. BC DxC 700 AU setting: target = target = 14, 1 SD = 4, range = 16, resulting in an acceptable range of 6 - 22. Level 5 Package insert target = 0, with a range of -999.9 - 5.0 (calculated range of values = 1004.9), and a calculated 1 SD of 167.48. BC DxC 700 AU setting: target = 0, 1 SD = 251.225, resulting in an acceptable range of -502.45 - 502.45. Leukocyte (measured in EUA/L) Level 3 Package insert target = 28, with a range of 8.0 - 75 (calculated range of values = 67), and a calculated 1 SD of 11.2. BC DxC 700 AU setting: target = 30, range = 65, 1SD = 16.25, resulting in an acceptable range of -2.5 - 62.5. Level 4 Package insert target = 55, with a range of 5 - 95 (calculated range of values = 90), and a calculated 1SD of 15. BC DxC 700 AU setting: target = 55, range = 80, 1SD = 20, resulting in an acceptable range of 15 - 95. Level 5 Package insert target = 0, with a range of -999.9 - 6.0 (calculated range of values = 1005.9), and a calculated 1 SD of 167.65. BC DxC 700 setting: target = 0, range = 1005.9, 1 SD = 251.475, resulting in an acceptable range of -502.95 - 502.95. Nitrite (measured in mg/dL) Level 1 Package insert target = 0.1, with a range of .03 - 0.20 (calculated range of values = .17), and a calculated 1 SD of .028. BC DxC 700 AU setting: target = .110, range = .17, 1 SD = .0425, resulting in an acceptable range of .025 - .195. Level 2 Package insert target = 0.50, with a range of 0.2 - .75 (calculated range of values = 0.55), and a calculated 1 SD of . 091. BC DxC 700 AU setting: target = .55, 1 SD = .1375, resulting in an acceptable range of 0.275 - .825. Level 5 Package insert target = 0, with a range of -999.9 - .05 (calculated range of values = 999.95), and a calculated 1 SD of 166.65. BC DxC 700 AU setting: target = 0 mg/dL, range = 999.95, 1 SD = 249.9875, resulting in an acceptable range of -499.975 - 499.975. pH Level 2 Package insert target = 7.8, with a range of 6.0 - 10 (calculated range of values = 4), and a calculated 1 SD of 0.666. BC DxC 700 AU setting: target = 7.8, range = 4, 1 SD = 1.0, resulting in an acceptable range of 5.8 - 9.8. Level 3 Package insert target = 5.5, with a range of 4.0 - 8.0 (calculated range of values = 4), and a calculated 1 SD of .667. BC DxC 700 AU setting: target = 5.7, 1 SD = 1.0, resulting in an acceptable range of 3.7 - 7.7. Level 5 Package insert target = 3.1, with a range of 1.5 - 5.5 (calculated range of values = 4), and a calculated 1 SD of .667. BC DxC 700 setting: target = 3.1, 1 SD = 1.0, resulting in an acceptable range of 1.1 - 5.1. Protein (measured in mg/dL) Level 3 Package insert target = 35, with a range of 18.0 - 62.0 (calculated range of values = 44), and a calculated 1 SD of 7.3. BC DxC 700 AU setting: target = 40, 1 SD = 11.0, resulting in an acceptable range of 18 - 62. Level 4 Package insert target = 10, with a range of 1.0 - 20.0 (calculated range of values = 19), and a calculated 1 SD of 3.16. BC DxC 700 AU setting: target = 9.0, range = 19, 1 SD = 4.75, resulting in an acceptable range of -0.5 - 18.5. Level 5 Package insert target = 0.0, with a range of -999.9 - 10.0 (calculated range of values = 1009.9), and a calculated 1 SD of 168.32 BC DxC 700 AU setting: target = 0, 1 SD = 252.475, resulting in an acceptable range of -504.95 - 504.95. Specific Gravity Level 1 Package insert target = 1.023, with a range of 1.010 - 1.042 (calculated range of values = .032), and a calculated 1 SD of .005. BC DxC 700 AU setting: 1 SD = .008, resulting in an acceptable range of 1.007 - 1.039. Level 4 Package insert target = 1.050, with a range of 1.022 - 1.070 (calculated range of values = .048), and a calculated 1 SD of .008. BC DxC 700 AU setting: 1 SD = .012, resulting in an acceptable range of 1.026 - 1.074. Level 5 Package insert target = 1.000, with a range of .800 - 1.006 (calculated range of values = .206), and a calculated 1 SD of .034. BC DxC 700 AU setting: target = 1.000, 1 SD = .0515, resulting in an acceptable range of .897 - 1.103. Urobilinogen (measured in mg/dL) Level 3 Package insert target = 3.0, with a range of 0.5 - 13.0 (calculated range of values = 12.5), and a calculated 1 SD of 2.08. BC DxC 700 AU setting: target = 4.2, range = 11, 1 SD = 2.75, resulting in an acceptable range of -1.3 - 9.7. Level 4

	Package insert target = 10, with a range of 1.5 - 25.0 (calculated range of values = 23.5), and a calculated 1 SD of 3.9. BC DxC 700 AU setting: target = 13.6, range = 22, 1 SD = 5.5, resulting in an acceptable range of 2.6 - 24.6. Level 5 Package insert target = 0.0, with a range of -999.9 - 5.0 (calculated range of values = 1004.9), and a calculated 1 SD of 167.48. BC DxC 700 setting: target = 0.0, 1 SD = 251.225, resulting in an acceptable range of -502.45 - 502.45. 6. A review of patient test reports revealed the following: Patient number 91571, collected on 03/06/25 was performed during the period when the QC lot numbers and corresponding QC ranges for the automated urinalysis/urine chemistry could not be determined. Patient order number PR0849336 (performed on 09/10/25), patient number 154994 (collected on 02/09/26) and patient 100538 (collected on 05/01/26) were performed for the automated urinalysis/urine chemistry analytes during the periods when the QC ranges were not set according to the manufacturer's package insert. 7. A review of an electronic interoffice mail communication revealed that approximately 42,441 patient automated urinalysis/urine chemistry panels were performed annually on the Beckman Coulter DxC 700 AU instrument. 8. The current technical consultant confirmed the survey findings during an interview on 05/06/26 at approximately 5:00 p.m. Word Key: mg /dL = Milligrams per Deciliter ug/dL = Micrograms per Deciliter EAU/L = Esterase Activity Units per Liter
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. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory records, review of the quality assessment plan, and staff interview, the laboratory failed to follow the quality assessment plan for review of laboratory records from November 2024 until September 30, 2025. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for the following test systems: urine microscopy, urine dipstick performed on the Clinitek Advantus (backup system), the Roche Cobas e411 used for PSA, SHBG, and Testosterone patient testing, and the Beckman Coulter DxC 700 AU used for automated urinalysis and urine chemistry. 2. A review of instrument maintenance records, laboratory environmental records, QC and calibration records revealed no documented review from November 2024 to September 30, 2025 for the Roche Cobas e411, the Clinitek Advantus, and the Beckman Coulter DxC 700AU. 3. A review of the laboratory's Quality Management procedure revealed that the laboratory would perform a quality review at least quarterly and review the results with the laboratory director or designee. The policy stated that the quality review would include the QC logs, Proficiency Testing, Personnel Competency, Quality Improvement Report, Procedure Manuals/Revisions, and review of corrective actions. 4. The current technical consultant confirmed the survey findings during an interview on 05/06/26 at approximately 5:00 p.m.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the

	qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on laboratory observation, review of testing personnel records, and staff interview, testing person two (one of six testing personnel) did not qualify to perform moderate complex patient testing for urine microscopy or urinalysis on the Clinitek Advantus due to a lack of documentation of degree equivalency. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on laboratory observation, review of testing personnel records, and staff interview, testing person two (one of six testing personnel) did not qualify to perform moderately complex patient testing for urine microscopy or dipstick urinalysis on the Clinitek Advantus due to a lack of documentation of degree equivalency, with intial competency documented on 03/11/25. The findings include: 1. Laboratory observation on 05/05/26 at approximately 9:00 a.m. revealed moderately complex patient testing for the following test systems: Urine microscopy, dipstick urinalysis on the Clinitek Advantus, the Roche Cobas e411 used for PSA, SHBG, and Testosterone, and the Beckman Coulter DxC 700 AU used for automated urinalysis and urine chemistry. During observations, the lead testing person stated that she performed testing on all platforms, and the other testing personnel performed urine microscopy and urine dipstick testing on the Clinitek Advantus. 2. A review of testing personnel records revealed the following for testing person two: The hire date was listed as 02/24 /25. Initial competency was documented on 03/11/25. A copy of an education document translated into English from a foreign country was in the personnel files. The document had not been evaluated for educational degree equivalency in the United States. 3. The interim technical consultant confirmed the survey findings during an interview on 05/05/26 at approximately 12:50 p.m.