Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0868940	11/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Urologic Care Sc	22285 N Pepper Rd, Lake Barrington, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review, the Food and Drug Administration (FDA), and an interview with the radiology manager, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for the subspecialty of Routine Chemistry during the year of 2020. Findings include: 1. The laboratory's manuals, FDA website, and the i-STAT manufacturer's logs and package inserts were reviewed. 2. The laboratory was using the Abbott i-STAT Crea and EC8+ cassette kits (cartridges) in the radiology laboratory. 3. Review of the i-STAT logs and package inserts showed the cartridges tested for the following Blood Chemistry analytes: BLUE CARTRIDGE: Sodium (Na); Potassium (K); Chloride (CL); Glucose (Glu); Blood Urea Nitrogen (BUN /Urea); Hematocrit (Hct); pH; and Carbon Dioxide Partial Pressure (PCO2); PINK CARTRIDGE: Creatinine (Crea) 4. The FDA categorized the i-STAT test system as "Moderate" (on 02/07/2020) when the Blue and Pink cartridges are used to test the analytes listed in findings #3. 5. The laboratory failed to enrolled in an approved PT program for the subspecialty of Routine Chemistry when it's iSTAT test system was categorized from "Waived" to "Moderate" by the FDA on 02/07/2020. 6. On a

	Recertification survey conducted on 11/23/2020 at 12:30 PM, the Radiology manager confirmed the above findings and stated he was unaware of the i-STAT category change and thought the test system was waived and did not require PT enrollment.
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 record review, the Laboratory Personnel Report (CMS 209), and an interview with the radiology manager; the laboratory failed to establish written procedures to include the assessment of employees performing Routine Chemistry testing, affecting 1 out of 1 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and procedures manual were reviewed. 2. The laboratory failed to have a written competency procedure to evaluate the TP performing Routine Chemistry testing. 3. TP3 was listed on the CMS 209 for performing Routine Chemistry testing using the i-STAT test system. 4. The personnel documents for TP3 did not include test performance training and evaluation. 5. On a Recertification survey conducted on 11/23/2020 at 12:50 PM, the radiology manager confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record and manual review, manufacturer's instructions, and an interview with the radiology manager, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for performing Routine Chemistry testing in the laboratory. Findings Include: 1. The laboratory failed to meet the following analytic systems requirements: *Failed to have written procedures for all assays and tests. See D5401. *Failed to establish control procedures. See D5441.
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: Based on review of the laboratory records and interview with the radiology manager, the laboratory failed to have written procedures for the Routine Chemistry testing performed in Radiology. Findings Include: 1. The laboratory's procedures manual was reviewed. 2. The laboratory performs Routine Chemistry testing using the i-STAT test system. 3. The procedures manual failed to include the following written policies and procedures for its blood chemistry testing: * Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral, as applicable. *Step-by-step performance of the procedure, including test calculations and interpretation of results, if applicable. *Preparation of solutions, calibrators, controls, reagents, and other materials used in testing; * Calibration or calibration verification procedures. * The established or verified reportable range for test results for the test system. * The Control procedures. * Corrective action to take when calculations or control results fail to meet the laboratory's criteria for acceptability. * Imminently life-threatening test results, or panic or alert values. * Limitations in the test methodology, including interfering substances. *Reference intervals (normal values). * 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; and * Description of the course of action to take if a test system becomes inoperable. 4. On survey date 11-23-2020, at 12:45PM, the radiology manager confirmed no individual written procedure were available for the i-STAT test system.
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 record review, manual, lack of documentation, and an interview with the radiology manager, the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for testing performed in the subspecialty of Routine Chemistry, affecting 700 patients. Findings: 1. The laboratory's manual, i-STAT manufacturer's logs and package inserts for Creatinine and EC8+, and patients' results were reviewed. 2. Review of the logs and package inserts showed the radiology laboratory is using the Abbott i-STAT test system to test for the following Blood Chemistry analytes: *Sodium (Na) *Potassium (K) *Chloride (CL) *Glucose (Glu) *Blood Urea Nitrogen (BUN/Urea) *Hematocrit (Hct) *pH *Carbon Dioxide Partial Pressure (PCO2) *Creatinine 3. Further review of these records revealed the laboratory failed to perform and document control procedures with external controls each day of patient testing. 4. The laboratory's manual failed to include a written quality control procedure for the Routine Chemistry testing performed using the i-STAT test system, prior to testing patients. 5. During the period

	of 02/07/2020 through 11/23/2020, the laboratory had tested 700 patients. 6. On a Recertification survey conducted on 11/23/2020 at 12:50 PM, the radiology manager confirmed the above 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 record review and an interview with the radiology manager, the laboratory failed to have a technical consultant (TC) who meets the qualification requirements of 493.1411 and provide technical oversight in accordance with 493.1413 for testing performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure a qualified TC was employed to provide technical oversight for the Routine Chemistry testing perfomed in the Radiology laboratory. See D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and an interview with the radiology manager, the laboratory failed to employ a qualified technical consultant (TC) who provides technical oversight for testing performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory manuals, i-STAT logs and test documents, CMS 209 and personnel files were reviewed. 2. The manuals and Chemistry testing documents revealed the following responsibilities not performed: * Selection of test methodology appropriate for the clinical use of the test results; *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; * Enrollment and participation in an HHS approved proficiency testing program; * Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; *Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory ' s established performance specification; *Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; * 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. 3. The CMS 209 and employee records showed that the laboratory director (LD1) had not designated any qualified employee to perform the duties of TC for the routine Chemisty testing conducted in the Radiology laboratory. 4. The laboratory failed to employ/designate a TC who had the certification credentials and experience needed to provide overall technical management of the Chemistry testing in Radiology 5. On a Recertification

	survey conducted on 11/23/2020 at 1:00 PM, the radiology manager confirmed the above findings.