Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088438	05/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Corpus Christi Urology Group Pllc	601 Texas Trail Ste 100, Corpus Christi, TX	

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	The laboratory was surveyed on May 2, 2018 and found to be in compliance with the CLIA regulations and recertification is recommended.
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: Based on review of laboratory environmental records, surveyor observation, review of manufacturer's instructions, and interview with facility personnel, the laboratory failed to monitor the temperature of the storage room where blood collection tubes were stored. The findings included: 1. Review of laboratory environmental records from October 2016 to January 2018 revealed there was no documentation of monitoring the storage room where blood collection tubes were stored. 2. At 09:15 hours on 05/02 /2018, the surveyor observed the following blood collection tubes in the storage room: Serum (Yellow top) BD blood collection tubes Lot: 7195894 50 tubes 3. Further observations made on 05/02/2018 in the store room revealed no means or instrumentation to monitor the room temperature could be located. 4. Review of the manufacturer's instructions located on the package labeling revealed the tubes are required to be stored at "4-25 degrees Celsius." 5. In an interview at 09:15 hours on 05 /02/2018 in the storage room, when asked if the laboratory monitored the temperature of the store room, Testing Person 6 stated, "I think so." No documentation was provided. Key: BD - Becton Dickinson

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to label 2 of 2 aliquots with preparation and expiration dates or storage requirements on May 2, 2018. The findings included: 1. At 15:36 hours on 05/02/2018 in POD 1, the surveyor observed a clear vial with a green liquid in it and a clear vial with a clear liquid it. The vials were not labeled. The bottle label did not contain preparation or expiration dates or storage requirements. 2. In an interview at 15:36 hours on 05/02/2018 in POD 1, the medical assistant revealed she could trace the green liquid to the original container and the clear liquid was water. She confirmed the vials were not labeled.
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 review of the laboratory's verification records for the Beckman Coulter Access 2 Immunoassay System (Serial Number 570426), and confirmed in interview of facility personnel, the laboratory failed to complete verification studies prior to patient testing in February 2018. The findings were: 1. Review of the verification records for the Beckman Coulter Access 2 Immunoassay System (P/N 105422D, October 2010) revealed no final approval by the laboratory director. 2. Further review of the verification records revealed precision and accuracy records failed to be approved. 3. Interview with the technical consultant on 05/02/2018 at 1600 hours in the conference room confirmed the findings. He confirmed that the laboratory director had approved the verification studies but could not locate the document at the time of the survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, review of laboratory records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing centrifuge verification as required by the manufacturer. The findings were: 1. Direct observation on 05/02/2018 during a tour of the facility's pods, the surveyor observed 4 Henry Schein centrifuges. 2. Review of the manufacturer's instructions for the PowerSpin LX Centrifuge with Variable Speed and Timer under, "Calibration" stated, "The centrifuge timer, however, should be checked for accuracy at least every 3 months." And; "3) the timer is a mechanical one and designed to be accurage to 5 min +/- 30 seconds. 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to perform centrifuge timer maintenance every 3 months. No documentation was provided. 4. An interview with the technical consultant on 05/02 /2018 at 1435 hours in the conference room confirmed the findings.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2016 and 2017, and confirmed in interview of facility personnel, the laboratory director failed to ensure attestation sheets were signed. The findings were: 1. Review of the laboratory's policy, "Proficiency Testing" approved by the laboratory director on July 20, 2014, it stated, " ...The attestation statement shall be signed and dated by testing personnel and the Laboratory Director at the time of testing." 2. Review of the laboratory's API records from 2016 and 2017 revealed the following attestation statements were not signed for 4 of 10 events reviewed. 2016 Chemistry - event 2 Not signed by Laboratory Director or designee 2017 Chemistry - event 1 Not signed by Laboratory Director or designee 2017 Hematology - event 1 Not signed by Laboratory Director or designee Not signed by testing person 2017 Hematology - event 3 Not signed by Laboratory Director or designee 3. The laboratory was asked to provide documentation of the signed attestation statements. No documentation was provided. 4. An interview with the technical consultant on May 2, 2018 at 1100 hours in the conference room confirmed the findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on review of personnel records, review of the laboratory's submitted Form CMS-209, review of proficiency testing records from American Proficiency Institute (API), and confirmed in interview of facility personnel, the laboratory failed to ensure testing person competency assessments included assessment of test performance through external proficiency test samples The findings included: 1. Review of proficiency testing records from 2016 and 2017 revealed 1 testing person performed each event reviewed: Hematology (urine sediment) 2016 - event 1 Performed by: attestation statement not signed Hematology (urine sediment) 2016 - event 2 Performed by: Testing Person 4 Hematology (urine sediment) 2016 - event 3 Performed by: Testing Person 13 Hematology (urine sediment) 2017 - event 1 Performed by: attestation statement not signed Hematology (urine sediment) 2017 - event 2 Performed by: Testing Person 5 Hematology (urine sediment) 2017 - event 3 Performed by: Testing Person 4 2. Review of the laboratory's submitted Form CMS-209 revealed the laboratory identified 13 testing personnel who performed urine sediment testing. 3. Review of the laboratory's competency assessments revealed each testing person's competency assessment listed participation in external proficiency testing. 4. The laboratory was asked to provide documentation of each testing person participating in external proficiency testing. No documentation was provided. 5. An interview with the practice manager on 05/02/2018 at 1600 hours confirmed the findings. She revealed that she performed after event competencies but has not currently been documenting them.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on personnel records, and confirmed in interview with facility personnel, the Technical Consultant failed to assess the competency of 2 of 12 testing personnel performing moderate complexity testing annually in 2016 and 2017. The findings included: 1. Based on review of the Form CMS-209 laboratory personnel report, Testing Person 9 and Testing person 10 performed moderate complexity urine sediments. No competency assessment was available for review at the time of the survey. 2. In an interview at 11:10 hours on 05/02/2018 in the conference room, the technical consultant revealed he did not have documentation of a competency assessment for Testing Person 9 and Testing Person 10 for 2016 or 2017.