Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0868565	09/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urological Clinic Of Valdosta, Pc	3294 N Oak Street, Ext, Valdosta, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 26, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 review of proficiency testing (PT) records, review of the Laboratory Personnel Report form (CMS 209) and staff interview, the laboratory failed to rotate testing of PT samples among all testing personnel who test patient samples. Findings include: 1. Review of the CMS 209 revealed 2 employees listed as testing personnel. 2. Review of PT attestation statements for event 3 of 2016, both events in 2017 and event 1 of 2018 revealed testing personnel # 1 signed all PT attestations. 3. Interview with testing personnel # 1 (see CMS 209) and the office administrator in the office assigned to the surveyor on September 26,, 2018 at approximately 5 pm confirmed testing personnel # 2 test patient samples but has not participated in testing PT samples.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from American Proficiency Institute (API) and staff interview, the laboratory failed to retain documentation signed by the testing personnel (TP) and laboratory director (LD) attesting to routine integration of samples into the patient workload for the 2nd testing event of 2017. Findings include: 1. Review of 2017 and 2018 attestation statements for PT from API in the speciality of endocrinology for testing of testosterone and PSA revealed no documentation of the attestation statement for the 2nd event of 2017. 2. Interview with the office administrator and testing personnel # 1, (see CMS 209) on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor confirmed the attestation statement for the 2nd event of 2017 is not available.
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 review of laboratory records, lack of records to review and staff interview, the laboratoy failed to meet the requirement for testing testosterone and prostate specific antigen in the speciality of endocrinology. Findings include: Refer to: D 5211, D 5311, D 5413, D5441
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records and staff interview the laboratory director failed to document review of PT evaluations for the 1st event of 2017 and the 1st event of 2018.. Findings include: 1. Review of 2017 and 2018 API PT records revealed no documentation that event 1 of 2017 and event 1 of 2018 PT evaluations were reviewed by the laboratory director. 2. Interview with the testing personnel #1 (see CMS 209) and the office administrator on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor confirmed there is no documentation of PT evaluation review for event 1 of 2017 and event 1 of 2018.
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 review of laboratory records, lack of Quality assessment records to review, lack of a Quality Assessment (QA) policy and staff interview, the laboratory failed to establish and maintain a QA program. . Findings include: 1. Review of the laboratory's 2017 and 2018 records revealed no documentation of QA activity after March 7, 2017. 2. Review of the laboratory's policy and procedure manual revealed no QA policy. 3. Interview with TP # 1 (See CMS 209) and the office administrator on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor confirmed the laboratory does not have a current QA policy and no documentation of QA activity after March 2017 is available.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the laboratory, review of the manufacturer's instructions for freezing specimens in serum separator tubes (SST), review of the specimen storage requirements, staff interview, and interview with the SST manufacturer's client services representative, the laboratory failed to follow manufacturer's instruction for storage of frozen specimens and failed to ensure specimens are stored at the proper temperature. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed specimens are stored in primary SST collection tubes and placed in a frost free freezer for storage until testing is performed. 2. Review of the manufacturer's recommendations for storing frozen specimens in SST tubes revealed the following statement, " It is not recommended to freeze the sample in the primary blood collection tube, on the gel barrier. The gel may separate when it is frozen and thawed, resulting in red cell contamination of the sample.". 3. Telephone interview with a client service representative from Becton Dickson (BD), the manufacturer of the SST tubes, on September 26, 2018 at approximately 3:30 pm in the physician's office confirmed specimens should not be stored frozen in SST tubes. 4. Review of the laboratory's instructions for specimen collection and preparation revealed specimens for PSA should be stored at negative 20 degrees or colder if not tested within 24 hours of collection and specimens for testosterone should be stored at negative 20 degrees or colder if not tested within 48 hours of collection. 5. Review of laboratory records revealed no documentation or temperature charts recording the temperature of the freezer where samples are stored. 6. Interview with TP # 1 (see CMS 209) and the office manager at approximately 4 pm in the office assigned to the surveyor confirmed specimens are stored frozen in SST primary collection tubes and the temperature of the freezer where they are stored is not monitored or recorded.
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 review of the laboratory's procedure manual and staff interview, the laboratory failed to include instructions for specimen storage and preservation which meet the manufacturer's requirements. Findings include: 1. Review of the laboratory's procedure for testing testosterone and prostate specific antigen (PSA) revealed specimen collection and preparation instructions do not include detailed instructions for centrifuging and storing specimens. 2. Interview with testing personnel # 1 (see CMS 209) and the office manager on September 26, 2018 in the office area asssigned to the surveyor at approximately 4 pm confirmed the laboratory's procedure does not meet manufacturer's recommendations and instructions.
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 observation by the surveyor during a tour of the laboratory, review of temperature requirements posted by the manufacturer on boxes of controls used in testing of testosterone and PSA levels on the Beckman Access 2 endocrinology analyzer, lack of documents to review and staff interview, the laboratory failed to store controls at the temperature required by the manufacturer. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed Liquicheck Immunoassay Plus Controls are stored in a frost free freezer. No documentation or temperature charts recording the temperature of the freezer are available. 2. Review of temperature storage requirements on the package insert for Liquicheck Immunoassay

	Plus Control levels 1, 2, and 3 used on the Beckman Access 2 endocrinology analyzer revealed the controls must be stored at negative 20 to negative 70 degrees centigrade. 3. Interview with testing personnel #1 (see CMS 209) and the office administrator on September 26, 2018 in the office assigned to the surveyor at approximately 3:45 pm revealed the lab was unaware of the storage requirements for the controls. Interview also confirmed the manufacturer's acceptable temperature range is negative 20 to negative 70 degrees centigrade and the temperature of the freezer is not monitored.
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 observation by the surveyor during a tour of the laboratory and staff interview, the laboratory failed to perform maintenance and function checks on the Mini E centrifuge used to prepare serum specimens for testing and the Horizon Mini B centrifuge used to prepare semen samples for testing.. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed a sticker on the Mini E centrifuge showing a rotations per minute (RPM) check on the centrifuge was last performed on 5/12/2009. The sticker on the Mini B centrifuge is dated 11/29/12. 2. Interview with testing personnel # 1 September 26, 2018 at 12 pm in the laboratory confirmed there is no documentation of centrifuge maintenance and RPM check after the dates recorded on the stickers and maintenance is not performed yearly as required.
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 review of the laboratory's 2017 and 2018 quality control (QC) records for testing performed on the Beckman Access 2 Endocrinology analyzer and staff interview, the laboratory failed to monitor over time, the accuracy and precision of test performance. Findings include: 1. Review of 2017 and 2018 QC records revealed no evidence of Levey-Jennings (LJ) charts or other means for reviewing control values to determine shifts or trends for testosterone and PSA testing performed on the Beckman Access 2 analyzer. 2. At the surveyor's request for LJ charts, charts for controls tested between 8/26/2018 and 9/26/2018 were generated for PSA. No other

	LJ charts were available and 2. Interview with the office administrator and testing personnel # 1 (see CMS 209) on September 26, 2018, in the office assigned to the surveyor at approximately 3 pm, confirmed LJ charts are not printed and the laboratory is not reviewing QC values for shifts and trends.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control(QC) records, lack of records to review and staff interview, the laboratory failed to document corrective action taken when controls fell outside the acceptable range. Findings include: 1. Review of QC records revealed PSA controls levels 1, 2 and 3 were outside the acceptable range on 9 /20/18 and levels 2 and 3 were outside the acceptable range on 3/15/18. Review also revealed testosterone level 3 control was outside the acceptable range on 3/15/18, level 1 was outside the acceptable range on 3/16/18 and all 3 levels of control were outside the acceptable range on 3/8/18. 2. No documentation of corrective action taken is available. 3. Interview with TP # 1 (see CMS 209) and the office administrator on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor confirmed corrective action other than the service representative's reports when instrument service is required is not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory failed to include units of measure, name and address of the laboratory location where testing was performed and patient normal values on patient test reports. Findings include: 1. Review of 2 of 2 patient test reports generated from the laboratory's electronic medical records revealed units of measure, normal values and the name and address of the laboratory location where testing was performed is not included on the report. A form containing the required information is used by the laboratory to document results prior to entering into the patient's medical record but this form is not retained in the

	patient's medical record. 2. Interview with the office administrator at 2 pm on September 26, 2018 in the administrator's office confirmed the required information is not part of the patient's test report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to rview and staff interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Findings include: Refer to: D 6007, D 6013, D 6016, D 6018, D 6020, D 6021,
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the laboratory, review of the manufacturer's instructions for freezing specimens in serum separator tubes (SST), review of the specimen storage requirements, staff interview, and interview with the SST manufacturer's client services representative, the laboratory director failed to ensure the laboratory provided quality laboratory services in the preanalytic phase of testing. Findings include: Refer to D 5311
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of performance validation records for the Beckman Access 2

	endocrinology analyzer and staff interview, the laboratory director failed to document review and acceptance of performance verification records prior to beginning patient testing. Findings include: 1. Review of performance verification records for the Beckman Access 2 analyzer put into use in December 2017, revealed no documentation of review by the laboratory director. 2. Interview with TP # 1 (see CMS 209) and the office administrator on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor revealed the documents were reviewed and signed by the consultant supplied by the manufacturer to install the analyzer. Interview also confirmed there is no documentation of review by the laboratory director.
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 proficiency testing records and staff interview, the laboratory director failed to ensure proficiency testing samples were rotated among all testing personnel who test patient samples and failed to ensure attestation statements were signed by the testing personal and laboratory director and retained as required. Findings include: Refer to D 2007 and D 2009
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory director failed to ensure all PT testing reports were reviewed. Findings include: Refer to D 5211
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, lack of records to review and staff interview, the laboratory director failed to ensure the quality control program was maintained. Findings include: Refer to D 5441 & D 5783
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of Quality assessment records to review, lack of a Quality Assessment (QA) policy and staff interview, the laboratory director failed to ensure a QA program was established and maintained. Findings include: 1. Review of the laboratory's 2017 and 2018 records revealed no documentation of QA activity after March 2017. 2. Review of the laboratory's policy and procedure manual revealed no QA policy. 3. Interview with TP # 1 (See CMS 209) and the office administrator on September 26, 2018 at approximately 5 pm in the office assigned to the surveyor confirmed the laboratory does not have a current QA policy and no documentation of QA activity after March 2017 is available.