# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0265055	**(X3) Date Survey Completed** 03/19/2018
Name of Provider or Supplier Waycross Urology Clinic	**Street Address, City, State** 1306 Alice Street, Waycross, 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 March 19, 2018. The laboratory was not in compliance with all 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 patient testing records and staff interview, the laboratory failed to rotate performance of proficiency testing samples among all personnel who test patient samples. Findings include: 1. Review of PT attestation statements and PT testing records revealed all PT samples in 2016, 2017 and 2018 were tested by testing personnel # 3 (see CMS 209). 2. Review of patient testing records revealed testing personnel #1 (See CMS 209) began testing patient samples in September 2016. 2. Interview with testing personnel #1 (see CMS 209) on March 19, 2018 at 11 am confirmed testing personnel # 3 performed testing on all PT samples in 2016, 2017 and 2018. .
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 the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) attestation statements and staff interview, both the laboratory director and testing personnel failed to sign attestation statements in 2016, 2017 and 2018. Findings include: 1. Review of AAB PT attestation statements for 2016, 2017 and 2018 revealed they are not signed by the testing personnel performing the testing or the laboratory director. 2. Interview with testing personnel # 1 (see CMS 209) on March 19, 2018 at 11 am confirmed attestation statements are not signed.
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 laboratory failed to meet requirements for quality control, maintenance and function checks, calibration and calibration verification, proficiency testing and Laboratory Director in the subspecialty of Endocrinology when performing Prostate Specific Antigen (PSA) testing. Findings include: D5221, D 5429, D5431, D5439, D5445, D 5481, D5783
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) records, review of the laboratory's PT records showing the value obtained and staff interview, the laboratory failed to take corrective action for unsatisfactory scores obtained on Prostate Specific Antigen (PSA) testing for the 3rd testing event of 2017. Findings include: 1. Review of AAB PT records revealed the laboratory scored 50% on event 3 of 2017. Review revealed the laboratory reported a value of 0.2. The acceptable range as reported by AAB is 7.0 to 13.1. No documentation of corrective action is available. 2. Review of the laboratory's testing records for 9/5/17 confirmed the laboratory obtained a value of 0.16 on sample # 2. 3. Interview with the office manager and testing personnel # 1 (see CMS 209) on March 19, 2018 at 11:30 am confirmed no corrective action was performed for the unsatisfactory scores.
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 the laboratory's quality assessment (QA) records and staff interview, the laboratory failed to follow its written policy and procedure for monitoring, assessing and correcting problems. Findings include: 1. Review of the laboratory QA records revealed the last documentation of activity is December 2016. No documentation of QA activity in 2017 and 2018 is available. 2. Interview with the office manager and testing personnel # 1, (see CMS 209) on March 19, 2018 at 1 pm confirmed no documentation of QA activity is available for 2017 and 2018.
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 Dianon Systems centrifuge used to prepare specimens for testing. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed no documentation that the rotations per minute (RPM) check on the centrifuge has been performed. 2. Interview with testing personnel # 1 on March 19, 2018 at 12 pm confirmed there is no documentation of centrifuge maintenance and RPM check is not performed yearly as required.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedure and reference guides for Prostate Specific Antigen (PSA) performed using the Qualigen Fast Pack system, review of laboratory records and staff interview, the laboratory failed to document the required yearly function check on the 100 microliter pipette used to pipette patient samples into the system. Findings Include: This is a repeat deficiency. 1. Review of the manufacturer's procedure including the "Quick Reference Task Log" and "Quick Reference Guide" revealed annual pipette re-calibration is required. 2. Review of laboratory records revealed a new pipette was received on 4/27/16. No records of re-calibration or receipt of a new pipette are available for 2017 and 2018. 3. Interview with the office manager and testing personnel # 1 (see CMS 209) on March 19, 2018 at 11:30 am confirmed no documentation of pipette re-calibration for 2017 and 2018 is available.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedure and reference guides for Prostate Specific Antigen (PSA) performed using the Qualigen Fast Pack System, review of laboratory records and staff interview, the laboratory failed to perform calibration verification at least every six months as required in 2016, 2017 and 2018. This is a repeat deficiency. Findings include: 1. Review of the manufacturer's procedure including the "Quick Reference Task Log" and Quick Reference Guide", revealed calibration verification is required every 6 months. 2 Review of laboratory records for 2016, 2017 and 2018 revealed no documentation of calibration verification. 3. Interview with the office manager and testing personnel # 1, (see CMS 209) on March 19, 2018 at 11:30 am confirmed no documentation of calibration verification in 2016, 2017 and 2018 is available.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for Prostate Specific Antigen (PSA) testing performed using the Qualigen Fast Pack system, review of the laboratory's Individual Quality Control Plan (IQCP), review of proficiency testing

	records and staff interview, the laboratory failed to perform QC testing in the frequency adequate to ensure quality patient results. Findings include: Refer to D 5481 1. Review of the laboratory's IQCP signed and approved by the lanboratory director on 12/8/2015 revealed weekly QC is acceptable when the laboratory consistently obtains accepatble results on both levels 1 and 2 of QC samples and scores passing results on proficiency testing. 2. Review of 2016 and 2017 QC records revealed the laboratory did not consistently obtain acceptable scores on QC material (refer to D5481). 3. Review of proficiency testing records revealed the laboratory failed proficiency testing with a score of 50% on event 3 of 2017. 4. Interview with testing personnel # 1 (see CMS 209) on March 19, 2018 at 12 pm confirmed QC is performed weekly even though the laboratory's QC failed multiple times and received a score of 50% on proficiency testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and staff interview, the laboratory reported patient test results when the values of control material fell outside the acceptable range (s). Findings include: 1. Review of the laboratory's QC records revealed QC is performed weekly and QC fell outside the acceptable range(s) in 2016 and 2017 on the dates listed below and patient test results were still reported. 05/23/16 Lot # 1507030-6 level 1 1.9 acceptable range 0. 77 to 1.8 level 2 32.1 acceptable range 12.4 to 29.0 06/01/16 level 1 2.0 level 2 35.9 06/06/16 level 1 2.1 level 2 34.4 06/13/18 level 1 1.9 level 2 35.7 06/20/16 level 1 1.9 level 2 37.2 09/27 /19 Lot # 1507030-9 level 2 11.2 range 12.4 to 29.0 10/10/16 level 1 2.6 range 0.77 to 1.8 10/17/16 Lot # 1606002-4 level 1 8.3 range 0.78 to 1.8 10/24/16 level 1 9.5 level 2 11.4 range 12.0 to 28.0 10/31/16 level 1 5.5 11/14/16 level 1 10.5 11/16/16 level 1 8.6 11/28/16 level 1 1.9 12/12/16 level 2 28.2 01/16/17 Lot # 1606002-12 level 2 29.4 range 12.0 to 28.0 10/02/17 Lot # 1706008-3 level 2 6.6 range 6.9 to 16.0 10/23/17 Lot # 1706008-3 level 1 7.9 range 0.74 to 1.7 2. Interview with testing personnel # 1 (see CMS 209) on March 19, 2018 at 12 pm confirmed controls were outside the acceptable ranges for the controls listed above on the dates given and patient results were still reported.
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 documents to review and staff interview, the laboratory failed to take corrective action when results of QC samples fell outside the acceptable ranges. Findings include: Refer to D 5481 1. Review of the laboratory's QC records revealed QC samples fell outside the acceptable ranges multiple times (refer to D5481) and no documentation of corrective action is available. 2. Interview with testing personnel # 1 (see CMS 209) on March 19, 2018 at 12 pm confirmed corrective action is not taken when controls fall outside acceptable limits.
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 and interview with the laboratoary director and staff, the laboratory director failed to provide management and direction of the laboratory. Findings include: D6016, D6022, D6025
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 2016, 2017 and 2018 proficiency testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT samples were tested as required under Subpart H. Findings include: 1. Review of 2016, 2017, and 2018 Prostate Specific Antigen (PSA) PT records revealed no documentation that attestation statements were signed by the LD, documentation that PT testing was not rotated among all testing personnel and no documentation that corrective action was performed for unsatisfactory results. 2. Interview with the office manager and testing personnel #1 (see CMS 209) on March 19, 2019 at 11:30 confirmed the LD did not assure the laboratory complied with PT regulations. Also reference: D2007, D2009, and D5221 .
D6022	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 and quality assessment programs

	are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of 2016, 2017 and 2018 quality control (QC) records, review of quality assessment (QA) records and interview with the laboratory director and staff, the laboratory director failed to ensure QC and QA programs were maintained. Findings include: Refer to D5221, D5291, D5429, D5431, D5439, D5445, D5481, D5783 1. Interview with the laboratory director on March 19, 2018 in his office at approximately 11 am confirmed he has not reviewed QC or QA records in 2016, 2017 and 2018. 2. Interview with testing personnel # 1 (see CMS 209) on March 19, 2018 at 12 pm confirmed there is no documentation of QA and QC review by the LD.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of patient test records, review of quality control (QC) records and interview with the laboratory director, the laboratory director failed to ensure patient test results for prostate specific antigen (PSA) were not reported when controls fell outside the acceptable ranges indicating the test system was not functioning properly. Findings include; Refer to D 5481 1. Interview with the laboratory director on March 19, 2018 at approximately 11:00 am in his office confirmed he has not reviewed QC results and was not aware QC values fell outside acceptable ranges when patient results were reported.