Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0104149	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
New Jersey Urology	42 Locust Avenue, 2nd Floor, Suite 5, Wallington, NJ	

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
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 the surveyor review of the Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate Prostate Specific Antigen (PSA) and Urine Colony count tests twice annually in the calendar years 2017 and 2018. The findings include: 1. There was no evidence of documented review of BA samples in 2017 and 2108. 2. This deficiency was cited on survey preformed on 2/28/17. 3. Plan of Correction (POC) stated "Laboratory Director (LD) will sign BA testing done twice annually and the LD will review all samples" but there was no evidence POC was followed. 4. The TP confirmed on 12/19/18 at 9:45 am that the laboratory did not document review of BA results.
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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish and follow a detailed procedure for Biannual Assessment (BA) from 2/28/17 to the date of survey. The findings include:

	1. This deficiency was cited on survey preformed on 2/28/17. 2. Plan of Correction (POC) stated "Laboratory Director (LD) will develop a BA." but there was no evidence POC was followed. 3. The TP confirmed on 12/19/18 at 9:55 am that a detailed BA procedure was not established.
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 surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the laboratory failed to meet the analytic system requirements for Prostate Specific Antigen (PSA) and Urine Colony count (UC) tests. The findings include: 1. The laboratory failed to follow Manufacturers Package Insert. Cross refer to D5411. 2. The laboratory did not have criteria for acceptable Room, Incubator and Refrigerator Temperature. Cross refer to D5413. 3. The laboratory did not put expiration dates on Quality Control (QC). Cross refer to D5415. 4. The laboratory did not calibrate pipette and centrifuge used for PSA tests. Cross refer to D5435. 5. The laboratory did not perform two levels of QC before testing patients for PSA. Cross refer to D5447. 6. The laboratory did not perform Quality Control (QC) on UC paddles. Cross refer to D5477. 7. The laboratory did not perform corrective action on failed PSA QC. Cross refer to D5783. 8. The laboratory failed to maintain an accurate information system for patient testing. Cross refer to D5787. 9. The laboratory failed to establish a procedure to verify new QC. Cross refer to D5791.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a discontinuance date for Urine Colony (UC) counts procedures no longer in use on the date of survey. The findings include: 1. The procedures for UC found in the PM was for Uri-Three plates, Bi-plates and Uricults which the laboratory did not use. 2. The TP confirmed on 12/19/18 at 10: 20 am the laboratory did not discontinue procedures no longer in use.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as

	determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Package Insert (MPI), Test Reports (TR), and interview with the Testing Personnel(TP), the laboratory failed to follow the manufacturer's instruction for reading Solar-Cult Dipslides from 2/28/17 to the date of survey. The finding includes: 1. The laboratory reported the results as Positive and Negative but the MPI interpretation was: a. Nonsignificant- 0-30 colonies. b. Doubtful - 31-300 colonies. c. Significant - 300 or more. 2. This deficiency was cited on survey preformed on 2/28/17. 3. Plan of Correction (POC) stated "Results in patient charts will be labeled instead of positive or negative. 1) Nonsignificant, 2) Doubtful 3) significant. TP will ensure deficiency will not recur" but there was no evidence POC was followed. 4. The TP confirmed on 12/19/18 at 12:10 pm that the laboratory did not follow the MPI.
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 surveyor review of the Temperature Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to define a temperature range for the Room, Incubator, and Refrigerator where Urine Cultures were stored from 2/28/17 to the date of the survey. The findings include: 1. This deficiency was cited on survey preformed on 2/28/17. 2. Plan of Correction (POC) stated "A range was defined for room temperature and incubator TP will ensure deficiency will not recur" but there was no evidence POC was followed. 3. The TP confirmed on 12/19/18 at 10:10 am that the above temperature ranges weren't defined
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 observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put expiration dates on QC material for Endocrinology tests at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put

	new expiration dates on Qualigan Fast Pack QC in use. 3) The TP confirmed on 12/19 /18 at 11:50 am the laboratory failed to put expiration dates on the control material.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of Maintenance Records and interview with the Testing Personnel (TP), the laboratory failed to perform or document calibration of pipettes and centrifuge used in Endocrinology tests from 2/28/17 to the date of survey. The TP confirmed on 12/19/18 at 11:00 am that pipette and centrifuge calibration and was not performed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to perform and document two level of controls on each day of patient testing for Prostate Specific Antigen (PSA) testing performed on the Qualigen Fast Pack analyzer in the calendar year 2018. The findings include: 1. There was no documented evidence two levels of QC were run on 12/2/18, 12/4/18, 12/10/18, 12/14/18, and 12/17/18. 2. Approximately one to three patients were run and reported each day QC was not done. 3. This deficiency was cited on survey preformed on 2/28/17. 4. Plan of Correction (POC) stated "Two levels of controls will be performed when PSAs are done. TP will ensure deficiency will not recur but there was no evidence POC was followed. 5. The TP confirmed on 12/19/18 at 10:30 am that two levels of QC were not performed every day of patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Urine Culture media for appearance, sterility, ability to support growth and select or inhibit organisms from 2/28/17 to the date of the survey. The findings include: 1. There was no documented evidence appearance was checked on the current lot in use 18G1572. 2. There was no documented evidence sterility, ability to support growth and select or inhibit organisms was checked on any lot number of media. 3. This deficiency was cited on survey preformed on 2/28/17. 4. Plan of Correction (POC) stated "Log in has been established for urine culture inspections. Visual, Sterility, Positive/Negative. TP will ensure deficient will not recur" but there was no evidence POC was followed. 5. The TP confirmed on 12/19/18 at 10:50 am the laboratory did not perform the above QC.
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 surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to take corrective action when controls were out of range for Prostate Specific Antigen (PSA) tests on the Qualigan Fast Pack System in the calendar year 2018. The findings include: 1. A review of the QC records revealed controls were out of range as follows: a. Level 1 : 1/22/18, 4/3/18, 5 /11/18, 8/3/18, 10/2/18, 11/5/18 and 12/26/18 b. Level 2: 4/3/18, 8/17/18 and 9/8/18 2. Approximately 10 to 20 patients were run and reported. 3. The TP confirmed on 12/19 /18 at 11:30 am that corrective action on failed QC was not performed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of an Accession Log (AL) and interview with the Testing Personnel

	(TP), the laboratory failed to maintain an Accession Log (AL) for Urine Colony Count and Prostate Specific Antigen (PSA) tests from 2/28/17 to the date of survey. The findings include: 1. This deficiency was cited on survey preformed on 2/28/17. 2. Plan of Correction (POC) stated "Log in has been established for documenting patients samples. TP will ensure" but there was no evidence POC was followed. 3. The TP confirmed on 12/19/18 at 11:15 am that the laboratory did not maintain an AL for laboratory tests.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure to verify new QC material used for Prostate Specific Antigen (PSA) tests before use from 2/28/17 to the date of the survey. The findings include: 1. This deficiency was cited on survey preformed on 2/28/17. 2. Plan of Correction (POC) stated "A QC verification procedure was established and TP will ensure deficiency will not recur" but there was no evidence POC was followed. 3. The TP confirmed on 2/28/17 at 11:25 am that the laboratory did not have a procedure to verify new PSA QC.
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 surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that FR for Prostate Specific Antigen (PSA) and Urine Colony count testing included all required information from 2/28/17 to the date of the survey. The findings include: 1. The FR did not have: a. Positive patient identification. b. The name and address of the laboratory location where tests were performed. c. The FR did not have the "Test Report Date". d. The specimen source. 2. The TP confirmed on 12/19/18 at 11:50 am that the laboratory did not have required information on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Range (RR) for Prostate Specific Antigen (PSA) tests and Urine Colony counts on the FR from 2/28 /17 to the date of the survey. The TP confirmed on 12/19/18 at 12:20 pm that the above tests did not have a RR on the FR.
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 surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure Plan Of Correction from survey dated 2/28/17 was followed and provide overall management and direction to the laboratory. The findings include: 1. The LD failed to document review of Biannual Assessment results. Cross refer to D5221. 2. The LD failed to establish a BA procedure. Cross refer to D5291. 3. The LD failed to ensure that Quality Control programs were established and maintained. Cross refer to D6020. 4. The LD failed to ensure that a Quality Assurance program was maintained. Cross refer to D6021. 5. The LD failed to ensure that prior to testing patients' samples all testing personnel had the appropriate education. Cross refer to D 6020. 6. The LD failed to ensure a Competency Assessment policy was established and maintained. Cross refer to D6030.
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 surveyor review of the Quality Control (QC) records, Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QC program was established for Urine Colony counts from 2/28/17 to the date of the survey. The TP confirmed on 12/19/18 at 10:40 am the LD did not ensure a QC plan was established.

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 surveyor review of the Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QA program was maintained from 2/28/17 to the date of survey. The TP confirmed on 12 /19/18 at 11:10 am the QA program was not maintained.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for one out of one TP from 2 /28/17 to the date of the survey. The findings include: 1. This deficiency was cited on survey preformed on 2/28/17. 2. Plan of Correction (POC) stated "Proper education proof has been established" but there was no evidence POC was followed. 3. The TP confirmed on 12/19/18 at 9:10 am that education records were not available.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements from 2/28/17 to the date of the survey. The findings include: 1. This deficiency was cited on survey preformed on 2 /28/17. 2. Plan of Correction (POC) stated "A competency assessment has been established by the LD and will be used" but there was no evidence POC was followed. 3. The TP confirmed on 12/19/18 at 9:20 am that a CA procedure was not established.