Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0718164	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Atlanta Urology Associates Pc	631 Professional Drive, Suite 490, Lawrenceville, 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 May 15, 2019. 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:
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 proficiency test (PT) document review and staff interview, the laboratory failed to enroll in a PT program that meets required CLIA criteria. Findings include: 1. American Proficiency Institute (API) PT document review revealed the laboratory was enrolled in only two Chemistry events per year for 2017 and 2018 which included only three PT samples each. 2. An interview with Staff #3 (CMS 209) in a medical office on 5/15/2019 at approximately 2:00 p.m. confirmed the lack of compliance with CLIA requirements for PT enrollment.
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 test (PT) documents and staff interview, the laboratory failed to include all of the testing personnel (TP), who routinely perform the laboratory testing, in the examination of PT samples. ;; Findings include: 1. American Proficiency Institute (API) PT document review revealed Staff #3 (CMS 209) performed all PT testing for the second and third 2018 Chemistry events. 2. An interview with Staff #3 (CMS 209) in a medical office on 5/15/2019 at approximately 2 p.m. confirmed she performed all PT testing for the aforementioned PT events.
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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a policy and procedure to assess testing personnel (TP) competency. Findings include: 1. SOP review revealed the laboratory did not include a policy and procedure to assess TP competency initially or semi-annually. 2. An interview with Staff #3 (CMS 209) in a medical office on 5/15/2019 at approximately 2:00 p.m. confirmed the lack of the aforementioned policies in their SOP.
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 policy and procedure manual (SOP), proficiency test (PT) document review, and staff interview, the laboratory failed to include or to follow required policies and procedures. Findings include: 1. SOP review revealed the SOP did not include a record retention policy and procedure. 2. SOP review revealed laboratory failed to follow the established PT policy and procedure. 2. An interiew with Staff #3 (CMS 209) in a medical office on 5/15/2019 at approximately 2:00 p.m. confirmed there was not a record retention policy and procedure in their SOP and the laboratory was not following the PT procedure in their SOP.
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 policy and procedure manual (SOP) and staff interview, the laboratory failed to include required policies and procedures. Findings include: 1. SOP review revealed there was no policy and procedure for the following: specimen acceptability and rejection, specimen storage, critical values, and corrective action when calibration or control results failed to meet the laboratory's criteria for acceptability, 2. An interview with Staff #3 (CMS 209) in a medical office on 5/15/19 at approximately 2 p.m. confirmed the lack of the aforementioned policies and procedures required for their SOP.
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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure that all PT reports were reviewed by appropriate staff as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD did not review the 2018 Chemistry First Event PT report. 2. An interview with Staff #3 (CMS 209) in a medical office on 5/15/2019 at approximately 2:00 p.m. confirmed the lack of LD review of the aforementioned PT report.
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 testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to perform an annual competency for TP as required. Findings include: 1. TP document review revealed the TC/LD did not perform an annual competency in 2018 for Staff #4 (CMS 209). 2. An interview in a medical office on 5/15/19 at approximately 2:00 p.m. confirmed the aforementioned TC/LD failure to perform an annual TP competency on Staff #4 (CMS 209).