

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2038076	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Urology Specialists Of Virginia, Pc	Street Address, City, State 8720 Stony Point Parkway - Suite 120, Richmond, VA	
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	An announced CLIA recertification survey was conducted at Urology Specialists of Virginia, PC on August 8, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, policies, and an interview, the laboratory failed to rotate PT among personnel performing patient Prostate-Specific Antigen (PSA) testing for the six (6) PT events reviewed. Findings include: 1. Review of the CMS 209 revealed three (3) laboratory testing personnel (TP A, B, D) performing patient PSA testing during the PT events reviewed. (See Personnel Code Sheet.) 2. Review of the laboratory's American Academy of Family Physicians (AAFP) chemistry PT documentation revealed Testing Personnel D signed the attestation and performed the testing for the following four (4) events: 2016 Event 3, 2017 Event 1, 2017 Event 2, 2017 Event 3. Review of the laboratory's American Association of Bioanalysts (AAB) chemistry PT documentation revealed Testing Personnel D signed the attestation and performed the testing for the following two (2) events: 2018 Event 1, 2018 Event 2. 3. Review of the laboratory's policies revealed a Qualigen Proficiency Testing Policy that stated: "Test the PT samples using staff members who routinely performs FastPack testing". 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the</p>

laboratory failed to rotate the proficiency testing among the personnel performing PSA testing for the six (6) events reviewed as outlined above.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a lab tour, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of the Post-Vasectomy slide readings at least two (2) times per year in 2016 and 2017. Findings include: 1. During a laboratory tour with the primary testing personnel at approximately 1:00 PM, it was revealed that the physicians perform Post-Vasectomy slide readings. 2. Review of the CMS 209 form revealed that three (3) of the six (6) testing personnel are physicians who perform and report patient Post-Vasectomy slide results. The testing personnel were identified as Testing Personnel C, E, and F. (See Testing Personnel Code Sheet.) 3. Review of the laboratory's PT documentation for 2016 to the date of survey on 8/8/17 revealed no record of PT, split sample testing or other accuracy check for the Post-Vasectomy slide testing. The inspector requested documentation of split sample comparison or accuracy checks for Post-Vasectomy slide testing. No documentation was available for review. 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory did not perform two (2) times a year comparison slide reading on Post-Vasectomy specimens in calendar year 2016 and 2017.

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:

A. Based on review of the policy and procedure manuals, proficiency testing (PT) documentation, and an interview, the laboratory failed to follow the established policy for Prostate-Specific Antigen (PSA) PT for two (2) challenges per shipment on four (4) of six (6) testing events reviewed. Findings include: 1. Review of the laboratory's policies revealed a Qualigen Proficiency Testing Policy that stated: "For PSA testing, the lab is to document two test challenges in each event shipment for satisfactory performance". 2. Review of the laboratory's American Academy of Family Physicians (AAFP) chemistry PT documentation revealed one (1) PSA challenge resulted and scored for the following four (4) events: 2016 Event 3, 2017 Event 1, 2017 Event 2, 2017 Event 3. 3. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to follow the established PT policy for performing two (2) PSA test challenges per event shipment for the events outlined above in 2016 and 2017. B. Based on a laboratory tour, records review, and interview, the laboratory failed to have a written procedure for Post-Vasectomy Slide Reading

during the twenty-four (24) month review period. Findings include: 1. During a laboratory tour with the primary testing personnel at approximately 1:00 PM, the inspector noted a microscope in the laboratory's adjacent testing area. It was revealed by the primary testing personnel that the physicians perform Post-Vasectomy slide readings. 2. During a review of the laboratory's policy and procedure manuals, the inspector noted that there was no written procedure for the Post-Vasectomy slide test including patient preparation, specimen labeling, storage preservation, transportation, criteria for specimen acceptability or rejection, or system for entering the patient results. 3. In the exit interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the procedure manual did not include a written procedure for Post-Vasectomy Slide Reading.

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 a review of the proficiency testing (PT) results, policies, and an interview, the laboratory director (LD) failed to document review of the laboratory's performance in chemistry PT for six (6) out of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) and American Association of Bioanalysts (AAB) chemistry PT records revealed no documentation of review of results by the lab director for the following six (6) events: 2016 AAFP Event 1, 2017 AAFP Event 1, 2017 AAFP Event 2, 2017 AAFP Event 3, 2018 AAB Event 1, 2018 AAB Event 2. 2. Review of the laboratory's procedure manual revealed a quality assurance policy that stated: "The Laboratory Director ensures that all aspects of proficiency testing are properly followed and PT results are reviewed". 3. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the lab director failed to document review and evaluation of the laboratory's PT performance on the six (6) events outlined above.