

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0901725	<b>(X3) Date Survey Completed</b>  08/12/2019
<b>Name of Provider or Supplier</b>  Virginia Allergy And Ped Assoc, Pc	<b>Street Address, City, State</b>  10134-D Colvin Run Road, Great Falls, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced CLIA off-site proficiency testing desk review of Virginia Allergy and Ped. Assoc., PC was conducted on August 7, 2019 and August 12, 2019 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER 0164S-PT Failure to Re-enroll Report for Test Year 2019, the laboratory's CASPER 0096D CLIA Application and Survey Summary Report, and interviews with the Laboratory Director (LD), the laboratory failed to enroll in a Center for Medicare and Medicaid Services (CMS) approved Proficiency Testing (PT) program for Bacteriology for 2019. Findings include: 1. Review of the CASPER 0164S report revealed the laboratory did not re-enroll in a CMS approved PT program for Bacteriology for 2019. 2. Review of the CASPER 0096D report revealed the following Medical Laboratory Evaluation (MLE) PT results: MLE 2018 Bacteriology Event 1=100%; MLE 2018 Bacteriology Event 2=100%; MLE 2018 Bacteriology Event 3=100%; MLE 2019 Bacteriology Event 1=No results; and MLE 2019 Bacteriology Event 2=No results. 3. In a telephone interview with the LD on 8/7</p>

/19 at 2:50 PM and on 8/12/19 at 11:05 AM, the LD confirmed the laboratory did not enroll in a CMS approved PT program for Bacteriology. The LD stated he/she forgot to enroll in 2019 PT testing.