

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231466	(X3) Date Survey Completed 07/03/2018
Name of Provider or Supplier Physician Associates Of Virginia, Pc	Street Address, City, State 4461 Starkey Road - Suite 201, Roanoke, 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 Validation survey was conducted at the Physicians Associates of Virginia on July 3, 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:
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures, quality control records, personnel competency assessments, and interviews, the laboratory director did not delegate, in writing, the job duties and responsibilities of technical consultant (TC) to the individual performing the duties of TC at the date of survey on July 3, 2018. Findings include: 1. The CMS CLIA 209 form indicates testing personnel (TP) A is TC for the laboratory. 2. Review of the quality control records in the specialties of hematology and chemistry, and competency assessments performed in 2017 revealed that TP A was performing duties of TC in the calendar year of 2017 and up to the date of survey in 2018. 3. Review of the policy and procedure manuals revealed no documentation of</p>

the delegation of duties of TC, in writing, by the laboratory director to the TP A. The inspector requested to review the above-mentioned documentation. The documentation was not available for review. 4. An interview with the TC at approximately 2:30 PM confirmed that the laboratory director did not delegate the job duties and responsibilities of TC to the individual that was performing the duties at the date of survey.