

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0661154	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Virginia Physicians, Inc Laboratory Services	Street Address, City, State 4900 Cox Road Suite 180, Glen Allen, 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 the Virginia Physicians, Inc Laboratory Services on September 11 and 12, 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:
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on the review of chemistry instrument correlation documents and interview, the laboratory failed to perform instrument comparison of test results for the two (2) Beckman Coulter DxC 660i chemistry analyzers twice a year in 2017. Findings include: 1. Review of the laboratory's "chemistry instrument correlation" documents revealed that the laboratory performed an instrument comparison of test results for the 2 Beckman Coulter DxC 660i chemistry analyzers (serial numbers 006581 and 006616) on July 27, 2017. The inspector requested to review additional documentation, a second comparison, performed in the calendar year 2017. The documentation was not available for review. 2. Interviews with the laboratory director, technical and general supervisors on September 12, 2018 at approximately 2:45 PM confirmed that the laboratory failed to perform the instrument comparison of test results for the 2 chemistry analyzers twice in 2017.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p>

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interviews, the technical supervisor (TS) failed to perform the semi-annual competency assessment for one (1) TP in 2018. Findings include: 1. Review of the CMS-209 Form revealed that TP A performs patient testing (See attached personnel code list). 2. Review of TP A records revealed training and initial assessment performed between June and September 2017. There was no documentation of the TS performing a semi-annual competency assessment for TP A in 2018. 3. Interviews with the laboratory director, technical supervisor and general supervisor on September 12, 2018 at approximately 2:45 PM confirmed that the TS failed to perform the semi-annual competency assessments for TP A in 2018.