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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>49D0661154        | <b>(X3) Date Survey Completed</b><br><br>08/27/2026 |
| <b>Name of Provider or Supplier</b><br><br>Virginia Physicians, Inc Laboratory Services                                    | <b>Street Address, City, State</b><br><br>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. |                                                                                   |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>D0000</b>              | An announced CLIA recertification survey was conducted at Virginia Physicians Laboratory Services on August 26 and 27, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Virginia Physicians Laboratory Services was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5400 493.1250 Condition: Analytic systems.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>D5400</b>              | <p><b>ANALYTIC SYSTEMS</b><br/>CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on a review of laboratory of the Centers for Medicare and Medicaid Services Application for Certification Form (CMS116), policy and procedures, temperature charts, maintenance records, lack of documentation and interviews, the laboratory failed to: -follow their established policy for acceptable room temperature for Syphilis Serology Rapid Plasma Reagen (RPR) testing (Cross reference D5401); - document performance of the monthly maintenance on the Cepheid GeneXper analyzer, and the Polymedco OC-Auto Micro 80 Immunochemical analyzer (Cross reference D5429) - REPEAT DEFICIENCY; and - establish a system to twice annually compare manual and automated White Blood Cell (WBC) differential counts (Cross reference D5775).</p> |
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**D5401**

PROCEDURE MANUAL  
CFR(s): 493.1251(a)

(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 a review of laboratory policy and procedures, temperature charts and interview, the laboratory failed to follow their established policy for acceptable room temperature for Syphilis Serology Rapid Plasma Reagen (RPR) testing for thirty-eight (38) days in nineteen (19) months reviewed. Review timeframe January 2025 - July 2026. Findings include: 1. Review of the laboratory's established RPR test procedure revealed reagents and samples are to be at a room temperature of 20 - 30 degrees Celsius (C) before use. The RPR procedure included the statement, "Temperature of the reagents and samples is crucial to test outcome, it should be between 20 and 30 C." 2. Review of the lab's Immunology Temperature and Humidity charts revealed an acceptable room temperature range of 18-28 degrees C. Review of the January 2025 - July 2026 Temperature and Humidity charts (19 months) revealed room temperatures recorded as less than 20 degrees C for 20 days in calendar year 2025, and 18 days in 2026 (a total of 38 days). 3. In an interview at 3pm on 8/27/26 with the Technical Supervisors, the findings above were confirmed.

**D5429**

MAINTENANCE AND FUNCTION CHECKS  
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Application for Certification Form (CMS116), maintenance records, lack of documentation, and interview, the laboratory failed to document performance of the monthly maintenance for four (4) months on the Cepheid GeneXper analyzer, and two (2) months on the Polymedco OC-Auto Micro 80 Immunochemical analyzer out of the nineteen (19) months reviewed. Review timeframe January 2025 - July 2026. \*\*This is a REPEAT deficiency.\*\* Findings include: 1. Review of the survey CMS116 revealed the laboratory utilizes the moderately complex Cepheid GeneXper analyzer to perform patient testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV), Severe Acute Respiratory Syndrome (SARS), Influenzas (Flu), and Respiratory Syncytial Virus (RSV); and the Polymedco OC-Auto Micro 80 Immunochemical analyzer for patient immunochemical fecal occult blood (iFoB). 2. Review of the laboratory's OC-Auto Sensor iO iFOB Operational and Maintenance Schedule for the Polymedco OC-Auto Micro 80 Immunochemical analyzer (serial number 21UL1490) revealed monthly maintenance tasks of Clean Sample Racks, Clean DiH2O bottle, Clean Wash bottle, and Clean Waste tank. The OC-Auto maintenance documentation for the 19 months of January 2025 - July 2026 lacked documented monthly maintenance for the 2 months of March 2025 and May 2025. 3. Review of the laboratory's GeneXpert System (serial number 844403) Maintenance Log revealed monthly maintenance tasks of Archive tests, Purge tests, and Replace

fan filters. The GeneXpert Maintenance Logs for January 2025 - July 2026 (19 months) lacked documented monthly maintenance for the following 4 months in 2025: February, May, August and October. 4. In an interview at 3pm on 8/27/26 with the Technical Supervisors, the findings above were confirmed.

D5775

COMPARISON OF TEST RESULTS  
CFR(s): 493.1281(a)(c)

(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.

This STANDARD is not met as evidenced by:  
Based on a review of the Centers for Medicare and Medicaid Services Application for Certification Form (CMS 116), lab tour, review of laboratory policy and procedures, correlation studies, lack of documentation and interviews, the laboratory failed to establish a system to twice annually compare manual and automated White Blood Cell (WBC) differential counts during calendar year 2025. Findings include: 1. Review of the survey CMS116 revealed patient Complete Blood Counts with differential (CBCD) analysis performed on the Beckman Coulter Hematology DCH 900 analyzer. 2. In an interview with the General Supervisor at 10:45 AM on 8/26/26 and a lab tour, it was noted that testing personnel perform manual microscopic analysis of patient blood smears to obtain a WBC differential count. 3. Review of the Laboratory's policy and procedures revealed no written criteria defining the method, frequency, and acceptable differences in test values for WBC differential results produced by the automated Hematology analyzer and manual microscopic methods. 4. When asked during an interview on 8/26/26 at 3:45 PM if the lab had a policy or documentation of an automated differential verses manual differential comparison study, the Technical Supervisor stated they did not. 5. Review of the available 2025 Instrument Correlation studies revealed a lack of WBC differential method comparison. 6. In an exit interview with the Technical Supervisors at 3 PM on 8/27/26, the above findings were confirmed.