Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661154	12/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Physicians, Inc Laboratory Services	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 Virginia Physicians, Inc-Laboratory Services on December 13-14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs COVID-19 testing and was in compliance with the applicable SARS-CoV-2 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 a review of policies and procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to follow their established policy for laboratory director (LD) review on one of six Immunology PT events (timeframe: January 2021 to 12/14/22). Findings include: 1. Review of the laboratory's policies and procedures revealed a PT protocol (title: "Proficiency Testing Surveys") that stated, "The director receives copies of all surveys. The director reviews the results, signs and dates the PT result form. After the director review, the appropriate senior tech is given the survey for review." 2. Review of the laboratory's American Proficiency Institute (API) Immunology PT events (2021 Events 1-3, 2022 Events 1-3) revealed no LD signature of review for API 2022 Immunology Event 2. The inspector requested to review documentation of the LD's signature of review. No record was available. 3. An exit interview with the laboratory manager on 12/14/22 at approximately 11 AM confirmed the above findings. B. Based on a review of policies and procedures, proficiency testing (PT) records, and interviews, the laboratory failed

	to follow their established policy of required review of non graded PT results on two of six Microscopy Vaginal Wet Preparation (KOH) events during the twenty-three months reviewed (January 2021 to 12/14/22). Findings include: 1. Review of the laboratory's policies and procedures revealed a PT protocol (title: "Proficiency Testing Surveys") that stated, "The senior tech will document any non graded PT results. This will be done by hi-lighting analyte not graded. A brief note will be written on the evaluation report as to where Virginia Physicians, Inc Laboratory falls in the expected result along with any other information." 2. Review of six American Proficiency Institute (API) Microscopy PT events (2021 Events 1-3, 2022 Events 1-3) revealed no documentation of review for the following non graded KOH PT challenge samples: API 2021 Event 3 KOH sample VKP-03, API 2022 Event 2 KOH sample VKP-02. The inspector requested to review documentation of an evaluation for the non graded challenges outlined above. No records were available for review. 3. An exit interview with the laboratory manager on 12/14/22 at approximately 11 AM confirmed the above findings
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 procedures, equipment user's guide, maintenance records, lack of documentation, and interviews, the laboratory failed to document hematology Hematek Stainer's quarterly preventative maintenance according to manufacturer and laboratory log protocols during the twenty-three months reviewed (timeframe: January 2021 to the date of the inspection on December 12, 2022). Findings include: 1. Review of the laboratory's procedures revealed a hematology protocol (title: Hema-Tek 1000 Slide Stainer) that stated "Replace Pump Tubing quarterly as tubing may lose its elasticity and later the volume of stain solution pumped. Replace the Under Platen Tubing quarterly". 2. Review of the hematology slide stainer user's guide revealed instruction, "Tubing should be replaced after three stain packs and at minimum quarterly". 3. Review of the laboratory's 2021 and 2022 Hematek monthly maintenance logs revealed indicator "Quarterly- Replace Tubing and Platen Tubing". The inspector noted documentation of the quarterly maintenance as performed: 2021 - 04/01/21 and 08/31/21; 2022 - 01/07/22 and 10/07/22. The inspector requested additional documentation of the quarterly tubing replacement maintenance. The laboratory supervisor stated on 12/13/22 at approximately 1:30 PM, "The tubing could have been changed more often than is documented on the logs". 4. An exit interview with the laboratory manager on 12/14/22 at approximately 11 AM confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of procedures, chemistry calibration verification records, lack of documentation, and interviews, the laboratory failed to perform linearity validation studies, every six months, for twenty-eight (28) of 28 analytes utilized for patient testing on two (2) of 2 chemistry instruments according to the policy in calendar 2022. Findings include: 1. Review of the laboratory's procedures revealed a policy to perform calibration verification at least once every six months (title: Calibration and Calibration Verification). The policy stated "every six months the laboratory must use calibration materials appropriate for the methodology to verify the established reportable range of patient test results which must include at least a minimal value, a mid point value, and maximum value at the upper limit of the range". 2. Review of the laboratory's two Beckman Coulter DxC 700 AU chemistry analyzers' calibration verification records for the review timeframe of January 2021 to 12/13/22 revealed the following documentation: Beckman Coulter DxC 700 AU "03" (Serial Number 2020031415) Calibration Verification performed and accepted by supervisor on 04/01 /21, 09/28/21, and 8/10/22; Beckman Coulter DxC 700 AU "04" (Serial Number 2020021358) Calibration Verification performed and accepted by supervisor on 04/01 /21, 09/28/21, and 8/10/22. 3. Review of the Beckman Coulter DxC 700 AU test menu revealed the following 28 analytes utilized for patient testing were included in the laboratory's linearity calibration verification guidelines on both analyzer's outlined above: Albumin Alkaline Phosphatase Alanine Aminotranserase Amylase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Cholesterol Cholesterol, High Density Lipoprotein Cholesterol, Low Density Lipoprotein Cloride Creatine Phosphokinase Carbon Dioxide Creatinine Direct Bilirubin Glucose Iron Magnesium Phosphorus Potassium Sodium Total Bilirubin Total Protein Triglyceride Uric Acid Urine Creatinine Urine Microalbumin Urine Total Protein 4. The inspector requested to review additional documentation of calibration verification for the 28 analytes outlined above utilized for patient testing on the two analyzers in calendar year 2022. No additional documentation was available for review. The supervisor stated on 12/13 /22 at approximately 2 PM, "We were behind this year and did not get the studies finished until August. I plan to do additional linearity studies by the end of this month". 5. An exit interview with the laboratory manager on 12/14/22 at approximately 11 AM confirmed the above findings.