Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0889860	09/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rva Pediatrics, Pc	10410 Ridgefield Pkwy, Richmond, 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 RVA Pediatrics, PC on September 21, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes one Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and an interview, the laboratory failed to rotate PT among the six personnel performing Complete Blood Count (CBC) patient testing during the twenty-three (23) months reviewed (timeframe October 2020 to September 21, 2022). Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified six testing personnel (TP) who were qualified and performed CBC patient testing on the Abbott Emerald hematology analyzer during the 23 months of review. 2. Review of the laboratory's College of American Pathologists (CAP) PT attestation documentation (2020 Event C, 2021 Events A-C, 2022 Event A) a total of five events, revealed TP A performed the following three of five CAP Hematology Automated Differential Survey FH1 module events reviewed: 2020 Event C, 2021 Event A, 2021 Event C. (See Personnel Code Sheet.) 3. An exit interview with the lab supervisor and lead testing personnel on 9/21 /22 at 3:00 PM confirmed the above findings.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on a review of manufacturer's operations manual, procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction, instrument maintenance records, quality assurance corrective action logs, lack of documentation, and interviews, the laboratory failed to follow the laboratory director's approved corrective action plan to document required preventative maintenance during a twelve month timeframe from July 30, 2021 through August 26, 2022 as reviewed on the day of the inspection, September 21, 2022. See D5429 (a repeat deficiency).
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 manufacturer's operations manual, procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), instrument maintenance records, quality assurance (QA) corrective action logs, lack of documentation, and interviews, the laboratory failed to document preventative maintenance as required every six months during a twelve month timeframe after July 30, 2021 through August 26, 2022 as reviewed on the day of the inspection, September 21, 2022. *REPEAT DEFICIENCY Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instruction to "perform Lubricating Syringe Pistons maintenance procedure every six months". 2. Review of the laboratory's procedures revealed the following two protocols: Quality Assurance protocol section (Maintenance) that stated "Abbott Emerald maintenance for bleach clean is done monthly, syringe piston maintenance every six months"; CMS-2567 POC (director signed/approved 12/7/20) which outlined a corrective action plan for documentation of every six month hematology analyzer piston maintenance that stated, "A new log sheet was put in place on November 2, 2020 to document every 6 months maintenance. The lab supervisor will oversee and monitor that the required preventative maintenance is performed going forward." 3. Review of the laboratory's Emerald hematology maintenance logs from October 2020 to the date of the inspection on 9/21/21, a twenty-three month timeframe, revealed piston syringe lubrication maintenance recorded on 3/25/21, 7/30/21, and 8/26/22. The inspector requested to review additional documentation of the piston syringe maintenance performed in calendar year 2022. The lead testing personnel stated, at approximately 2:30 PM on 9/21/22, "We relied on our Peak field service technician to perform the

	piston procedures whenever onsite for a PM. We can reach out for the maintenance reports from Peak Service of other records for the piston syringe work that was due in January 2022." No additional records of the required hematology analyzer's syringe piston maintenance were made available for the inspector's review. 4. The inspector noted no corrective action was documented on the laboratory's QA monthly checklist logs for the lack of documentation outlined above. 5. An exit interview with the lab supervisor and lead testing personnel on 9/21/22 at 3:00 PM confirmed the above findings.