Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0889860	10/21/2020
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 on-site CLIA recertification survey was conducted at RVA Pediatrics, PC on October 21, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 10/05/2020 and virtual record review conducted on 10/19/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 instrument maintenance records, manufacturer's operations manual, lack of documentation, and an interview, the laboratory failed to document performance of Abbott Emerald maintenance as required (twice annually) during the review timeframe of July 2018 to October 2020. Findings include: 1. Review of the laboratory's Emerald hematology maintenance logs from July 2018 to the date of the record review on 10/19/20, revealed one maintenance record of piston syringe lubrication (dated 08/11/19). The inspector requested to review additional documentation of the piston syringe maintenance. No other records were available. The lead testing personnel stated, at approximately 12:30 PM on 10/19/20, "We relied on our Peak field service technician to perform the piston procedures when it was required. I have checked emails for the maintenance reports from Peak Service, but cannot find any other records for the piston syringe procedure". 2. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 3. In an interview with the lead testing personnel, on 10/21/20 at approximately 11:00 AM, the above findings were confirmed.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records, policies and procedures, lack of documentation, and an interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) patient testing according to the procedure in calendar year 2019. Findings include: 1. Review of the Abbott Emerald hematology analyzer calibration documentation from December 2018 to the date of the record review on 10/19/20, a total of twenty-two (22) months, revealed the following calibration records: 12/14/18, 05/23/19, 03/20/20, and 09/16/20. The inspector requested to review additional Emerald analyzer calibration records for calendar year 2019. No additional calibration documentation was available for review. The lead testing personnel stated, at approximately 11:30 AM on 10/19/20, "I do not see any additional calibrations for 2019. It was missed in November. It should have been done at the six month timeframe." 2. Review of the laboratory's procedures revealed a quality assurance policy that stated "calibration frequency for CBC is at least once every six (6) months". 3. In an interview with the lead testing personnel, on 10/21/20 at approximately 11:00 AM, the above findings were confirmed.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory failed to document a validation or check of their hematology analyzer's automated interface in order to verify transmission of Complete Blood Count (CBC) results from January 2019 to the date of the laboratory tour on October 21, 2020. Findings include: 1. During a laboratory tour, on 10/21/20 at approximately 10:00 AM, the inspector noted a testing personnel (TP) performing a patient CBC test on the Abbott Emerald. The testing personnel

	placed the instrument print out in a bin. The inspector asked the TP to describe how the patient results are sent to the provider and patient record. The TP stated "We do not have to scan the results or manually enter them now. They go automatically over into the EMR." 2. Review of the laboratory's procedures and records revealed no QA records of a validation of the Reli Med electronic interface for the transmission of the Abbott Emerald CBC results from the date of the interface installation in January 2019 to the date of the survey on 10/21/20. The inspector requested to review validation documentation of the Reli Med transmission of patient results. No validation records were available for review. 3. In an interview with the lead testing personnel, on 10/21/20 at approximately 11:00 AM, the above findings were confirmed.