

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0863830	(X3) Date Survey Completed 05/01/2019
Name of Provider or Supplier Rva Peds	Street Address, City, State 7000 Patterson Avenue, 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 PEDS on May 1, 2019 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:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's hematology instrument operations manual, maintenance records, and an interview, the laboratory failed to perform and document Abbott Emerald hematology instrument monthly and semi-annual maintenance procedures for twenty-four (24) of 24 months reviewed. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed maintenance instructions that stated: Monthly Maintenance- "Cleaning the system with bleach solution is to be performed monthly using 3.6 percent (%) hypochlorite (bleach) solution"; Semi-annual Maintenance- "For optimal operation, the syringe pistons are to be lubricated every six months". 2. Review of the laboratory's Emerald hematology maintenance logs revealed no documentation of performance of the monthly or semi-annual maintenance during the review timeframe of April 2017 to the date of the survey on 5 /1/19. The inspector requested documentation of the required monthly and semi-annual maintenance procedures. The primary testing personnel stated, "We have had to clean with bleach occasionally but have not documented it. We have never performed the semi-annual maintenance. Our field service representative may have</p>

performed it on the preventative maintenance in 2017 and 2018". 3. In an exit interview with the primary testing personnel at approximately 1:00 PM, the above findings were confirmed.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments to include review of intermediate test results or worksheets, quality control (QC) records, and preventative maintenance records for testing personnel A and B in calendar years 2017 and 2018. Findings include: 1. Review of the CMS 209 form revealed that the lab director (LD) performed the duties of TC and that two (2) testing personnel (TP) performed hematology patient testing. 2. During a review of the 2017 and 2018 laboratory personnel files, the inspector noted no Abbott Emerald hematology Complete Blood Count (CBC) competency assessments that included the competency procedures of review of intermediate test results, worksheets, QC records, and preventative maintenance for TP A and B. (See Personnel Code Sheet) The inspector requested to review additional CBC competency documentation. The primary testing personnel stated, "our competency check sheet only includes direct observation of patient testing". 3. In an interview with the primary testing personnel at approximately 1:00 PM, the above findings were confirmed.