Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0663445	08/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Pediatric & Adolescent Center	8316 Traford Lane, Springfield, 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 Pediatric & Adolescent Center on August 7, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's procedure manual, quality control (QC) package insert, QC records and an interview, the laboratory failed to follow manufacturer's instructions to establish assay means and standard deviations for each lot number of ABX Minotrol 16 quality control from June 2016 to June 2018. Findings include: 1. Review of the laboratory's procedure manual revealed no procedure for the establishment of assay means and standard deviations for each lot number of ABX Minotrol 16 quality control. 2. Review of the ABX Minotrol QC package insert revealed manufacturer's instructions that state: "At least five consecutive analyses, on a correctly calibrated analyzer, are needed to establish the assay means and standard deviations for each ABX Minotrol 16 parameter." 3. Review of laboratory's ABX Minotrol 16 QC records from June 2016 to August 2018 revealed no records of assay means and standard deviations being established for each lot numbers ABX Minotrol 16. 4. An interview with the Technical Consultant at approximately 12:45 PM confirmed that the laboratory failed to establish assay means and standard deviation of each lot numbers of ABX Minotrol. B. Based on review of the laboratory's procedure manual, quality control (QC) package insert, QC records

	and an interview, the laboratory failed to follow manufacturer's instructions to establish assay means and standard deviations for each lot number of Quantimetrix Bilirubin Control-Pediatric quality control from June 2016 to August 2018. Findings include: 1. Review of the laboratory's procedure manual revealed no procedure for the establishment of assay means and standard deviations for each lot number of Quantimetrix Bilirubin quality control. 2. Review of the Quantimetrix Bilirubin QC package insert revealed manufacturer's instructions that state: "Each laboratory should establish its own precision parameters." 3. Review of laboratory's Quantimetrix Bilirubin QC records from June 2016 to August 2018 revealed no records of assay means and standard deviations being established for each lot number of Quantimetrix Bilirubin QC. 4. An interview with the Technical Consultant at approximately 12:45 PM confirmed that the laboratory failed to establish assay means and standard deviation of each lot number of Quantimetrix Bilirubin QC.