

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0898583	(X3) Date Survey Completed 12/12/2024
Name of Provider or Supplier Virginia Pediatric Group	Street Address, City, State 131 Elden Street Suite 312, Herndon, 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 Group (Herndon) on December 12, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, manufacturer's package inserts, quality control (QC) records and interviews, the laboratory failed to follow the manufacturer's package insert and ensure Quantimetrix Bilirubin Control-Pediatric/Levels 1 & 2 QC material in use for monitoring neonatal bilirubin testing on the Reichert Bilirubinometer was within the listed open stability requirements of 21 days for two-hundred twenty-nine (229) of three-hundred fifty-six (356) patient testing days from February 7, 2023 until the date of the survey on December 12, 2024. The findings include: 1. In a tour of the laboratory on December 12, 2024 at 9:00 AM, the surveyor noted two vials of Quantimetrix Bilirubin Control-Pediatric labeled as Levels 1 (lot number 241431 exp date 3/31/2026) & 2 (lot numbers 241432 expiration date 3/31/2024) stored in the laboratory refrigerator with open dates of "12/4/2024" written on the label. The surveyor inquired with the Technical Consultant (TC) as to the expiration date of the QC material. The TC stated "We use a syringe to withdraw enough of the QC to run the test on the bilirubinometer. Because we use a syringe the QC is good longer." The surveyor asked how long the laboratory uses the vial once opened. The TC stated they use the vial until there is no QC left in the vial or until the manufacturer's expiration date. 2. Review of the laboratory's policies and</p>

procedures revealed a statement, "All controls, test kits and devices will be stored and handled according to mfg recommendation." 3. Review of the package insert for the Quantimetrix Bilirubin Control-Pediatric/Levels 1 & 2 QC material revealed the statements, "Storage and Stability-The control should be stored at 2C-8C. When stored unopened at 2C-8C, the control is stable to the expiration date on the label. If the stopper is removed or air is introduced into the vial, the stability of the control is limited to twenty-one (21) days at 2C-8C. Longer stability may achieved by removing the sample with a syringe. Discard the control if it is turbid...." and "Expected Range-The expected ranges have been established from interlaboratory data. Each laboratory should establish its own precision parameters." 4. In an interview with the TC on December 12, 2024 at 10:30 AM, the surveyor inquired if the laboratory has established the "longer stability" requirements or their own "precision parameters" for the Quantimetrix Bilirubin QC. The TC stated, "We run the new lot numbers of QC for a few days prior to putting the QC in use to verify the manufacturer's range." 5. Review of the QC logs for the Reichert Bilirubinometer revealed a column for each level of QC labeled, "Date Opened", The TC explained this is used to list when the vial was first used. Further review of the log revealed the following number of patient testing days when the Quantimetrix Bilirubin Control-Pediatric Levels 1 & 2 controls were used beyond the manufacturer's 21 day expiration date out of the total number of patient testing days in the month: February 2023- 16 of 19 days March 2023-21 of 21 days April 2023-13 of 18 days May 2023-8 of 17 days June 2023-15 of 15 days July 2023-10 of 17 days August 2023-17 of 21 days September 2023-12 of 15 days October 2023-14 of 17 days November 2023-12 of 12 days December 2023-1 of 7 days January 2024-no bilirubins performed February 2024-1 of 1 days March 2024-11 of 11 days April 2024-11 of 24 days May 2024-12 of 20 days June 2024-8 of 19 days July 2024-7 of 19 days August 2024-0 of 22 days September 2024-9 of 20 days October 2024-8 of 22 days November 2024-4 of 7 days December 2024-9 of 9 days A total of 229 of 356 days of patients testing when QC was used outside of the manufacturer's stability limits. 6. In an exit interview with the TC and primary testing personnel on December 12, 2024, at 12:15 PM, the findings were confirmed.