Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1082243	11/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Valley Health Urgent Care - Front Royal	65 Riverton Commons Plaza, Front Royal, 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 validation survey was conducted at Valley Health Urgent Care - Front Royal on November 3, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The surveyor noted the laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policy and procedures, quality control (QC) records, lack of documentation, patient test data and interview, the laboratory failed to follow their established policy and procedure for performing external QC materials on the i-STAT system for three (3) of twenty-one (21) months from January 1, 2021 up to the date of the survey on November 3, 2022 while reporting one-hundred forty-two (142) patients. Findings include: 1. During a tour of the lab on November 3, 2022 at approximately 9:15 AM, the surveyor noted the laboratory utilizes the i-STAT system with the non-waived Chem 8+ cartridge to analyze patient specimens for Sodium (NA), Potassium (K), Urea Nitrogen (BUN), Glucose (GLU), Creatinine (CRE), Ionized Calcium (iCA), Total Carbon Dioxide (TCO2), and Hematocrit (HCT). 2. Review of the laboratory's policies and procedures revealed a procedure, "i-STAT One Chem 8 + Procedure" approved by the laboratory director on "03/2022", that stated "Equipment/Materials...5. Frequency 1. The Chem 8+ aqueous control is analyzed on each inventory shipment and once per month." 3.

	Review of QC records and patient test data from January 1, 2021 until the date of the survey on November 3, 2022 revealed lack of documentation of external QC materials for the following months, analytes and number of patients tested: February 2022 - NA, K, BUN, GLU, CRE, iCA, TCO2, and HCT/54 patients; April 2022 - NA, K, BUN, GLU, CRE, iCA, TCO2, and HCT/47 patients; May 2022 - NA, K, BUN, GLU, CRE, iCA, TCO2, and HCT/41 patients. Total = 142 patients. The surveyor requested to review the monthly i-STAT QC records for February 2022, April 2022 and May 2022. The laboratory provided no documentation to review. 4. In an exit interview with the Laboratory Director on November 3, 2022 at approximately 12:00 PM, the findings were confirmed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, refrigerator temperature logs and interviews, the laboratory failed to ensure the refrigerator's temperature was within the established policy's storage requirements for quality control (QC) materials and reagent cartridges for thirty-one (31) of six-hundred thirty-eight (638) days reviewed from January 1, 2021 until November 3, 2022. Findings include: 1. In a tour of the lab on November 3, 2022 at approximately 9:15 AM, the surveyor noted the laboratory utilizes a refrigerator in the laboratory to store QC materials for the Medonic M-series Hematology Analyzer, i-STAT system QC and Chem 8+ reagent cartridges. 2. Review of the laboratory's policies and procedures revealed the following established storage requirements: Medonic M-Series Hematology analyzer Boule Con-Diff Controls-store at 2-10 degrees Celsius; i-STAT System Aqueous Controls and Chem 8+ reagent cartridges-store at 2-8 degrees Celsius. 3. Review of the refrigerator temperature logs from January 1, 2021 until the date of the survey, November 3, 2022, revealed temperatures recorded as warmer than 8 degrees Celsius for the following number of days: November 2021- 3 days; December 2021-7 days; January 2022-14 days; February 2022-2 days; April 2022-1 day; June 2022-1 day; July 2022-1 day; August 2022-1 day; and September 2022-1 day. A total of 31 days. 4. In an exit interview with the Laboratory Director on November 3, 2022 at approximately 12:00 PM, the findings were confirmed.