Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2022946	04/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care At Bedford Medical Park Laboratory	5 Washington Pl, Ste 1b, Bedford, NH	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to follow Chemistry control procedures and failed to implement a quality assurance system that can identify and correct problems with Chemistry control testing in 2021, 2022, and 2023. Findings include: 1. The lab failed to follow it's procedure to perform i-STAT Chem8+ cartridge control testing for each new lot/shipment and monthly. Refer to D5445. 2. The lab's policies and procedures for monitoring i-STAT Chem8+ cartridge control testing failed to identify and correct problems associated with the lab's failure to perform control testing on each new lot/shipment and monthly. Refer to D5791.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to perform control procedures for new lot/shipments of chemistry test cartridges before testing patient samples in 2021, 2022 and 2023. This is a repeat deficiency from the recertification survey completed 5/5/2021. Findings include: 1) Review on 4/6/2023 of the lab's procedure "i-STAT1 System - Chem8+ Cartridge" revealed instructions to perform quality control (QC) testing for each new lot or shipment of i-STAT Chem 8+ (Chem 8+) test cartridges, and monthly thereafter. Chem8+ test cartridges include the following measured analytes: chloride, potassium, sodium, blood urea nitrogen, ionized calcium, glucose, creatinine, and carbon dioxide. 2) Review on 4/6/2023 of control records from 5/5/2021 to 4/6/2023 revealed 10 new lots (H21125, H21290, H21323, H21328, H22114, H22138, H22176, H22263, H22311, and H23010) Chem 8+ test cartridges received during this period had been tested with QC monthly; with exception to July 2022, no QC was documented for July 2022. Further review of the QC records revealed no documentation of when the Chem8+ test cartridge lot numbers were changed and QC documented prior to patient testing. 3) Review on 4/6 /2023 of patient testing from September 2022 to April 2023 revealed 4 lot numbers (H22176, H22263, H22311, and H23010) of Chem8+ test cartridges had been used for patient testing. Further review revealed patient testing had occurred before QC testing was performed for all 4 of 4 Chem8+ lot numbers in use during this period; 11 patients had been tested before QC using Chem8+ lot H22176, 5 patients had been tested before QC using Chem8+ lot H22263, 10 patients had been tested before QC using Chem8+ lot H22311, and 14 patients had been tested before QC using Chem8+ lot H23010. 4) Interview on 4/6/2023 at 11:15 a.m. with a Technical Consultant (TC) confirmed the above findings. The TC revealed it had been the two TCs' responsibility to perform QC for each new lot/shipment until the lab changed the delivery address directly to the physical location of the lab, at which point the TCs did not know when a new delivery was made and the personnel at the lab were not notified to perform QC before putting each lot and shipment into use.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, the laboratory's (lab) policies and procedures to monitor and correct problems with quality control (QC) testing failed to identify issues with chemistry QC testing in 2021, 2022, and 2023. Findings include: 1. Review on 4/6 /2023 of the lab's policy titled "i-STAT1 System - Chem8+ Cartridge" and the laboratory's corrective action plan resulting from deficiencies cited from a certification survey completed 5/5/2021 revealed instruction to review QC monthly. 2. Review on 4/6/2023 of Chem8+ QC and patient testing records from May 2021 through April 2023 revealed monthly QC had been missed in July 2023 and QC had not been tested prior to patient use for 4 of 4 lots reviewed since September 2022. Refer to D5445. 3. Review on 4/6/2023 of QC records from May 2021 through April

	2023 for the i-STAT Chem8+ (Chem8+) test cartridge revealed QC had been reviewed monthly. The review failed to identify and correct that there was no QC documented in July 2022. The review also failed to identify and correct that there was no lot numberss associated with the monthly QC record and it was not verified that QC had been performed for each new lot/shipment of Chem8+ test cartridge before it had been placed into use.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interivew, the Technical Consultants failed to ensure chemistry quality control testing was performed following the laboratory's procedure in 2021, 2022, and 2023 resulting in a repeat deficiency. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the Technical Consultants failed to ensure chemistry quality control (QC) testing procedures were followed and quality assurance procedures monitoring chemistry QC were adequate to identify and correct problems as they occur in 2021, 2022 and 2023. Findings include: 1) Review on 4/6/2023 of the laboratory's (lab) procedure titled "i-STAT1 System - Chem8+ Cartridge" revealed on page 6 instructions to perform QC testing with each new lot or shipment and monthly thereafter. It also provides instruction to mark Chem8+ cartridge boxes with "QC done" upon initial QC testing. 2) Observation on 4/6/2023 at 11:00 a.m. of Chem8+ cartridges stored in the refrigerator revealed no indication on 3 of 3 boxes that QC had been done (same lot, H23010). 3) Review on 4/6/2023 of Chem8+ control testing from 5/5/2021 to 4/6/2023 revealed control records did not include Chem8+ cartridge lot numbers and QC had not been performed in July 2022. There was no indication on the QC records that QC had been performed for each new lot and shipment of Chem8+ cartridges. The lab received 10 new lots of Chem8+ cartridges during this period. 4) Review on 4/6/2023 of Chem8+ patient testing from September 2022 through 4/6/2023 revealed 4 Chem8+ cartridge lots had been used; 4 of 4 had been used for patient testing before any QC was performed. 5) Interview on 4 /6/2023 at 11:15 with 1 of 2 Technical Consultants (TC) confirmed the above findings.