

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2022946	(X3) Date Survey Completed 05/05/2021
Name of Provider or Supplier Urgent Care At Bedford Medical Park Laboratory	Street Address, City, State 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform quality control testing for routine chemistry following the laboratory's established control procedures in February, April, and May of 2021. Findings include: 1) Review on 5/5/2021 of the Quality Control Plan in the laboratory's individualized quality control plan (IQCP) for the i-STAT Chem8+ Cartridge revealed on pages 8 and 9 instruction for liquid control materials to be performed for each new test cartridge lot number prior to patient testing and performed every 30 days for the test cartridge lot number in use. 2) Review on 5/5/2021 of Chem8+ Cartridge control testing from 5/1/2020 through 5/5/2021 revealed no control testing (before use or after 30 days of use) had been performed for the current lot number in use (H21026); and, the previous test cartridge lot (H20320) had been tested using control materials on 1/21/2021 and again 48 days later on 3/10/2021. 3) Review on 5/5/2021 of patient test records from April and May 2021 revealed the current lot number (H21026) of Chem8+ test cartridges had been put into use on 4/1/2021 and 296 tests (sodium, potassium, chloride, total carbon dioxide, glucose, blood urea nitrogen, creatinine, and ionized calcium) had been performed by the laboratory using this lot of Chem8+ Cartridges. 4) The laboratory performs an annual volume of 2,600 tests (sodium, potassium, chloride,</p>

total carbon dioxide, glucose, blood urea nitrogen, creatinine, and ionized calcium) using the Chem8+ Cartridge. 5) Interview on 5/5/2021 at 10:30 a.m. with testing personnel confirmed the above findings.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director (LD) failed to ensure quality control and quality assessment procedures outlined in the individualized quality control plan (IQCP) for the i-STAT Chem8+ Cartridge were maintained to identify failures in quality for routine chemistry testing in 2020 and 2021. Findings include: 1) The laboratory failed to perform quality control testing for the i-STAT Chem8+ Cartridge following the laboratory's established quality control plan outlined in the laboratory's IQCP. Refer to tag D5445. 2) Review on 5/5/2021 of the laboratory's Chem8+ Cartridge IQCP signed by the LD on 3/4/2020 revealed on page 9, under Quality Assurance, instruction that quality control (QC) records will be reviewed monthly. 3) There was no documentation that any of the QC records for Chem8+ Cartridge testing from May 2020 through May 5, 2021 had been reviewed monthly. 4) Interview on 5/5/2021 at 10:30 a.m. with testing personnel confirmed the above findings and revealed the QC records for Chem8+ cartridge testing had not been reviewed since beginning patient testing in May 2020 through May 5, 2021.