Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2075200	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Summit Express Urgent Care Llc	1360 Montgomery Hwy, Suite 114, Vestavia Hills, AL	

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
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 review of the temperature records and an interview with the Laboratory Director (also the Technical Consultant), the laboratory failed to monitor and document the refrigerator and freezer temperatures on four days in 2019. The findings include: 1. A review of the temperature records revealed no documentation of temperature monitoring of Refrigerator #1 on 04/07/2019 and 09/14/2019. The laboratory indicated an established, normal range of 36 - 46 degrees Fahrenheit (F) as acceptable. The temperature of the freezer (normal range: less than or equal to -20 degrees Celsius) was not documented on 04/08/2019 and 09/10/2019. 2. During an interview on 11/19/2020 at 1:20 PM, the Laboratory Director confirmed there were days where the temperatures were not documented without any corrective action documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on a review of the AcT Diff 2 quality control records, a review of the calibration verification records for the Alere Triage Meter, and an interview with the Laboratory Director (also the Technical Consultant), the laboratory used expired control material for Complete Blood Count (CBC) testing (ran controls 5 days pass the expiration date) and expired calibrators for verification procedures on cardiac analytes. This affected five days of CBC testing and two of five calibration verification reports reviewed by the surveyor. The findings include: 1. A review of the AcT Diff 2 quality control records revealed low (lot # 68900), normal (lot # 78900), and high (lot # 88900) controls expired on 04/08/2019. The laboratory continued to run the expired controls from 04/09/2019 to 04/13/2019. During this time period, six patients were tested. 2. During an interview on 11/19/2020 at 11:20 AM, the Laboratory Director (LD) confirmed the laboratory used expired controls and performed patient testing during this time period. 3. A review of the calibration verification records for cardiac analytes revealed on 8/7/2020, the staff used lot #428256 with expiration 6/23/2020 to perform verification procedures for Myoglobin, Troponin I, CK-MB (Creatine kinase-MB) and Ddimer. 4. During an interview on 11 /19/2020 at 1:24 PM, the LD confirmed expired calibrator material was used to perform verification procedures on 8/7/2020.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, a review of the calibration verification records for the Alere Triage Meter and an interview with the Laboratory Director, who also serves as the Technical Consultant, the surveyor determined the laboratory failed to follow the laboratory's policy to verify the calibration of the Ddimer at least every six months. This affected one of five opportunities to perform

	the procedure from April 2018 - date of the survey (11/19/2020). The findings include: 1. A review of the laboratory's policy and procedure manual revealed the calibration verification should be performed at least every six months on the cardiac analytes, tested on the Triage Meter. 2. The calibration verification records included verification procedures performed in August of 2018, February and August of 2019, and February and August of 2020 for Myoglobin, Troponin I and CK-MB (Creatine Kinase - MB). The verification reports for Ddimer included all of the above months, except the February report was dated 2018 (This was an instrument result strip). Thus, the laboratory failed to provide documentation Ddimer calibration verification was performed every six months between August 7, 2018 and August 14. 2019. 3. During an interview on 11/19/2020 at 1:24 PM, the Laboratory Director reviewed the records and recognized the date at 2018. He then reviewed the electronic submission of the calibration verification, which also indicated the date as February 2018, thus confirming the above noted findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the temperature records and an interview with the Laboratory Director (also the Technical Consultant), the laboratory failed to document corrective action when temperatures were outside of the acceptable limits. This was noted on four days of 6 months, reviewed from October 2018 to October 2020. The findings include: 1. A review of the temperature records revealed Refrigerator 1's temperature (normal range: 36 - 46 degrees Fahrenheit) was below the acceptable limits on 11/28/18, 04/11/19, and 04/18/19. Refrigerator #2's temperature (normal range: 36 -46 degrees Fahrenheit) was above the acceptable limits on 10/05/2020. 2. During an interview on 11/19/2020 at 1:20 PM, the Laboratory Director confirmed there were days where the temperatures were either out of range or not documented without corrective action documented.