

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2075200	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Summit Express Urgent Care Llc	Street Address, City, State 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the AcT Diff calibration records, the procedure manual, and an interview with the Laboratory Director (also the Technical Consultant), the laboratory failed to perform two of three calibrations at least every six months per the laboratory's policy. The findings include: 1. A review of the AcT Diff calibration records revealed a calibration was performed in April of 2016 and November of 2017 by the laboratory; however no other documentation of calibration were provided during the survey. 2. A review of the procedure manual revealed "... Calibration performed every six months". 3. During an interview on 4/10/2018 at 2:01 PM, the Laboratory Director was asked if the laboratory had any other calibration records, the Laboratory Director reviewed the calibration records with the surveyor and confirmed the laboratory had no other calibration records on file.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the Technical Consultant failed to ensure semi-annual evaluations were performed during the first year of employment for two of five testing personnel. The findings include: 1. A review of the personnel records revealed no semi-annual evaluations were performed for Testing Personnel (TP) #1 and TP # 5. TP #1 was hired in September of 2017 and initially trained in July of 2017. TP #5 was hired in July of 2017 and initially trained in August of 2017. 2. In an interview with the Laboratory Director conducted on 4/10/2018 at 10:30 AM, the Laboratory Director was asked if there were semi-annual evaluation records for TP #1 and #5. The Laboratory Director reviewed the personnel records and confirmed no semi-annual evaluation were performed for TP #1 and #5. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor