

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2070237	(X3) Date Survey Completed 09/01/2020
Name of Provider or Supplier Afc Urgent Care Of Southington	Street Address, City, State 365 Queen St, Southington, CT	
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	A complaint investigation of the Urgent Care of Southington LLC Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow the manufacturer's package insert for reagent storage and handling and quality control (QC). Findings include: 1. Record review on 9/1/2020 of the laboratory's quality control records revealed: a. Siemens Multistix 10SG Lot# 912045 exp. 6/30/2021. No QC records for this lot number. b. Siemens Multistix 10SG Lot#003014 exp. 8/31/2021. Does have QC but control lot numbers are not recorded. 2. Record review on 9/1/2020 of the Siemens Multistix 10SG package insert revealed: "CLIA Waived Laboratories: Test positive and negative quality controls with new lots new shipments of reagents and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days." 3. Surveyor observation on 9/1/2020 at 10:30 AM of the contents of the laboratory refrigerator revealed: a. Control - Consult DX Premium Liquid Urine Control level 1 (5) mL exp. 1/2019. Store at 2-8 degrees Celsius. Lot #K302278 b. Control - Consult DX Premium Liquid Urine Control level 2 (5) mL exp. 2/2019. Store at 2-8 degrees Celsius. 4. Record review on 9/1/2020 of the laboratory's 2019 and 2020 'Vaccine Refrigerator/Freezer Temperature' logs revealed: a. The refrigerator temperature range listed on the form is 2 to 8 degrees Celsius. b. The bottom of the form states, "Corrective Action-Initiate if out of acceptable range, close door for 15 minutes, then repeat the reading. If acceptable</p>

range cannot be obtained, contact clinic manager." c. The refrigerator temperature was out of range with no corrective action noted for 38 of 365 days in 2019. d. The laboratory failed to record the refrigerator temperature for 11 of 365 days in 2019 with no corrective action. e. The refrigerator was out of range with no corrective action noted for 15 days from 1/1/2020 through 8/31/2020. f. The laboratory failed to record the refrigerator temperature for 9 days from 1/1/2020 through 8/31/2020. 5. Staff interview with the Laboratory director on 9/1/2020 at 12:01 PM confirmed the above findings. 6. Observation of the Quintet AC Blood Glucose Test Strips on 9/1/2020 at 10:45 AM revealed: a. Current test strips lot number in use, #2118B0525 expiration 11/19/2020. b. Above open vial contained no open or expiration date. c. Another box containing 2 of 2 vials of test strips, lot # 211940315, expiration 5/4/2021 and the box labeled as QC passed on 7/21/2020. d. 1 of 2 vials of lot # 211940315 was opened with no written discard/expiration date. 7. Record review of the McKesson Quintet AC User Manual on 9/1/2020 revealed, "Record the date of opening a new test strip vial for the first time. Discard the vial of test strips after 3 month from opening". 8. Staff interview with shift supervisor on 9/1/2020 at 10:50 AM confirmed the glucose vials were not dated as to when opened or expired and he/she was unaware that the manufacturer expiration date changed to 3 months once opened. 9. Observation of the Eurotrol- Hemotrol Level 1 control on 9/1/2020 at 10:55 AM revealed: a. Current lot number in use, # (10) 82665 expiration 1/31/2020. b. Above open box marked containing 2 vials opened 12/4/18 with no expiration date. 10. Record review of the Eurotrol manufacturer instructions revealed: Storage and stability: 'After opening the vial, it is stable for one month when properly recapped and stored at 2-30 degrees Celsius. 11. Staff interview with the shift supervisor on 9/1/2020 at 10:55 AM confirmed the Eurotrol currently in use was expired and he/she was unaware the expiration date changed to 1 month once opened.