

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2030726	<b>(X3) Date Survey Completed</b>  02/01/2018
<b>Name of Provider or Supplier</b>  Afc Urgent Care - Englewood	<b>Street Address, City, State</b>  901 W Hampden Ave, Englewood, CO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel policy, laboratory personnel assessment documents, and interview with the laboratory administrator, the laboratory failed to follow written procedures in the assessment of 3 of 9 employees. Findings include: 1. The policy contained in the facility's Employee Laboratory Training Plan and Guidelines states "All employees who are performing lab tests and handling patient specimens will be evaluated every 90 days by the Lab Director and the Center Administrator". 2. Review of the laboratory personnel assessment documents revealed Testing Personnel 4, 7, and 9 were not assessed, per policy, every 90 days in 2016 and 2017. 3. In an interview conducted on 02/01/2018 at approximately 11:00 AM, the laboratory administrator confirmed Testing Personnel 4, 7, and 9 were not assessed, per policy, every 90 days in 2016 and 2017.</p>
<b>D5313</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on review of lab temperature records, as well as staff interviewed, the laboratory failed to record temperatures in the laboratory. Findings include: 1. Review of temperature log for the refrigerator labeled #2 stated the temperature range was</p>

	<p>between 2 - 6 degrees Celsius. 2. Review of temperature logs in the laboratory revealed temperatures were not recorded for Refrigerator #2 Temp- AM. a. Refrigerator #2: 2 of 30 days in September 2017. b. Refrigerator #2: 1 of 30 days in January 2018. 3. Interview with the Clinic Staff conducted on 01/01/2018 @ 0900 confirmed temperature were not recorded on the dates specified above.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory administrator, the laboratory failed to have a written policy for 1 of 1 tests in hematology. Findings include: 1. Review of hematology documentation revealed there was no procedure for Complete Blood Counts (CBC) performed on the Medonic M Series CBC analyzer. 2. In an interview conducted on 02/01/2018 at approximately 11:00 AM, the laboratory administrator confirmed there was not a policy for CBCs performed on the Medonic M Series CBC analyzer. The policy in the procedure manual was from the analyzer used prior to the Medonic M Series to perform CBCs.</p>
<p><b>D5431</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory administrator, the laboratory failed to perform maintenance on 1 of 1 centrifuges for 2016 and 2017. Findings include: 1. Review of maintenance documentation revealed the Horizon mini E centrifuge had maintenance last performed on March 7, 2012. 2. In an interview conducted on 02/01/2018 at approximately 11:00 AM, the laboratory administrator confirmed maintenance on the centrifuge had not been performed on the Horizon mini E centrifuge during the time period of the current survey cycle.</p>
<p><b>D5781</b></p>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(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</p>

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 review of lab temperature records and interviewed with the clinic administrator the laboratory failed to provide corrective action for temperatures on the refrigerator labels #2 in the laboratory. Findings include: 1. Review of temperature log for the refrigerator labels #2 stated the temperature range was between 2 - 6 degrees Celsius for years 2016 and 2017. 2. Interview with Lab administrator on 01/01/2018 revealed there is no corrective action log for 2016 and 2017. 3. Review of temperature logs in the laboratory revealed there was no corrective action documented for the following in 2016: a. Refrigerator #2: 5 of 29 days in February 2016. b. Refrigerator #2: 2 of 31 days in March 2016. c. Refrigerator #2: 1 of 31 days in April 2016. d. Refrigerator #2: 3 of 31 days in July 2016. e. Refrigerator #2: 2 of 30 days in September 2016. f. Refrigerator #2: 2 of 30 days in November 2016. 4. Review of temperature logs in the laboratory revealed there was no corrective action documented for the following in 2017: a. Refrigerator #2: 1 of 28 days in February 2017. b. Refrigerator #2: 3 of 31 days in May 2017. c. Refrigerator #2: 1 of 30 days in June 2017. d. Refrigerator #2: 6 of 31 days in July 2017. e. Refrigerator #2: 2 of 30 days in August 2017. f. Refrigerator #2: 2 of 30 days in September 2017. g. Refrigerator #2: 4 of 31 days in October 2017. 5. Interview with the Clinic administrator conducted on 01/01/2018 @0900 confirmed there was no corrective performed on the temperatures recorded on the dates specified above.