

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2115207	<b>(X3) Date Survey Completed</b>  07/06/2021
<b>Name of Provider or Supplier</b>  Ael - Conway	<b>Street Address, City, State</b>  2425 Dave Ward Drive, Conway, AR	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined that the laboratory failed to monitor room temperature in one of three rooms in which storage temperature dependent supplies were stored. Findings follow: A) In a tour of the laboratory at 2:20 p.m. on 7/6/21, fifty ea. of BD EDTA blood collection tubes lot # 0100223 expiration date of 2021-08-31 and fifty ea. Vacuette Red Top blood collection tubes lot # 455010P expiration date 2022-01-12 were observed in a separate sample collection room identified as the "Covid Sample Collection Room". B) Upon request, the laboratory was unable to provide documentation of the room temperature of the room identified above. C) In an interview on 7/6/21 at 2:45 p.m. the laboratory staff members, identified as numbers one and seven on the CMS 209 form, confirmed that temperature dependent supplies were stored in the "Covid Sample Collection Room" and room temperature was not monitored in the room.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Through observations made during a tour of the laboratory and interviews with staff, it was determined the laboratory had supplies available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory on 7/6/2021 at 2/20 p.m., the surveyor observed one plastic bag containing 12 BD Blue Top Trace Element blood collection tubes lot# 0133402 expiration date 2021-5-21. B) In an interview on 7/6//21 at 2:20 p.m.. laboratory employees, identified as numbers one and seven on the CMS 209) confirmed the supplies were available for use when they had exceeded their expiration date.