

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  32D0689349	<b>(X3) Date Survey Completed</b>  01/16/2024
<b>Name of Provider or Supplier</b>  Bernalillo Health Care Corp	<b>Street Address, City, State</b>  4500 Montbel Pl Ne, Albuquerque, NM	
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>D0000</b>	An onsite recertification survey conducted at Bernalillo Health Care Corp dba Albq Ambulance on January 16, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: D6063 - 42 C.F.R. 493.1421 Condition: testing personnel moderate complexity testing
<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: Based on review of Albuquerque Ambulance i-STAT procedure, patient test list, and interview the laboratory failed to monitor and document room temperature for the mobile units, and in house storage of i- STAT instruments and cartridges for 2023. Findings included: 1. Review of Albuquerque Ambulance i-STAT procedure lists the following storage conditions. 1. i-STAT: operating temperature, 16 - 30 Celsius (C) 2. i-STAT Cartridges: Stored for limited time at room temperature, 18 - 30 C 2. A patient test list from November 2023 through December 2023 was requested which showed the following patients were tested on the following dates. 1. Patient 1: 12/25 /2023 2. Patient 2: 12/25/2023 3. Patient 3: 12/15/2023 4. Patient 4: 12/15/2023 5. Patient 5: 11/30/2023 Confirming patients were being tested, and the instruments and cartridges needed to be stored in proper room temperature conditions. 3. The laboratory was asked to provide documentation that room temperature was being</p>

	<p>documented on the mobile units and in house storage for 2023. None was provided. 4. Interview on 1/16/2023 at 12:12 pm with technical consultant #3 stated, i-Stat cartridges are removed from refrigerated storage and placed in a kit with the i-Stat instrument. The kit is then stored at room temperature on the mobile unit, then transferred to room temperature in house storage when not in use. This confirmed the findings.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of CMS 209 form and interview the laboratory failed to provide education records for 1 of 10 testing personnel. Refer to D6065</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 form and interview the laboratory failed to provide education records for 1 of 10 testing personnel (testing person #5). Finding included: 1. Review of CMS 209 form showed testing person #5 (TP#5) listed to perform moderate complexity testing. 2. The laboratory was asked to provide documentation of TP#5 education. None was provided. 3. Interview on 1/16/2024 at 1:21 pm with technical consultant #1 confirmed the findings.</p>