

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0671486	<b>(X3) Date Survey Completed</b>  02/27/2024
<b>Name of Provider or Supplier</b>  Poarch Band Of Creek Indians Health Department Lab	<b>Street Address, City, State</b>  429 Buford Rolin Drive, Atmore, AL	
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>	A recertification survey was conducted on February 27, 2024. The facility was found NOT in compliance with the following 42 CFR Part 493, requirements for Laboratories for the specialties/subspecialties for which it was surveyed.
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Directory of Services (LDS) and interview with the laboratory director, the laboratory failed to ensure written policies and procedures included defined temperature ranges for specimen collection and transportation. The laboratory performs approximately 57,000 tests per year. Findings include: 1. The laboratory failed to define temperature ranges to ensure specimen storage and transportation maintained specimen integrity for testing in 2022 through 2024. 2. A review of the LDS and procedure manual titled "Specimen Submission, Handling and Referral" found the laboratory did not define or include temperature ranges for room, cold and frozen specimens received in the lab. Preanalytical requirements had not been established and defined in the laboratory procedure manual. The majority of all testing is performed in the laboratory. The LDS states " room temperature, refrigerate, or freeze samples " a temperature range was not included. 3. During an interview with the laboratory director on 2/27/2024 at 2:00 pm, confirmed the laboratory temperature ranges were not defined in policies and procedures.</p>

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory thermometer procedure and interview with the laboratory director, the laboratory failed to include procedure information for monitoring the Viltek freezer digital thermometer. The laboratory performs approximately 57,000 tests per year. Findings include: 1. A review of laboratory procedure titled "Laboratory Thermometers" revealed the laboratory did not have any information on how to monitor, interpret or use the OnVue digital thermometer for the Xiltek freezer. The laboratory failed to provide instructions on how to evaluate the readings for digital thermometer temperature ranges. The Xiltek freezer was installed August 5, 2022. 2. During an interview with the laboratory director on 2/27/2024 at 3 pm confirmed the laboratory digital temperature information was not included in the temperature procedures.