

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0671486	(X3) Date Survey Completed 01/21/2026
Name of Provider or Supplier Poarch Band Of Creek Indians Health Department Lab	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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:</p> <p>I. Based on direct observation, review of manufacturer's instructions, and interview with the Laboratory Director (LD), the laboratory failed to monitor and document temperature conditions in two of two laboratory draw rooms. Findings: 1. During a laboratory tour on 01/21/2026 at approximately 9:30 a.m., draw room 1 (N1D06) was observed to contain approximately 1 pack (100 tubes each) of BD Vacutainer collection tubes including: Na Citrate (blue top), Serum (red top), Gel and Lithium Heparin (light green top), Lithium Heparin (green top), K2EDTA (purple top), SST (tiger top), and MAP K2EDTA (pink microtainer top) tubes. All tubes had a printed manufacturer's required storage temperature of 4-25C. 2. During a laboratory tour on 01/21/2026 at approximately 9:35 a.m., draw room 2 (N1D08) was observed to contain approximately 9 packs (100 tubes each) of BD Vacutainer SST (tiger top) tubes, 5 packs of Gel and Lithium Heparin (light green top) tubes, 4 packs of K2EDTA (purple top) tubes, 3 packs of Lithium Heparin (green top) tubes, and 4 packs of Greiner Bio-One Vacuette Z Serum Sep Clot Activator tubes. All tubes had a printed manufacturer's required storage temperature of 4-25C. 3. No thermometer or hygrometer was observed in either draw room. 4. Interview with the LD on 01/21</p>

/2026 at approximately 9:45 a.m. confirmed that the laboratory was not monitoring or documenting the temperature in the draw rooms. II. Based on direct observation, review of laboratory procedure, and interview with the Laboratory Director, the laboratory failed to set the correct temperature range for its one of one Xiltek chemistry freezer according to the manufacturer's instructions for the supplies stored inside. Findings: 1. During a tour on 01/21/2026 at approximately 10:00 a.m., supply room N1D21 was observed to contain a Xiltek chemistry freezer. Inside the freezer were 1 box of SIEMENS Dimension EXL LOCI VITD Calibrator, 1 box of LOCI THYR Calibrator, and 1 box of CKI/MBI Calibrator. All boxes had a printed manufacturer's temperature requirement of -25C to -15C. 2. Review of laboratory procedure titled "Onevue Sense Monitor for Electronic Temperature of Laboratory Refrigerator" stated: "Xiltek Chemistry Freezer's OneVue Sense normal temperature will be zero to negative 30C." 3. Interview with the LD on 01/21/2026 at approximately 10:25 a.m. confirmed that the laboratory had set a temperature range for the freezer that was not consistent with the manufacturer's temperature requirements for the supplies stored inside the freezer. III. Based on direct observation and interview with the Laboratory Director (LD), the laboratory was using two of two thermo-hygrometers with expired calibrations to monitor its room temperature conditions. Findings: 1. During a tour on 01/21/2026 at approximately 10:00 a.m., a Fisherbrand Traceable thermo-hygrometer was observed in supply room N1D21 with a manufacturer sticker indicating serial number 170646746 and a calibration due date of September 12, 2019. 2. During a tour on 01/21/2026 at approximately 10:30 a.m., a Fisherbrand Traceable thermo-hygrometer was observed in main lab room N1D102 with a manufacturer sticker indicating serial number 170684499 and a calibration due date of September 29, 2019. 3. Interview with the LD on 01/21/2026 at approximately 10:45 a.m. confirmed that the laboratory was using thermo-hygrometers with expired calibrations to monitor room temperature in the supply room and main lab room.