

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2093540	(X3) Date Survey Completed 09/06/2023
Name of Provider or Supplier Absentee Shawnee Tribal Health System -	Street Address, City, State 15702 E Highway 9, Norman, OK	
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
D0000	The recertification survey was performed on 09/06/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the laboratory director and testing person #2 at the conclusion of the survey.
D5413	<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 observation, a review of records, and interview with testing person #2, the laboratory failed to ensure Vacutainer brand tubes were stored as required by the manufacturer for three of three months reviewed. Findings include: (1) Observation of the laboratory on 09/06/2023 at 11:00 am, identified multiple BD Vacutainer tubes stored in the the laboratory with a manufacturer's storage requirement of 4-25 degrees Celsius; (2) A review of temperature logs for three months showed the acceptable temperature range defined as 18-28 degrees Celsius. In addition, temperatures had been documented as warmer than 25 degrees Celsius for three of three months as follows; (i) June 2023 - two of 30 days (ii) July 2023 - nine of 31 days (iii) August 2023 - eight of 31 days (3) Interview with testing person # 2 on 09/06/2023 at 11:00 am confirmed the acceptable temperature range allowed for temperatures warmer than 25 degrees Celsius and the Vacutainer tubes had not been stored as required by the manufacturer.</p>