

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D2047709	<b>(X3) Date Survey Completed</b>  08/12/2025
<b>Name of Provider or Supplier</b>  Premier Primary Care	<b>Street Address, City, State</b>  1109 E Cherokee, Sallisaw, OK	
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>	The initial survey was performed on 08/12/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the general supervisor at the conclusion of the survey.
<b>D5413</b>	<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: Based on observation and interview with the laboratory director and general supervisor, the laboratory failed to ensure four of four packages of Copan ESwab 480c collection devices were stored as required by the manufacturer in the storage area located outside the laboratory. Findings include: (1) Observation of the storage area located outside the laboratory and interview with the laboratory director and general supervisor on 08/12/2025 at 10:05 am, identified the following: (a) Two packages of Copan ESwab 480c collection devices, lot #N40277000, storage temperature requirement of 5-25 degrees (C) centigrade; (b) Two packages of Copan ESwab 480c collection devices, lot #N50006700, storage temperature requirement of 5-25 degrees (C) centigrade; (2) Interview with the laboratory director and general supervisor on 08/12/2025 at 10:20 am confirmed the laboratory was not monitoring the temperature of the storage area located outside of the laboratory.</p>