

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2012798	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier West Cancer Center	Street Address, City, State 1290 Kelley Dr, Paris, TN	
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>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 of the laboratory, staff interview, review of manufacturer package inserts, the form used for monitoring freezer temperatures, interview with the technical consultant, and subsequent email communication, the laboratory failed to define frozen storage ranges for the Ortho Vitros reagents, controls and calibrators that was consistent with manufacturer requirements, and failed to monitor temperature fluctuations that might occur as a result of freezer defrost cycles in 2022 and 2023 for four of four months reviewed. The findings include: 1. Observation of the laboratory on 09/07/23 at 8:30 am revealed frozen storage of reagents, calibrators, and controls that were used on the Ortho Vitros 350 chemistry instrument in a Midea refrigerator /freezer combo. The labeling on the chemistry boxes indicated a storage temperature of -18 degrees Celsius. No buildup of frost was observed in the freezer. 2. During an interview with the lead testing person on 09/07/23 at 8:45 am, the lead testing person stated that they never had to do anything to keep the freezer free of frost buildup and that the freezer defrosted itself. 3. Review of manufacturer package inserts for the reagents, calibrators and controls that were stored in the freezer revealed a storage requirement of -18 degrees Celsius or less when frozen. 4. Review of the form used for monitoring freezer temperatures revealed ranges that were inconsistent with manufacturer requirements for December 2022, February 2023, March 2023, and July</p>

2023. The range in use was -10 to -20 degrees Celsius. There was no record for monitoring of the minimum and maximum temperatures. 5. Interview with the technical consultant on 09/07/23 at 2:30 pm confirmed the laboratory failed to define freezer temperature ranges that were consistent with the manufacturer's requirements. 6. Email communication received on 09/12/23 at 3:14 pm with the technical consultant confirmed the laboratory did not have records for monitoring of temperature fluctuations that may occur during defrost cycles in 2022 and 2023.