

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1060837	<b>(X3) Date Survey Completed</b>  07/08/2025
<b>Name of Provider or Supplier</b>  Bradley Physician Svcs, Llc DbA Bradley Physician	<b>Street Address, City, State</b>  1060 Peerless Crossing Drive, Suite 200, Cleveland, TN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review, review of the laboratory procedure manual, calibration verification records, and staff interview, the laboratory failed to follow its written policy for calibration verification frequency in 2024. The findings include: 1. Record review on 07.08.2025 at 10:30 a.m. revealed that a Sysmex XS-1000i hematology analyzer (Serial Number: 75299) was used for patient Complete Blood Count (CBC) testing from the date of last survey (10.05.2023) through May 6, 2025. 2. A review of the laboratory's Complete Blood Count procedure revealed, "The laboratory must verify calibration every six months or on an "as needed" basis to ensure accuracy of the system." 3. A review of laboratory calibration verification records revealed the laboratory failed to perform calibration verification every six months in 2024 (calibrations performed on 09.14.2023 and 03.07.2025). 4. An interview with the technical consultant on 07.08.2025 at 11:35 a.m. confirmed the above survey findings.</p>
<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</p>

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.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the manufacturer's storage requirements, lack of documentation, and an interview with the technical consultant, the laboratory failed to ensure proper temperature storage for blood collection tubes in 2024 and 2025. The findings include: 1. Observation of the blood collection room on 07.08.2025 at 9:50 a. m. revealed the following blood collection tubes stored in the cabinet: -9 packs, containing 50 tubes per pack, of Greiner bio-one 5mL Lithium Heparin Sep tubes -1 pack containing 50 tubes of Greiner bio-one 6mL Serum Clot Activator tubes -7 packs, containing 50 tubes per pack, of Greiner bio-one 5mL Serum Sep Clot Activator tubes -6 packs, containing 50 tubes per pack, of Greiner bio-one 8mL Serum Sep Clot Activator tubes -5 packs, containing 50 tubes per pack, of Greiner bio-one 4mL dipotassium (K2) Ethylenediaminetetraacetic Acid (EDTA) tubes -1 pack containing 100 tubes of Becton Dickinson (BD) 4 mL K2 EDTA tubes -1 opened pack containing 47 Greiner bio-one 6mL Lithium Heparin tubes -1 opened pack containing 40 Greiner bio-one 3.5mL Sodium Citrate tubes 2. A review of the Greiner bio-one and BD manufacturer's storage requirements revealed that the acceptable temperature range for tube storage is 4C to 25C. 3. A request for environmental records for the blood collection room revealed no records available for surveyor review for 2024 through the survey date, 07.08.2025. 4. Interview with the technical consultant on 07.08.2025 at 9:50 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius mL = milliliters Sep = Separator