Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0906482	05/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Community Blood Center Of The Ozarks	220 W Plainview, Springfield, MO	

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	A validation survey was performed on 05/08/25. Standard-level deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on the laboratory's written procedure, manufacturers' instructions, patient test reports, and interview with general supervisor #1, the laboratory failed to follow their written procedure and manufacturers' instructions for sample stability for six of seven patient specimens. Findings include: 1. Interview on 05/08/25 at 10:00 am with general supervisor #1 confirmed the laboratory performed CBC (Complete Blood Count) testing using the Horiba ABX Micros 60. 2. Review of the laboratory's written procedures titled, "PCL.03.0925 Operation and Calibration of the Micros 60 Hematology Analyzer Version Number: 31" page 1 of 22 section, stated the following: a. "I. Purpose: This document describes the procedure for performing a CBC (Complete Blood Count) on whole blood specimens, platelet enumeration on Pheresis platelet products and hematocrit determination for RBC products quality control and repeatability and calibration procedures on the Micros 60 Hematology Analyzer." b. "C. Stability:" stated, "Well-mixed, whole blood specimens, collected in EDTA and run within 8 hours after collection, provide the most accurate results for all parameters ...." 3. Review of the manufacturers' instructions titled, "ABX Micros 60 - User Manual - RAB043IEN-13" section "4.2.2. Sample Stability" stated, "Well mixed, Whole Blood specimens, collected in EDTA anti-coagulant and run within 8

	hours after collection, provide the most accurate results for all parameters." 4. On 05 /08/25, review of seven patient reports from 04/19/25 through 04/24/25 revealed the laboratory failed to follow the manufacturers' instructions for six of seven patients as follows: a. Patient Seq #13 - collected on 04/20/25 at 01:19 pm and analyzed/reported on 04/21/25 at 09:10 am (19 hours 51 minutes after collection) b. Patient Seq #15 - collected on 04/21/25 at 03:49 pm and analyzed/reported on 04/22/25 at 09:02 am (17 hours 57 minutes after collection) c. Patient Seq #17 - collected on 04/21/25 at 04:33 pm and analyzed/reported on 04/22/25 at 09:06 am (16 hours 33 minutes after collection) d. Patient Seq #32 - collected on 04/23/25 at 04:05 pm and analyzed /reported on 04/24/25 at 11:26 am (18 hours 21 minutes after collection) e. Patient Seq #31 - collected on 04/23/25 at 04:11 pm and analyzed/reported on 04/24/25 at 11: 25 am (19 hours and 14 minutes after collection) f. Patient Seq #18 - collected on 04 /23/25 at 02:59 pm and analyzed/reported on 04/25/25 at 10:59 am (20 hours after collection) 5. Interview on 05/08/25 at 02:30 pm with general supervisor #1confirmed the findings above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on manufacturers' instructions, lack of humidity records, and interview with general supervisor #1 and director of distribution, the laboratory failed to ensure the humidity was maintained (monitored and documented) as required by the manufacturer for three of three months. Findings include: 1. Interview on 05/08/25 at 01:30 pm with general supervisor #1 confirmed the laboratory used the QIAcube to extract DNA (Deoxyribonucleic Acid) for PCR (Polymerase Chain Reaction) antigen typing. 2. Review of the manufacturer's "QIAcube User Manual" page A-1 required a relative humidity of "15-75%". 3. Record review on 05/08/2025 of humidity records from January 2025 through March 2025, revealed no evidence the laboratory monitored the humidity as required by the manufacturer for three of three months 4. Interview on 05/08/25 at 01:55 pm with the director of distribution confirmed the findings above.