

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315382	(X3) Date Survey Completed 06/17/2026
Name of Provider or Supplier Baptist Memorial Medical Group Inc-Ucdc	Street Address, City, State 1412 East Reelfoot Ave, Union City, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of calibration records, review of calibration verification records, staff interview, and electronic mail communication the laboratory failed to perform calibration verification every six months for Vitamin B-12 and Total Iron Binding Capacity (TIBC) analytes performed on the Ortho Vitros 5600 chemistry instrument in 2024 and 2025, with approximately 520 Vitamin B-12 and 1260 TIBC test performed annually. The findings included: 1. Laboratory observation on 6/16 /2026 at 11:00 a.m. revealed the Ortho Vitros 5600 chemistry instrument used for patient testing. 2. A review of the laboratory's calibration records revealed the following: a. Vitamin B-12 was calibrated on 11/5/2024, 4/21/2025, and 12/3/2025

using two calibrators. b. TIBC was calibrated on 12/4/2024, 5/7/2025, and 11/12/2025 using two calibrators. 3. A review of the laboratory's calibration verification records from 2024, 2025, and 2026 revealed the following: a. No documented six-month calibration verification for Vitamin B-12 prior to 11/24/2025. b. No documented six-month calibration verification for TIBC prior to 1/6/2026. 4. The findings were confirmed by technical consultant two during an interview on 6/17/2026 at 11:40 a.m. 5. Technical consultant two stated through electronic mail communication on 6/22/2026 at 10:28 a.m. that the laboratory performed approximately 520 Vitamin B-12 and 1260 TIBC analytes annually.