Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0688159	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Boyette Orthpedics & Sports Medicine	4205 Ben Franklin Boulevard, Durham, NC	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory records, absence of records, and interview with the technical consultant (TC) 04/30/2025, the laboratory failed to establish a policy for TC competency assessment and failed to assess competency of the TC in 2023, 2024, and 2025, a period of approximately 3 years. Findings: Review of laboratory records revealed no documentation of a policy for TC competency assessment. Review of laboratory records revealed no documentation of TC competency assessments in 2023, 2024, and 2025. During interview at approximately 10:38 a.m., TC said he wasn't aware that was a thing, and confirmed no TC competency assessments were available for 2023, 2024, and 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as

established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of 2024 and 2025 quality control (QC) records, review of laboratory procedures and interview with TC 04/30/25, the laboratory procedure for the testing performed on the TOSOH G8 analyzer was incorrect and incomplete. 1. The laboratory procedure for the TOSOH G8 analyzer failed to include the correct type and levels of QC reagent utilized by the laboratory and failed to include the correct frequency of QC performed by the laboratory. Findings: a. Review of QC records revealed the laboratory performs two levels of QC each day of patient testing. b. Review of laboratory procedure "Tosoh G8 Glycohemoglobin Analyzer" revealed the following; "Page 8...5. Materials: a. Reagents - Supplied by Tosoh Bioscience...Part numbers are subject to change....Page 15...IX...Quality Control (QC) Procedures...1. Quality Control...a. Quality Control Preparation....Donors are recruited and compensated for their donation of blood. Blood products are pooled together, mixed for at least 30 min, and aliquoted under refrigerated conditions...Page 16....e. Routine Quality Control Testing...i. Normal and Abnormal level (elevated) controls are run at the beginning and at the end of a run, AND controls are run every 19 samples, alternating between normal and elevated levels...". The procedure fails to state the correct type and levels of QC utilized by the laboratory and fails to include the correct frequency of QC performed by the laboratory. c. During interview with TC at approximately 5:44 p.m., the TC stated the laboratory performs 2 levels of QC each day of patient testing and the QC reagent is not collected and prepared from donors, but is purchased from a manufacturer. The TC also confirmed the procedure for TOSOH G8 analyzer fails to include the correct type and levels of QC utilized by the laboratory and the procedure fails to include the correct frequency for the performance of QC. 2. The laboratory procedure for the TOSOH G8 analyzer failed to include the correct type and levels of calibration reagents utilized by the laboratory and failed to include the correct frequency of calibration performed by the laboratory. Findings: a. Review of calibration records revealed the laboratory performs a monthly two point calibration. b. Review of laboratory procedure "Tosoh G8 Glycohemoglobin Analyzer" revealed the following; "Page 8...5. Materials: a. Reagents - Supplied by Tosoh Bioscience...Part numbers are subject to change...Page 8...VI. Calibration and Calibration Verification Procedure...1. Calibrator Preparation...Donors are recruited and compensated for their donation of blood...whole blood tubes are pooled together, mixed for at least 30 min, and aliquoted under refrigerated conditions...Page 9...2. Calibration Frequency: Calibration is to be performed: a. Daily prior to the fist analytical batch of the day on the instrument...b. If a drift in QC is observed...". The procedure fails to state the correct type and levels of calibration reagent utilized by the laboratory and the correct frequency of calibration performed by the laboratory. c. During interview with TC at approximately 5:44 p.m., the TC stated the laboratory performs a monthly two point calibration and the calibration reagent is not collected and prepared from donors, but is purchased from a manufacturer. The TC also confirmed the procedure for the TOSOH G8 analyzer fails to include the correct type

	and level of calibration reagents utilized by the laboratory and the correct frequency for the performance of calibrations.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, review of QC reagent package inserts and interview with TC 04/30/25, the laboratory failed to ensure 6 bottles of reconstituted QC reagent were labeled with preparation and expiration dates. Findings: At approximately 5:15 p. m. surveyor observed the following 6 reconstituted bottles of QC reagent in the laboratory refrigerator with a hand written date of 4/28; 1. 3 bottles of Bio-Rad Lyphochek Immunoassay Plus Control, Levels 1, 2 and 3, Lot #'s 40431, 40432 and 40433. 2. 3 bottles of Bio-Rad Lyphochek Specialty Immunoassay Control, Levels 1, 2 and 3, Lot #'s 88751, 88752 and 88753. Review of package insert for Bio-Rad Lyphochek Immunoassay Plus Control revealed "STORAGE AND STABILITY... Reconstituted and Refrigerated; After reconstituting and storing tightly capped at 2 to 8 (degrees) C (Celsius), this product will be stable as follows: All analytes: 7 days... Except: - Folate and PSA (Prostate Specific Antigen) (Total); 3 days at 2 to 8C ...". Review of package insert for Bio-Rad Lyphochek Specialty Immunoassay Control revealed "STORAGE AND STABILITY... Reconstituted and Refrigerated; After reconstituting and storing tightly capped at 2 to 8C, this product will be stable as follows: - All analytes: 30 days....Except: - PTH (Parathyroid Hormone) (intact); 4 days - Procalcitonin: 3 days". Interview with TC at approximately 5:15 p.m. confirmed the QC reagent bottles did not indicate if the written date was the preparation date or the expiration date. He stated they replace the bottles of QC reagent every 7 days. He also stated he was unaware that Folate and PSA (Total) had a 3 day expiration date in which QC reagent was stable.
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 review of 2024 and 2025 calibration records for the TOSOH G8 analyzer, absence of documentation and interview with TC 04/30/25, the laboratory failed to perform a three point calibration verification for the testing performed on the TOSOH G8 analyzer at least once every 6 months since testing began in August of 2024, a period of approximately 8 months in which a calibration verification was not performed. Findings: Review of calibration records for the TOSOH G8 analyzer revealed the laboratory performs a two point monthly calibration. There was no documentation of a three point calibration verification utilizing minimal, mid-point and maximum values since testing began in August of 2024. Interview with TC at approximately 12:30 p.m. confirmed the laboratory had not performed a three point calibration verification since testing began in August of 2024.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of 5 random laboratory patient test reports from 2023, 2024, and 2025, and interview with TC 04/30/2025, the laboratory test reports failed to include the name and address where the testing was performed. Findings: Review of 5 random laboratory patient test reports revealed the name and address were missing from 5 of 5 reports. Medical Record Number's (MRN's) reviewed: 6075099-27061 6082255-27061 6089651-27061 6090237-27061 6094973-27061 During interview at approximately 1:45 p.m., the TC acknowledged the name and address were missing from the patient test reports, and confirmed testing was performed at the laboratory's physical address.