Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305199	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Washington County Hospital	14600 St Stephens Avenue, Chatom, AL	

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) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 a review of the Ortho Diagnostics Vitros XT 7600 Chemistry Calibration Verification records, a review of the Audit MicroControls Vitamin D Linearity package insert, and an interview with Testing Personnel #1, the laboratory failed to perform and document calibration verification procedures at least once every six months as specified by CLIA requirements. The surveyor noted the laboratory failed to perform and document one out of two Vitamin D calibration verifications due in

	2022 on the Vitros XT 7600 chemistry analyzer. The findings include: 1. A review of Chemistry records for the Ortho Diagnostics Vitros XT 7600 revealed the laboratory performed Vitamin D calibration verifications on 10/27/2021 and 11/17/2022. There was no documentation of calibration verification on Vitamin D performed the first half of 2022. 2. A review of the Audit MicroControls Vitamin D Linearity package insert revealed the following under "Procedure", "...Calibration verification linearity material should be run every six months..." 3. During an interview on 1/11/2023 at 12: 50 PM, Testing Personnel #1 confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC)/patient test records, a review of the IQCP (Individualized Quality Control Plan) documents, and an interview with Testing Personnel #1, the laboratory failed to ensure two levels of controls were run each day of patient testing or at the interval specified by the laboratory's IQCP for D-Dimer, C. diff (Clostridium difficile), and Serum hCG. This was noted 27 times from January 2022 - December 2022. The findings include: 1. A review of IQCP documents, QC and patient records revealed the following: (I) Serum hCG (Human Chorionic Gonadotropin) 1) A review if the IQCP revealed QC should be performed every 30 days and with each new lot or shipment. 2) A review of the quality control/patient test records revealed the last QC was performed on 9/6/2022, however, patient tests were performed on 10/13/2022, 10/14/2022, 10/21/2022, and 12/4/2022. There was no documentation of QC in October or December 2022. (II) C. diff 1) A review of the IQCP revealed QC should be performed every 30 days and with each new lot or shipment. 2) A review of the quality control/patient test records revealed the following: a) QC was performed on 2/18/2022, however, patient tests were performed on 3/10/2022, 3/23/2022, 4/19/2022, and 5/20/2022. There was no documentation of QC performed in March, April or May 2022. b) QC was performed on 6/7/2022, however, patient tests were performed on 7/15/2022, 7/27/2022, 7/30/2022, 7/31 /2022, 8/9/2022, 9/7/2022, and 10/12/2022. There was no documentation of QC performed in July, August, September or October 2022. (III) D-Dimer 1) A review of the IQCP revealed D-Dimer QC should be performed every 30 days and with each new lot or shipment. 2) A review of the quality control/patient test records revealed QC was performed each month of patient testing, however, the laboratory failed to follow the IQCP as written. 2. During an interview on 1/11/2023 at 4:00 PM, Testing Personnel #1 confirmed the above findings.