Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2049579	08/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biomontr Lab	15200 Weston Parkway, Suite 106, Cary, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the laboratory's policies and procedures, review of 2021, 2022, and 2023 laboratory records, and interview with TP (testing personnel) #1 on 8/29 /2023, the laboratory's external quality assurance procedure had not been updated to reflect current practice. Findings: The laboratory's procedure "QS-006.05 External Quality Assurance" states in Section 2.0, on page 1 of 7, "(the laboratory) participates in the CAP PT program...". In Section 4.1, on page 3 of 7, "Three times a year, (the laboratory) receives 5 samples from CAP for HIV RNA testing...". In Section 4.2 on page 3 of 7, "Three times a year, (the laboratory) receives 5 samples from CAP for

	HCV RNA testing...". In Section 5.1, page 5 of 7, "(the laboratory) does not currently perform clinical testing on analytes for which there is no External Quality Assurance or Proficiency testing available." Review of 2021, 2022, and 2023 laboratory records revealed the laboratory performed blind sample testing in-house to verify the accuracy of the HIV-1 SuperLow Assay and the HBV pgRNA 2.0 Assay. During interview at approximately 10:35 a.m., TP #1 stated they do not use CAP for proficiency testing because samples for the HIV-1 SuperLow Assay and the HBV pgRNA 2.0 Assay are not commercially available. She confirmed they perform in-house blind sample testing to verify the accuracy of these tests.