Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040074	(X3) Date Survey Completed 01/10/2023
Name of Provider or Supplier Harris Medical Services, Llc	**Street Address, City, State** 3328 Jenkins Rd, Ste 200, Chattanooga, 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
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 a review of the laboratory's procedure manual and interview with the laboratory's office manager and technical consultant, the laboratory manual failed to include panic or alert values for the Complete Blood Count (CBC) test for 2022. The findings include: 1. A review of the laboratory's procedure manual for 2022 revealed no panic or alert values included for CBC testing. 2. An interview on 01/10/2023 at 2 pm with the laboratory's office manager and technical consultant, confirmed there were no panic or alert values included in the procedure manual for CBC testing for 2022.

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 review of laboratory's procedure manual and Quality Control Plan (QCP) for Sight OLO performing complete blood count (CBC) testing, lack of Quality Control (QC) documentation and interview with the laboratory's office manager and technical consultant, the laboratory failed to follow their IQCP for performing quality control (QC) on new shipments and lots of OLO CBC Test Kits for 2022. The findings include: 1. Review of the laboratory's procedure manual revealed the laboratory director accepted a Quality Control Plan (QCP) for CBC testing performed on the Sight OLO analyzer on 03/01/2022. 2. The laboratory's QCP for CBC's performed on the Sight OLO states the laboratory will run all three levels of controls for every new shipment and with each new lot. 3. Lack of QC documentation for new shipments and new lots of OLO CBC Test Kits since 03/01/2022. 4. Interview on 01/10/2023 at 2 pm with the laboratory's office manager and technical consultant confirmed the laboratory did not perform and record QC for each new shipment or lots of OLO CBC Test Kits since 03/01/2022.