Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0310018	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Yium, Shenouda, Miller Partnership	251 N Lyerly St, Suite 100, 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 laboratory observation, review of patient test results, testing policies, manufacturer's instructions, procedure manual, and staff interviews, the laboratory's policies and procedures failed to include a protocol for verifying flagged complete blood count (CBC) test results. The findings include: 1. Observation of the laboratory on 09/24/2024 at 9:15 a.m. revealed a Sysmex XN-550 (ID: 25966) instrument used for CBC patient testing. 2. A random review of patient test reports from the XN-550 revealed the following: - Patient 107277 contained "WBC IP MessageBlasts/ Abn Lympho?". The neutrophil, lymphocyte, monocyte, and immature granulocyte

	parameters had asterisks. - Patient 74636 contained "WBC IP MessageLeft Shift?" The neutrophil, eosinophil, and immature granulocyte parameters had asterisks. - Patient 107427 contained "PLT IP MessagePLT Abn Distribution." The mean platelet volume parameter had an asterisk. 3. A review of the laboratory's CBC policy titled "Whole Blood and Body Fluids on the Sysmex XN-550 Automated Hematology Analyzer" revealed the following statements: - "Abnormal samples on the XN-L Series are identified using flagging systems to alert the user of possible abnormality." - "Refer to the Sysmex XN-L Series Automated Hematology Systems Flagging Interpretation Guide for additional information on flagging." - "Staff will follow all manufacturer's recommendations for patient testing." 4. A review of the "Sysmex XN-L Series Flagging Interpretation Guide" revealed the following: - "All analyzer flags, error messages, and results must be interpreted together and in consideration of the patient's clinical condition prior to results being reported from the laboratory." - "Any asterisk (*) next to a parameter indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." 5. A review of the laboratory's procedure manual revealed no protocol for confirming flagged CBC test results. 6. An interview with the technical consultant on 09/24/2024 at 3:30 p.m. confirmed the laboratory procedures failed to include a protocol for confirming flagged CBC results obtained from the Sysmex XN-550 analyzer.