Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0890514	07/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Methodist Healthcare Community Care Associates	8035 Club Parkway, Cordova, 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 observation of the laboratory, review of patient Complete Blood Count with automated White Blood Cell Differential (CBC with Diff) records, the patient's electronic medical record, the laboratory procedure manual, and interview with the technical consultant, the laboratory failed to have a written procedure for reporting of patient CBC with Diff results on the date of the survey (07/10/23). One of four patients reviewed was not reported in the electronic medical record. The findings include: 1. Observation of the laboratory on 07/06/23 at 08:10 am revealed the Medonic M Series instrument (serial #28620) on the counter in use for patient testing

	for CBC with Diff. 2. Review of patient data logs and instrument printouts revealed performance of CBC with Diff for patient number 1057689 on 05/06/2023. 3. Review of the patient 1057689 electronic medical record revealed the patient's CBC was not reported. 4. Review of the laboratory's procedure manual revealed there was no written procedure for the system in place for reporting of patient test results. 5. Interview with the technical consultant on 07/06/23 at 11:30 am confirmed the laboratory's procedure manual did not include the process for entering patient results in the patient record.