Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661966	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Of Lafayette County	800 Clay St, Darlington, WI	

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 surveyor review of laboratory procedures, records, and information systems, and interview with the technical consultant, three of three procedures reviewed did not include reference ranges (normal values). Findings include: 1. Review of procedures for troponin testing on the Access and Triage analyzers and the ESR (erythrocyte sedimentation rate) Diesse MiniCube showed no reference ranges (normal values). 2. Review of troponin result printouts from the Triage analyzer showed the normal range was 0.00- 0.4 ng/ mL (nanograms per milliliter). 3. Review of the troponin normal range for the Triage analyzer in the laboratory information system showed the normal

	range was 0.00 - 0.05 ng/mL. 4. Interview with the technical consultant on December 7, 2022 at 2:00 PM confirmed the procedures for the two troponin methods and the ESR did not include the reference ranges for the tests.