Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1093815	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Margaret R Pardee Memorial Hospital	800 North Justice Street, Hendersonville, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the absence of a quality assessment plan on 8/14/2024, the laboratory failed to establish and follow written policies and procedures to monitor, assess and correct identify problems. The evidence includes the following: 1. The laboratory failed to establish policies and procedures to ensure confidentiality of patient information throughout all phases of the testing process; 2. The laboratory failed to establish policies and procedures to ensure positive identification and integrity of patients' specimens through all phases of testing; 3. The laboratory failed to establish policies and procedure to identify and document all complaints and problems reported to the laboratory; 4. The laboratory failed to establish policies and procedures to identify and document problems that occur because of a breakdown in communication between the lab and an authorized person who orders or receives test results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 the absence of a laboratory procedure manual, and staff interview the laboratory did not have the following information available to testing personnel: 1. Procedure for collections of blood gases including the laboratory's policy for labeling specimens; 2. The laboratory's policy for reporting results, including adults and pediatrics reference ranges, alert or panic values, if appropriate: 3. The laboratory's policy for running and accepting quality control specimens; 4. The protocol to follow if the test system is inoperable. 5. During the interview with the laboratory manager and assistance manager at 12:05 p.m. on 8/14/2024, it was confirmed that the director had not signed off on a Policy and Procedure Manuel for the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the absence of documentation and interview with the Respiratory Therapy Manager on 8/14/2024, the laboratory failed to provide or demonstrate that it had confirmed the performance specifications comparable to those established by the manufacturer prior to reporting patient test results. Findings: 1. The laboratory first reported patient test results on the ABL 90 Blood Gas analyzers on approximately 11 /22/2022. the laboratory failed to verify the performance specifications of accuracy, precision, and reportable ranges for the blood gas and co-oximeter results performed on the analyzers prior to reporting patient test results. 2. During the interview at 12:05 p.m. on 8/14/2024, the Respiratory Therapy Manager acknowledged that he did not have the ABL 90 Blood Gas Analyzers installation documentation. He did confirm that the analyzers were installed on 10/25/22, and patient testing began on 11/8/22..
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the absence of records and staff interview at 12:05 p.m. on 8/14/2024, the Respiratory Therapy Manager could not provide the documentation that demonstrated the director's efforts to ensure that the verification procedures used were adequate to determine the accuracy, precision, and performance characteristics of the ABL 90 Blood Gas analyzers. The laboratory staff could not locate the installation documentation nor any records that the director had accepted the verification procedures (see D5421).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the absence of an approved laboratory procedure manual the staff did not have available the written guidance covering all aspects of the testing process they were responsible for. During interview with Respiratory Therapy Manager, at 12:05 p. m. on 8/14/2024, he could not produce the director approved policy and procedure manual that should be available to the staff.