Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0904155	02/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Galen Medical Group	1651 Gunbarrel Road, Suite 302, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, direct observation, and interview with the laboratory's technical consultant, determined the laboratory failed to provide specimen labeling instructions for Complete Blood Count (CBC) specimen collection from 2020 to February 23, 2023. The findings include: 1. Review of the laboratory's CBC procedure manual failed to provide specimen labeling instructions for CBC specimen collection. 2. Direct observation of one CBC fingerstick specimen on 2.23.2023 at approximately 10:00 a.m. revealed the specimen was not labeled with any patient identifier. 3. Interview with the laboratory's technical consultant on 2.23.2023 at 11:00 a.m. confirmed the laboratory failed to provide specimen labeling instructions for Complete Blood Count (CBC) specimen collection from 2020 to February 23, 2023.
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 review of the laboratory's procedure manual and upon interview with the laboratory's technical consultant, determined the laboratory manual failed to include requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection for the Complete Blood Count (CBC) test since 2020. The findings include: 1. Review of the laboratory's procedure manual revealed no requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection for the Complete Blood Count (CBC) test since 2020. 2. Interview with the laboratory's technical consultant on 2.23.2023 at 11:00 a.m. confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 observation of the laboratory, request for verification documentation, and interview with the laboratory's technical consultant, determined the laboratory failed to verify the accuracy, precision, and reference intervals (normal values) for the Advanced Instruments Bilirubin analyzer. The findings include: 1. Observation of the laboratory on 2.23.2023 at 10 a.m. revealed the Advanced Instruments Bilirubin analyzer in use for patient bilirubin testing (new 08.2022). 2. Request for verification documentation of the Advanced Instruments Bilirbuin analyzer revealed none. 3. Interview with the laboratory's technical consultant on 2.23.2023 at 11 a.m. confirmed the laboratory did not verify the accuracy, precision, and reference intervals (normal values) for the Advanced Instruments Bilirubin analyzer.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on Testing Personnel (TP) listed on the Center for Medicare and Medicaid (CMS) Form 209, competency documentation and interview with the laboratory's technical consultant, determined the technical consultant failed to document training and competencies for 2021 and 2022. The findings include: 1. Four of twelve Testing Personnel (TP#3, TP#4, TP#9 & TP#10) listed on the CMS Form 209, hired 5.4.2022 (TP#3), hired 6.29.2022 (TP#4), hired 8.25.2021 (TP#9) and hired 11.8.2021 (TP#10), lacked training and competency documentation upon hire. 2. An interview with the laboratory's technical consultant on 2.23.2023 at 11:00 a.m. confirmed that 4 of 12 TP lacked training and competency upon hire dates of 6.27.2022, 6.29.2022, 8.25.2021, and 11.15.2022.