Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0256803	**(X3) Date Survey Completed** 07/29/2025
Name of Provider or Supplier Harbin Clinic Medical Oncology	**Street Address, City, State** 255 West 5th Street, Rome, GA	
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**
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 29, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview, the laboratory failed to ensure that PT samples were rotated and tested by all approved testing personnel (TP) for the 2024 events of 1, 2, & 3. Findings: 1. Reveiw of the American Profociency Institute (API) PT attestation sheets for the year of 2024 revealed that TP# 4 (CMS 209) did not participate in the testing of PT samples during the 2024 events #1, #2, or #3. 2. Interview with TP#1 (CMS 209) in the conference room on 7 /29/25 at 1 PM, confirmed TP# 4 (CMS 209) did not participate in the testing of PT samples during the 2024 events #1, #2, & #3.
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 SOP review and staff interview, the laboratory failed to include a procedure for the course of action to take if a test system becomes inoperable. Findings include: 1. SOP review reveals the laboratory did not have a written procedure for a course of action to take if a test system becomes inoperable. (Downtime procedure) 2. An interview with testing personnel #2 (CMS 209) on 07/29/25 at 12:56 p.m. in the conference room confirmed the lack of a downtime procedure.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person involved in all phases of the testing process. Findings include: 1. SOP review revealed the LD failed to specify, in writing, the duties and responsibilities of the laboratory director, clinical consultant, and the technical consultant. 2. An interview with testing personnel #1 (CMS 209) in the conference room on 7/29/25 at 12:57 p.m. confirmed the SOP did not contain the duties and responsibilities for the aforementioned lab personnel.