Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2174210	(X3) Date Survey Completed 03/17/2025
Name of Provider or Supplier Augusta Oncology	**Street Address, City, State** 222 University Parkway, Aiken, SC	

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	An on-site announced CLIA recertification survey was conducted at clinical laboratory of Augusta Oncology Associates - Aiken by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare Standard at 42 CFR Part 493, CLIA Rquirements for Laboratories. Standard level deficiencies were identified for the recertification during the survey:
D2121	HEMATOLOGY CFR(s): 493.851(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to attain a score of at least 80 percent in proficiency testing for the specialty of Chemistry and subspecialty Endocrinology. The analyte for 2023 2nd Event Bilirubin, Total and 2024 3rd Event CA 27.29. Findings included: 1. Review of American Proficiency Institute (API) records revealed the following scores for Augusta Oncology-Akien: a. Erythrocyte Count Hematocrit 0% Hemoglobin 0% Leukocyte Count 0% Mean Corpuscular Hemoglobin (MCH) 0% Mean Corpuscular Hemogloblin Concentration (MCHC) 0% Mean Corpuscular Volume (MCV) 0% Mean Platelet Volume (MPV) 0% Platelet Count 0% RDW-CV 0% White Blood Cell Differential 0% Lymphocytes 0% Monocytes 0% Neu/Gran 0% b. 2023, Event 2: Bilirubin 40% c. 2024, Event 3: CA 27.29 60% 2. In an interview on 03/17/2025 at 3:00pm in the office the scores were confirmed.
D2123	HEMATOLOGY CFR(s): 493.851(c)

	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the American Proficiency Institute (API) proficiency testing records review and staff interview reveals the laboratory unsuccessfully participated in a proficiency testing subspecialty Hematology program approved by CMS. Findings included: 1. Review of API records reveals failure to successfully participate in a CMS approved proficiency testing (PT) program by scores of 0% for 1 of 3 events in 2022 as follows for Erythrocyte, Hematocrit, Hemoglobin, Leukocyte Count, Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Corpuscular Volume (MCV), Mean Platelet Volume (MPV), Platelet Count, Red Cell Distribution Width-Coefficient of Variation (RDW-CV), White Blood Cell Differential. 2. Failure to participate in a testing event is unsatisfactory performance and results in a score of 0% for the testing event. 3. Review of CLIA regulations reveals that successful participation in a CMS approved PT program is testing scores of a minimum of 80% for each analyte tested. 4. In an interview on 03/17/2025 at 3:00 pm, in the office with the staff, the findings were confirmed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing record review, and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 3 proficiency testing events reviewed form 2022 through 2025 (2022, Event 1). Findings include: 1. Review of proficiency testing results revealed the following scores: Hematology 2022,1st Event the laboratory received an unsatisfactory score of 0% for: Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count MCH MCHC MCV MPV Platelet Count RDW-CV White Blood Cell Differential Lymphocytes Monocytes Neu/Gran
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on instrument operator manual review, instrument maintenance records review, and staff interview the laboratory failed to document monthly maintenance on the Medonic hematology instrument for five of twenty-four months reviewed from both instruments A & B (Sept. 2023, April 2023, May 2023, July 2023, Oct. 2023). Findings included: 1. Review of the Medonic hematology analyzer operator's manual on 03/17/2025 at 2:00 pm revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a monthly cleaning and monthly clot prevention. 2. Review of the Medonic hematology analyzer maintenance logs on 03/17/2025 at 2:05 pm revealed the monthly maintenance had not been documented for five of twelve months reviewed from 2022 through 2023 (Sept. 2023, April 2023, May 2023, July 2023, Oct. 2023). 3. In a staff interview on 03/17/2025 at 3:00 pm in the office the staff confirmed that the monthly maintenance had not been performed for the reviewed months.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on records reviewed, policies and procedures, and staff interview the laboratory failed to establish a mechanism to periodically verify the accuracy of its calculated data, results sent to interfaced systems and patient specific data. Findings include: 1. Review of the laboratory Quality Assurance Plan and checklist on 03/17/2025 at 11: 00 am revealed the laboratory failed to include language on how the laboratory will ensure electronic test system verification of test results or calculations performed by the instrument and sent to the interface. 2. The laboratory QA checklist did not include documentation that a review of electronic test report was verified with the client or laboratory. The laboratory was asked but failed to provide documentation of review for test report accuracy. 3. An interview with the staff in the laboratory office on 03/17/2025 at 3:00 pm confirmed the laboratory did not include electronic test verification process for clients or laboratories.
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 lack of documentation and staff interview, the laboratory director failed to sign the Vitros "Operator's Manual" for moderately complex laboratory testing. Findings include: 1. Review of the laboratory procedure manual revealed a lack of documentation that the laboratory director had reviewed or signed off the manual. 2. According to the CMS 209 personnel report form, MD 1 is listed as laboratory director for the moderately complex laboratory. 3. In an interview on 03/17/2025 at 3: 00 pm, in the office with the staff, the findings were confirmed.