Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0979524	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Augusta Oncology Associates	1303 D'Antignac Street, Suite 1000, Augusta, 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 January 18, 2023. The labratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedure (SOP) and staff interview, the laboratory failed to establish a safety procedure for the eyewash. The Findings include: 1. SOP document review revealed that the laboratory failed to establish a safety procedure for the sink eyewash in the laboratory. The laboratory does perform weekly flushing of the sink eyewash and document. 2. During an interview with Testing Personnel#1 (CMS-209) on January 18, 2023, at approximately 1:10 PM, in the conference room, confirmed that the laboratory failed to establish a safety procedure for the eyewash. The laboratory does have documention of the weekly flushing of the sink eyewash.
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 general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. A review of the SOP confirmed that a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) was not available for staff to follow when sending specimens to a reference laboratory. 2. During an interview, on January 18, 2023, at 1:20 PM, with Testing Personnel#1 (CMS-209), in the conference room, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on standard operating procedure (SOP) review and staff interview, the laboratory failed to develop a corrective action procedure for the operation of the testing patient specimens in a manner that ensures accurate and reliable patient test results and reports The Findings include: 1. SOP review reveals the laboratory failed to develop and implement a corrective action procedure for any operation testing for the laboratory. 2. During an interiew with Testing Personnel#1(CMS-209) on January 18, 2023 at approximately 1:45 PM in the conference room, confirmed the lack of developing a corrective action procedure for the laboratory. Testing Personnel #1 (CMS-209) stated that they have not had to document any corrective actions for the operation of any testing type for the laboratory.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on laboratory record review and staff interview, the Laboratory Director(LD) failed to develop a corrective action procedure for the operation of the laboratory for all testing. The Findings include: 1. Standard Operating Procedures revealed that the Laboratory Director (LD) failed to ensure that a corrective action procedure was developed for the operation of the laboratory for all testing. 2. During an interveiw

	with Testing Personnel#1(CMS-209) on January 18, 2023 at 2:15 PM in the conference room, confirmed that the Laboratory Director(LD) failed to develop a corrective action procedure for the operation of the laboratory for all testing.