

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262875	(X3) Date Survey Completed 02/12/2018
Name of Provider or Supplier Augusta Oncology Associates P C	Street Address, City, State 3696 Wheeler Road, 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 February 12, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency. Findings include: 1. SOP review revealed there was not a six-procedure competency policy established and followed to assess TP competency. 2. An interview with Staff #2 (CMS 209) in a medical office on 2/12/18 at approximately 5 p.m. confirmed there was not a TP competency policy and procedure in the laboratory SOP.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the</p>

type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (TC/LD) failed to ensure the testing personnel (TP) received the appropriate training for the type and complexity of the laboratory services offered. Findings include: 1. TP document review revealed the LD/TC failed to perform 2017 initial competencies for the following TP, Staff #5 (CMS 209) and Staff #7 (CMS 209). 2. TP document review revealed the LD/TC failed to perform 2018 initial competencies for the following TP, Staff #3 (CMS 209) and Staff #8 (CMS 209). 2. An interview with Staff #2 (CMS 209) on 2/12/18 in a medical office at approximately 5 p.m. confirmed the LD/TC did not perform initial competencies for the aforementioned TP in 2017 and 2018.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of TP performing moderate complexity testing annually after the first year. Findings include: 1. TP document review revealed the TC/LD failed to perform and document TP annual competencies for Staff #2 (CMS 209), Staff #4 (CMS 209), and Staff #6 (CMS 209) in 2017. 2. An interview with Staff #2 (CMS 209) in a medical office on 2/12/18 at approximately 5 p.m. confirmed the TC/LD did not perform annual competencies in 2017 for the aforementioned TP.