

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2270484	<b>(X3) Date Survey Completed</b>  07/18/2023
<b>Name of Provider or Supplier</b>  Alabama Oncology	<b>Street Address, City, State</b>  70 Plaza Drive, Pell City, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 a review of the Policies and Procedures and an interview with Testing Personnel #1, the laboratory failed to establish and follow written policies and procedures to assess the competency of employees. This was noted from the implementation of the Policy and Procedure Manual, 2/10/2023, to the date of the current survey, 7/18/2023. The findings include: 1. A review of the Policies and Procedures revealed no procedure on performance of competency assessments for testing personnel. 2. During an interview on 7/18/2023 at 12:00 PM, Testing Personnel #1 confirmed no other policies were available to review.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures and an interview with Testing Personnel #1, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems. This</p>

was noted from the implementation of the Policy and Procedure Manual, 2/10/2023, to the date of the current survey, 7/18/2023. The findings include: 1. A review of Policies and Procedures revealed no evidence of a Quality Assurance plan for the facility. 2. During an interview on 7/18/2023 at 12:00 PM, Testing Personnel #1 confirmed the above findings.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(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 a review Personnel files and an interview with Testing Personnel #1, the Laboratory Director failed to have duties and responsibilities of each person involved in all phases of the testing process specified in writing. The findings include: 1. A review of Personnel files revealed that Clinical Consultant, Technical Consultant, and Testing Personnel specified duties and responsibilities were not available for review at the time of the survey. 2. During an interview on 7/18/2023 at 12:00 PM, Testing Personnel #1 confirmed the above findings.