

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0710009	<b>(X3) Date Survey Completed</b>  05/23/2022
<b>Name of Provider or Supplier</b>  Summit Medical Associates Pc	<b>Street Address, City, State</b>  1874 Piedmont Rd Ste 500-E, Atlanta, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 23, 2022. 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:
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on AAB (American Association of Bioanalysts) Proficiency Testing(PT) documents review and staff interview, the laboratory director (LD) failed to ensure that Proficiency Testing(PT) was done on a timely manner and results submitted to the appropriate agency in 1st Event of 2022. Findings include: 1. PT document review revealed that the LD failed to ensure that 2022 Q1 NonChemistry (D Rh O Typing) PT was performed for the 1st event of 2022. The failure to participate in the 1st event in 2022 resulted in a "Failure to participate" performance grade by AAB. 2. An interview with the office manager and staff on 05/23/2022, at approximately 12:20 pm, in the review room, confirmed no participation in Event #1 of 2022.</p>