

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2154847	<b>(X3) Date Survey Completed</b>  12/21/2021
<b>Name of Provider or Supplier</b>  Amg Hematology & Oncology	<b>Street Address, City, State</b>  1000 Galloping Hill Road, Union, NJ	
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>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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with the College of Pathologists (CAP) for the second and third event in the calendar year 2021. The TP #5 as listed on CMS form 209 confirmed on 12/21/21 at 1:15 pm that the PT results were not reviewed.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:  
Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 5/1/19 to the date of the survey. The TP # 5 as listed on CMS form 209 confirmed on 12/21/21 at 1:30 pm that a QA plan had not been established.