

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0106272	<b>(X3) Date Survey Completed</b>  05/30/2018
<b>Name of Provider or Supplier</b>  Amg Hematology & Oncology	<b>Street Address, City, State</b>  99 Beauvoir Avenue, Overlook Med Ctr, Summit, 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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when the laboratory received an unacceptable score in PT for Hematology Auto Differentials, FH9 performed with the College of American Pathologists (CAP) in 2017. The finding includes: 1. There was no review or evaluation documented when the laboratory received an unacceptable result for BCP-05 RBC Agglutinates event A 2017. 2. The TP #6 on CMS form 209 confirmed on 5/30/18 at 11:00 am that the laboratory did not perform and document an evaluation of unacceptable PT performance.</p>
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to have an accurate system in place to ensure test results are accurately reported for Hematology testing from 7/18/17 to the date of the survey. The finding includes: 1. The laboratory reported both Automated Differential and the Manual Differential (MD) results on all patients that had a MD test performed. 2. The TP #6 on CMS form 209 confirmed on 5/30/18 at 11:30 AM that the laboratory did not report results accurately.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to ensure that a qualified professional performed Competency Assessment (CA) on six out of six Testing Personal (TP) in the calendar year 2017. The finding includes: 1. The TP had a high school diploma and was not qualified to perform CA. 2. The TP #6 on CMS form 209 confirmed on 5/30/18 at 12:00 pm that the TC did not perform CA.