

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0687909	<b>(X3) Date Survey Completed</b>  04/03/2019
<b>Name of Provider or Supplier</b>  Amg-Livingston, Llc	<b>Street Address, City, State</b>  4120 Bradford Hicks Drive, Livingston, TN	
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>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Vaginal Wet Preparation (KOH) Proficiency Testing (PT) records for 2017-18 and interview with the primary testing person, determined the PT samples were not tested by one of three testing personnel as listed on the Laboratory Personnel Report Form 209. The findings include: 1. A review of the KOH PT records for 2017-18 revealed only two of three testing personnel's signature on the attestation sheets. 2. An interview with the KOH primary testing person at approximately 10:00am on April 3, 2019, confirmed only two of three, listed on the Laboratory Personnel Report Form, who tested the proficiency testing samples for 2017-18. 3. An interview with the primary testing person at approximately 10:00am on April 3, 2019, confirmed two of three KOH testing personnel had attested by signature to testing the PT samples for the 2 year period.</p>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) record's attestation statements for 2017-</p>

18 and an interview with the primary testing person (TP), the laboratory failed to ensure the laboratory director and TP analysts performing the PT event's analyte signed the attestation statements in 2018. Findings include: 1. A review of attestation statements failed to reveal the laboratory director's and TP analyst's signature on and participation in testing events for the 2nd and 3rd events 2018 for Hematology /Coagulation. 2. In an interview, April 3, 2019, at 10:30am, the primary TP confirmed the missing laboratory director and TP analyst's signatures on the attestation statements for the 2nd and 3rd events 2018 for Hematology/Coagulation.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
Based on a review of proficiency testing (PT) records and interview with the primary testing person (TP), the laboratory failed to verify accuracy for Vaginal Wet Prep (Microscopic) at least twice a year by obtaining unsatisfactory scores in 2017-2018. Findings include: 1. Review of PT records for scores during the American Proficiency Institute (API) PT for Vaginal Wet Prep (Microscopic) was 0% on both PT results in the 2nd and 3rd events of 2018. 2. An interview with the primary testing person on April 3, 2019, at 10:45am, confirmed the laboratory failed to verify accuracy twice a year by obtaining unsatisfactory scores for Vaginal Wet Prep (Microscopic) was 0% on both PT results in the 2nd and 3rd events of 2018.