

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0316263	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Amg- Livingston, Llc	Street Address, City, State 500 West Main Street, Livingston, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of the laboratory's procedure manual and staff interview, the laboratory failed to establish a written policy for competency assessments of testing personnel (TP) in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's policy and procedure manual revealed no written policy for employee competency assessments. 2. Interview with the Office Manager and TP-1 on 12/06/23 at 11:30 a.m. confirmed the laboratory did not have a written policy for competency assessments.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review testing procedures, and staff interview, the laboratory personnel failed to follow the policy for preparation of the urinary sediment used in patient urine sediment examinations for one of one specimen observed on the date of the survey (12/06/23). The findings include: 1. Observation of</p>

the laboratory on 12/06/23 at 9:35 a.m. revealed laboratory personnel centrifuged two milliliters of patient urine for three minutes in preparation for urine sediment microscopic examination. 2. Review of the laboratory procedure titled "Complete Routine Urinalysis" section "Microscopic Examination of the Urinary Sediment" item three "Preparation of the Urinary Sediment" revealed the statements "Pour 10 - 12 ml into a conical-tipped centrifuge tube" and "Centrifuge at 2000 rpm for 5 min." 3. Interview with the office manager and testing personnel on 12/06/2023 at 11:30 a.m. confirmed the laboratory failed to follow their policy for preparing patient urinary sediment used for urine sediment microscopic examinations.

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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS-209) and Clinical Laboratory Improvement Amendments Application for Certification (CMS-116), testing personnel competency assessment records, and staff interview, the laboratory's technical consultant (TC) failed to document all six required criteria for assessing personnel competency for 1 of 1 testing personnel (TP) performing direct wet mount preparations, urine sediment examinations, and complete blood count (CBC) patient testing in 2021, 2022, and 2023. The findings include: 1. Review of the CMS-209 and CMS-116 provided by the laboratory on 12/06/2023 revealed one testing personnel (TP-1) who performs direct wet mount preparation, urine sediment examination, and CBC patient testing. 2. Review of competency assessment records for TP-1 revealed the following: - Assessment completed on 11/20/23 failed to include documentation of 1) monitoring the recording and reporting of test results; 2) review of preliminary test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; 3) assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; 4) and, assessment of problem solving skills. - The 2021, 2022, and 2023 competency records did not include assessments for direct wet mount preparations and urine sediment examinations. 3. Interview with the office manager and TP-1 on 12/06/23 at 11:30 a.m. confirmed the laboratory's technical consultant failed to document all six required criteria for assessing personnel competency for TP-1 performing direct wet mount preparations, urine sediment examinations, and complete blood count (CBC) patient testing in 2021, 2022, and 2023.