

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2052844	<b>(X3) Date Survey Completed</b>  09/27/2018
<b>Name of Provider or Supplier</b>  Agm Laboratories	<b>Street Address, City, State</b>  10199 Woodfield Lane, Suite 10, Creve Couer, MO	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency records for 2017, 2018 and interview with the laboratory director, the laboratory failed to verify the accuracy of 6-acetylmorphine (6AM) twice annually. Findings: 1. Review of proficiency records for 2017 and 2018 revealed the laboratory failed to prove accuracy on the nonregulated analyte, 6AM. 2. Interview with the laboratory director on September 27, 2018 at 10:00 AM confirmed the laboratory failed to twice annually verify the accuracy of the nonregulated analyte, 6AM for 2017 and to date 2018.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals</p>

(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the laboratory director, the laboratory failed to include reference intervals(cutoff values). Findings: 1. Review of the procedure manual revealed a lack of reference intervals(cutoff values) for 6-acetylmorphine(6AM). 2. Interview with the laboratory director on September 27, 2018 at 10:00 AM confirmed the laboratory failed to include cutoff values for 6AM.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the Carolina CLC 720 manual, laboratory documentation and interview with laboratory staff, the laboratory failed to monitor and document the room temperature and humidity for toxicology testing. Findings: 1. Review of the manual for the Carolina 720 toxicology analyzer revealed to operate the analyzer in a room temperature of 15-30 degrees Celsius and a humidity of 35-85 percent without condensation. 2. Review of the laboratory documentation showed the laboratory failed to document room temperature and humidity. 3. Interview with the laboratory director and testing personnel on September 27, 2018 at 10:00 AM confirmed the laboratory failed to document the room temperature and humidity in the laboratory.