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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D2110703 | (X3) Date Survey Completed 09/01/2020 |
| Name of Provider or Supplier Agm (Advanced Geriatric Management) | Street Address, City, State 10199 Woodfield Ln Suite 10, Saint Louis, MO | |
| 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 |
|---------------------------|---|
| D5217 | <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 the lack of proficiency testing records for toxicology testing and interview with the laboratory director, the laboratory failed to verify the accuracy of 58 of 58 analytes performed on the toxicology instrument at twice annually during 2019. Findings: 1. The laboratory did not have documentation to show it verified the accuracy at least twice a year during 2019 for the following toxicology analytes: Amphetamine, Methamphetamine, Fluoxetine, Norflouxetine, Amitriptyline, Doxepine, Imipramine, Nortriptyline, Butalbital, Phenobarbital, Secobarbital, Diazepam, Alprazolam, Clonazepam, Lorazepam, Oxazepam, Temazepam, THC-COOH, Cannabinoids (Synthetic) AM-2201 4-OH-Pentyl, JWH-018 N-Pentanoic acid, XLR-11 4-OH-pentyl, MDPV, Mephedrone, 6- MAM (heroin), Benzocgonine (Cocaine), MDA, MDMA (Ecstasy), Phencyclidine (PCP), Carisprodol, Meprobamate, Cyclobenzprine, Gabapentin, Pregamalin, Naltrexone, Codeine, Hydrocodone, Morphine, Oxycodone, Oxymorphone, Propoxyphene, Opiates (Synthetic) EDDP, Methadone, Fentanyl, Norphentanyl, Buprenorphine, Norbuprenorphine, Meperidine, Normeperidine, Mitagynine, Ritalinic Acid, Methyphenidate, Tapentadol, Zaleplon, Zolpidem and Zopiclone. 2. Interview with the laboratory director on September 1, 2020 at 1:00 PM confirmed the laboratory failed to verify the accuracy of toxicology analytes not included in subpart I at least twice annually during 2019.</p> |
| D5311 | <p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> |

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and review of two of two test reports from 2020, the laboratory failed to follow the written policy for sample rejection. Findings: 1. The sample rejection policy states, "Specimens with the following characteristics may have to be rejected: - Inadequate specimen ID or unlabeled specimens -Mislabeled specimens -Leaking urine sample cup -Frozen or heated specimens -Improper storage or transportation Communicate rejected sample to appropriate client and document in the Rejected Sample log book. 2. Review of test report #1 showed the specimen was collected on May 26, 2020 at 3:44 PM, received in the laboratory on July 30, 2020 at 3:44 PM and tested/resulted on August 17, 2020 at 3:19 PM. Review of test report #2 showed the specimen was collected on June 11, 2020 at 3:46 PM, received in the laboratory on June 12, 2020 at 3:46 PM and tested/resulted on July 14 at 5:16 PM. 3. Interview with the laboratory director on September 1, 2020 at 1:00 PM revealed the specimens identified in test reports # 1 and # 2 were frozen and tested months/weeks later. Interview with the laboratory director confirmed the laboratory failed to follow the sample rejection policy.