

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2102433	(X3) Date Survey Completed 05/07/2019
Name of Provider or Supplier Genesis Reference Laboratories Llc	Street Address, City, State 7924 Forest City Rd, Orlando, FL	
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 record review and interview, the laboratory failed to verify the accuracy of the testing methods for urine toxicology and ethanol biomarkers in 2018 at least twice annually. Findings: Review of the College of American Pathologist (CAP) records showed that the laboratory received remedial samples on 12/27/18 for urine toxicology and ethanol biomarkers. review of the test result printout showed that the urine toxicology samples were run on 3/5/19 and the ethanol biomarkers were run on 2/27/29. The laboratory failed to perform proficiency testing on the following analytes: 4-Methylethcathinone, 6-Acetylmorphine, 7-Aminoclonazepam, 7-Hydroxymitragynine, 7-Hydroxyquetiapine, Alpha-PVP (Alpha Pyrrolidinopentiophenone) Alpha-Hydroxyalprazolam, Alpha-Hydroxytriazolam, Alprazolam, Amitriptyline, Amphetamine, Barbiturate, Benzodiazepine, Benzoylcegonine, Buprenorphine, Bupropion Butabarbital, Butalbital, Carbamazepine, Carisoprodol, Citalopram, Clonazepam, Cocaine, Codeine, Cotinine, Cyclobenzaprine, Desalkylflurazepam, Desmethyloxepin, Desipramine, Dextromethorphan, Dextrorphan, Diazepam, Dihydrocodeine, Doxepin, Ecstasy (MDMA), EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), Ethanol, Fentanyl, Flunitrazepam, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Imipramine, JWH-018 4-Hydroxypentyl, JWH-073 3-Hydroxybutyl, JWH-018 5-Pentanoic Acid, JWH-073 4- Butanoic Acid, Ketamine, Lorazepam, Maprotiline, Meprobamate, MDA (3,4 Methylenedioxyamphetamine), MDEA (3,4-Methylenedioxy-N-ethylamphetamine), MDPV (Methylenedioxypropiovalerone), Meperidine, Mephedrone, Methylone, Methadone, Methamphetamine, Methlyphenidate, Midazolam, Mitragynine, Morphine, Naloxone, Naltrexone,</p>

Norbuprenorphine, Nordiazepam, Norfentanyl, Norketamine, Noromeperidine, Norpropoxyphene, Noroxycodone, Nortriptyline, Opiate, Oxazepam, Oxcarbazepine, Oxycodone, Oxymorphone, Paroxetine, Pentabarbital, pH, Phencyclidine, Phenobarbital, Pregabalin, Propoxyphene, Quetiapine, Ritalinic Acid, Sertraline, Specific Gravity, Sufentanil, Secobarbital, Tapentadol, Temazepam, THC (Tetrahydrocannabinol), THC-COOH (11-nor-9-carboxy-THC), Trazodone, Tramadol, Triazolam, Urine Creatine , UR-144 (Synthetic Cannabinoid), Venlafaxine, XLR-11 (Synthetic Cannabinoid), Zaleplon, Zolpidem, and Zopiclone. During an interview on 5/06/19 at 2:08 PM, the Technical Supervisor acknowledged the 2018 remedial samples were not run until 2019, and that no split testing was done in 2018.