

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2120455	(X3) Date Survey Completed 03/16/2023
Name of Provider or Supplier Cleanse Clinic Psc	Street Address, City, State 645 S Roy Wilkins Ave, Ste 100, Louisville, KY	
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
D0000	A recertification survey was conducted on 03/16/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
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 review of the laboratory's policies, proficiency testing records, and interview, the laboratory failed to have a procedure manual that included current procedures for the performance of twice annual accuracy verification for eight (8) of eight (8) of the urine toxicology analytes (amphetamines, benzodiazepines, buprenorphine, cannabinoids; cocaine metabolites; methadone; opiates; and oxycodone). This was noted for four (4) out of four (4) PT events. The findings include: Review of the laboratory's policy titled, "Proficiency Testing and Employee Competency," dated 02/11/2023, specified "The laboratory will utilize a CLIA [Clinical Laboratory Improvement Amendments] approved proficiency company to provide samples for proficiency testing." A review of the laboratory urine toxicology proficiency testing records for 2021 and 2022 on 03/16/2023 at 11:10 AM revealed the laboratory did not perform PT for urine toxicology as specified in their procedure manual. This was noted for four (4) out of four (4) PT events reviewed. During an interview with the General Supervisor (GS)/Testing Personnel (TP) #2, on 03/16/2023 at 11:20 AM, she stated the laboratory no longer performed external PT and the standard operating procedure manual was outdated. She stated the laboratory stopped performing external PT in 2018 and instead performed performed twice annual</p>

accuracy verification for urine toxicology by re-testing PT samples from another CLIA-approved laboratory that used the same instrumentation on the days when the laboratory was not in operation. During continued interview with GS/TP #2, she stated the laboratory performed testing on the samples after the other laboratory submitted their results to the PT provider to ensure there was no communication between the two (2) laboratories about the values obtained. When the event was graded and results were received from the PT provider, a comparison was made between the results obtained by both laboratories.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of the "MAS DOA Total" package insert, observation, and interview, the laboratory used quality control material for urine toxicology that was beyond the expiration date. This was noted for all levels of the "MAS DOA" quality control material in use on the day of the survey. The findings include: A review of the "MAS DOA Total" package insert, revised October 2020, revealed, "Once opened, vials of control are stable for 30 days when stored tightly capped at 2-8 [degrees] C [Celsius]." Review of the laboratory's policy titled, "Toxicology Quality Control," dated 02/11/2023, revealed, "Once the controls are opened they are stable for 30 days." Observation of the reagents and quality control materials in use, on 03/16/2023 at 1:10 PM, revealed the "MAS DOA Total" quality control materials (lot numbers DAT24031, DAT24032 and DAT24033) were labeled with a date of 01/23/2023. During an interview with the General Supervisor (GS)/Testing Personnel (TP) #2, on 03/16/2023 at 1:20 PM, she stated the date on the DOA testing quality controls was the date they were opened. She stated the materials were being used almost one (1) month past their expiration date, which was thirty (30) days, according to the laboratory's standard operating procedure and the manufacturer's package insert. The laboratory reported a test volume of 4,830 urine toxicology screens per year on the CMS 116 form signed by the Laboratory Director on 03/12/2023.