Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2087524	09/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Compliance Monitoring Systems	2685 Palmer Street Ste 2c, Missoula, MT	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a record review and interview with general supervisor (GS) #1, the laboratory failed to enroll in an HHS-approved proficiency testing program for creatine and pH performed on the Thermo Scientific Indiko Plus from April 21, 2022, to September 19, 2023. Findings: 1. A review of the CMS-116 form on September 19, 2023, at 11:00 AM revealed the laboratory test analyte list included creatine and pH. 2. A review of a patient's (04000000701) "Test Result Final Report" dated 09/15/2023 revealed test results for creatine and pH. 3. A review of 2022 and 2023 College of American Pathology (CAP) proficiency testing records lacked documentation for creatine and pH. 4. An interview with GS #1 on September 19, 2023, at 11:15 AM confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for creatine and pH performed on the Thermo Scientific Indiko Plus from April 21, 2022, to September 19, 2023.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a record review and interview with the general supervisor (GS) #1, the laboratory failed to perform biannual accuracy verification or proficiency testing for specific gravity performed on the Thermo Scientific Indiko Plus from April 21, 2022, to September 19, 2023. Findings: 1. A review of a patient's (04000000701) "Test Result Final Report" dated 09/15/2023 revealed test results for specific gravity. 2. A review of 2022 and 2023 College of American Pathology (CAP) proficiency testing records lacked documentation for specific gravity. No biannual external validation studies for specific gravity were available for review. 3. A review of the laboratory's "Proficiency Testing Procedures" revealed the laboratory failed to follow their procedures to "perform split-sample analysis with other CLIA certified laboratories as an external validation of all non-regulated analytes". 4. An interview with GS #1 on September 19, 2023, at 11:15 AM confirmed the laboratory failed to perform biannual accuracy verification for specific gravity performed on the Thermo Scientific Indiko Plus from April 21, 2022, to September 19, 2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, procedures, product insert, and interview with general supervisor (GS) #1, the laboratory failed to follow their procedure to verify new lots of assayed drugs of abuse quality controls performed on the chemistry analyzer from April 21, 2022, to September 19, 2023. Findings: 1. A review of procedure "New Lot Quality Control Parallel Testing/Verification" revealed the laboratory failed to follow their procedure as stated: "run the assay with the current control set and run the new lot of control as unknowns for two consecutive days" and "verify the new control is within range for the new lot number". 2. No parallel testing or verification studies for new lots of MAS DOA TOTAL assayed drugs of abuse controls performed on the Thermo Scientific Indiko Plus chemistry analyzer for analytes Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Ethyl Glucuronide (EtG), Methadone Metabolite (EDDP), Opiates, Oxycodone, and Cannabinoid were available for review. 3. No parallel testing or verification studies for new lots of Fentanyl, Ecstasy (MDMA), THC, Hydrocodone, and Tamadol quality controls were available for review. 4. An interview with GS#1 on September 19, 2023, at 2:30 PM confirmed the laboratory failed to follow their procedure to perform

	parallel testing to verify new lots of assayed drugs of abuse controls for each analyte tested on the Thermo Scientific Indiko Plus from April 21, 2022, to September 19, 2023.