Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2027185	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Community Action Against Addiction	5209 Euclid Ave, Cleveland, OH	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of analytes not evaluated or scored by the College of American Pathologists (CAP) proficiency testing (PT) provider on five out of five Toxicology urine drug screen (UDS) testing events between 2021 and 2023. This deficient practice had the potential to affect 153,000 out of 153,000 patient toxicology testing procedures performed. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policy", approved by the Laboratory Director on 08 /28/2021 and provided for the inspection, found the following statement: "Any analyte not evaluated by the PT provider (due to lack of consensus, limited participants, a zero score for non-participation, or late return of results) will require further investigation and documentation." 2. Review of five out of five CAP PT events for the third event of 2021, the first, second and third events of 2022 and the first event of 2023 for the high complexity UDS testing revealed the following ungraded results without any documentation of self-evaluation: 2021 UDS-C UDS-14 Fentanyl-insufficient peer group 2022 UDS-A UDS-04 Fentanyl-insufficient peer group UDS-05 Benzodiazepine-lack of consensus UDS-B UDS-06 Fentanyl-insufficient peer group UDS-C UDS-13 Fentanyl-insufficient peer group 2023 DAI-A DAI-01 qual; pH, specific gravity-edu. chal. DAI-02 qual; pH, specific gravity-edu. chal. DAI-03 qual; pH, specific gravity-edu. chal. DAI; drug adulterant indicator qual; qualitative edu. chal.; educational challenge 3. The Inspector requested the laboratory's self evaluation

	documentation for the ungraded PT results listed above from the GS. The GS, via electronic mail (email) on 04/12/2023 at 1:39 PM, stated "Moving forward we will perform PT self-evaluation for samples not graded.".
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to take and document necessary quality control (QC) corrective actions to ensure the reporting of accurate and reliable high complexity patient urine drug screen (UDS) testing in the subspecialty of Toxicology when there were unusual QC shifts and trends. This deficient practice had the potential to affect 153,000 out of 153,000 patient UDS tests procedures performed between 10/6/2021 through 04/12 /2023. Findings Include: 1. Review of the laboratory's 2021, 2022 and 2023 QC documentation for the urine drug testing performed found QC results shifted above or below the mean with no evidence of any documented corrective action and patient testing continued to be performed. 2. Further review of the laboratory's 2021, 2022 and 2023 QC Levy-Jennings documentation revealed the following consistent ten or more QC data points shifted above (A) or below (B) the mean with review comments by TP#1 and TP#2 regarding trending above or below the mean target, as applicable, however no corrective action was documented: Oct Apr Jul Oct Jan Mar 2021 2022 2022 2022 2023 2023 Alcohol Level 1 A A A A A A Level 2 OK OK OK B B B Amphetamine Level 1 A A A A A A Level 2 B B B B B B Barbiturates Level 1 A A A A A A Level 2 B B B B B B Benzodiazepine Level 1 A A A A A A Level 2 B OK A A OK A Buprenorphine Level 1 OK OK OK A OK OK Level 2 OK OK OK OK OK OK Cannabinoid Level 1 A OK OK OK OK OK Level 2 OK B B B B B Cocaine Level 1 A A A A A A Level 2 B B B B B B Ecstasy Level 1 OK B B B B B Level 2 OK OK OK OK OK OK Heroin Level 1 OK OK A OK B OK Level 2 B B B B B B Methadone Level 1 A A A A A A Level 2 B B B B B B Opiates Level 1 A A A A A A Level 2 B B B B B B Oxy100 Level 1 A A A A A A Level 2 B B B OK B B Oxycodone Level 1 A A A A A A Level 2 B B B B B B Phencyclidine Level 1 A A A A A A Level 2 B B B B B B Oxidants Level 1 B B B B B B Level 2 OK OK A OK OK OK Urine pH Level 1 B B B B B B Level 2 A A A A A A Level 3 A A A A A A Level 4 OK OK OK OK B B Specific Gravity Level 1 OK OK OK OK OK OK Level 2 B B B B B B 3. The Inspector requested the laboratory's 2021, 2022 and 2023 documentation of QC corrective action from the GS. The GS stated, on 04/12/2023 at 1:39 PM "We have not had any corrective actions to report." and was unable to provide the requested documentation.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring

	that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate the competency of one out of two testing personnel (TP) in 2021 and 2022 to assure they maintained their competency to perform high complexity test procedures and report test results promptly, accurately, and proficiently. This deficient practice had the potential to affect 153,000 out of 153,000 patient urine drug screen (UDS) testing procedures performed in the subspecialty of Toxicology from 10/06/2021 through 04/12/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 03/01/2023, found one individual, the Laboratory Director, listed as the sole TS, one individual who was credentialed and listed as the sole GS and Testing Personnel (TP) #1 and one individual credentialed and listed as a TP (#2) only. 2. Review of the laboratory's policies and procedures requested and provided for the inspection did not find any instructions indicating who is responsible for assessing the competence of TP and the frequency of the TP competency assessments. 3. Review of the laboratory's 2021 and 2022 competency assessment documentation (2023 not completed yet), provided for the inspection, revealed TP#2 (not assigned a GS position by the Laboratory Director) assessed the competency of TP#1 on 08/19 /2021 and 08/26/2022 for the high complexity UDS testing procedures performed. 4. The GS confirmed, via electronic mail (email) on 04/12/2023 at 10:34 AM, that TP#2 was only listed as a TP on the CMS-209.