Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2117256	(X3) Date Survey Completed 07/09/2018
Name of Provider or Supplier Access Recovery Mental Health Services (Armhs)	**Street Address, City, State** 2727 W Cleveland Ave #204, Milwaukee, WI	
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) results and interview with testing personnel, the testing personnel have not attested to the routine integration of the PT samples into the patient workload using the laboratory's routine methods for events one or two in 2018. Findings include: 1. Review of PT records for the first and second events in 2018 show the attestation statements have not been signed by testing personnel. 2. Interview with the testing personnel on July 9, 2018 at 10:00 AM confirmed the attestation statements were not been signed by the individual testing the samples.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and procedures, and interview with testing personnel, the laboratory did not verify the accuracy of the

	opiate assay when the PT result was identified as non-consensus and has not included this requirement in their procedures. Findings include: 1. PT results from event one in 2018 showed the UD2 result for opiate was identified as non-consensus. The PT records show no evidence of evaluation of the result by the laboratory to verify accuracy of opiate test results. 2. Review of laboratory procedures for evaluation of PT results showed no requirement to evaluate not scored or non-consensus results. 3. Interview with testing personnel on July 9, 2018 at 10:00 AM confirmed the accuracy of the UD2 opiate assay PT result was not verified and that the laboratory procedures do not require evaluation of not scored and non-consensus results.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with testing personnel, the laboratory did not remove or identify as discontinued the "Supplies for Panel, Calibration, and Controls" procedure when a new version was initiated on May 18, 2018. Findings include: 1. Review of the laboratory procedure manual shows two versions of the "Supplies for Panel, Calibration, and Controls" procedures. One shows an initiation date of May 18, 2018. The two procedures are not the same, neither are identified as discontinued or have a discontinued date. 2. Interview with testing personnel on July 9, 2018 at 12:30 PM confirms there are two "Supplies for Panel, Calibration, and Controls" procedures and confirms the inactive procedure does not include a discontinued date.
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 surveyor observation of control materials, review of manufacturer's instructions, and interview with testing personnel, the laboratory used Drug of Abuse Total (DOAT) control material after the open expiration date of June 13, 2018 for level four and June 24, 2018 for level five. Findings include: 1. Observation of control materials in the laboratory refrigerator on July 9, 2018 at 9:45 AM revealed a bottle of DOAT 4 (Control level four) labeled 5/14 and a bottle of DOAT 5 (Control level five) labeled 5/25. 2. The DOA Total manufacturer's instructions state "Once opened, vials of control are stable for 30 days when stored tightly capped at 2 - 8 degrees C (Celsius)." 3. Interview with testing personnel on July 9, 2018 at 9:45 AM confirmed the bottles were opened on May 14, 2018 (DOAT 4) and May 25, 2018 (DOAT 5). Further interview confirmed the open bottles of DOAT 4 and DOAT 5 in the laboratory refrigerator were the control materials currently used for testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

	Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor observation of test systems in use in the laboratory and interview with the clinic CEO (Chief Executive Officer), the laboratory uses a test system for Ethyl Glucuronide (ETG) that has not been cleared or approved by the FDA (Food and Drug Administration) and the laboratory has not established performance specifications for the test. Findings include: 1. Observations of test systems in use in the laboratory on July 9, 2018 at 9:30 AM revealed an ETG Panel, Single Dip Test Card kit available for testing in the laboratory. The test kit was labeled "For Forensic Use Only". 2. Interview with the CEO on July 9, 2018 at 9:30 AM confirmed the ETG Panel was used for clinical testing and confirmed the laboratory had not established performance specifications for the test system prior to using it for patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review and comparison of procedures and maintenance logs, and interview with testing personnel, the laboratory has not performed and documented required maintenance for the Mindray BS 200. Findings include: 1. Review of the laboratory's "Maintenance - Mindray BS 200" procedure shows requirements for daily, weekly, monthly and every six month maintenance for the analyzer. 2. Comparison of the maintenance procedure and the laboratory checklist shows the following maintenance tasks are not included or documented on the checklist but are in the procedure: Daily: Check to ensure probe is not bent, dirty, containing remaining liquid, or clogged Check sample/reagent syringe Weekly: Clean analyzer unit panels Clean sample and reagent compartment Every six months: Clean analyzer dust screens Replace water tank filter assembly Replace cuvettes if necessary 3. Review of the checklists provided from May and June 2018 show testing was performed on seven days in May (2, 3, 9, 14, 15, 25, and 26) but weekly maintenance was only performed twice (9 and 25). The June checklist shows testing was performed five days (1, 12, 14, 22, and 28) and weekly maintenance was only performed twice (1 and 12). The checklists show no evidence of review by the technical supervisor. 4. Interview with testing personnel on July 9, 2018 at 12:00 PM confirms the weekly maintenance has not been performed as required and that the 'Every 6 month' maintenance required in the procedure is not included on the checklist and has not been documented.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory procedures, quality control (QC) records and patient reports, and interview with testing personnel, 49 patient opiate results were reported when control results did not meet the laboratory's criteria for acceptability on May 26, 2018. Findings include: 1. Review of the laboratory's "Quality Control Guidelines" revealed the following statement, "Quality Controls must be run, and in control to begin testing the daily patient samples. If the control is "out", DO NOT run samples until determining what causes the control to be out, and solving the irregularity." 2. Review of QC Data Summary reports for the Drugs of Abuse Total level 5 (DOAT 5) quality control material show the acceptable range for opiate is 2000 - 3000 ng/dL (nanograms per deciliter). The acceptable range for level 4 (DOAT 4) is 1200 - 1800 ng/dL. The reports show the following results from testing on May 25 and 26, 2018: May 25, 2018 10:52 AM DOAT 5: 3136.4 Flagged out of range, high 1:20 PM DOAT 4: 1866.3 Flagged out of range, high DOAT 5: 2755.2 May 26, 2018 1:21 PM DOAT 4: 1813.3 Flagged out of range, high DOAT 5: 3077.9 Flagged out of range, high 5:41 PM DOAT 4: 1751.4 DOAT 5: 3545.9 Flagged out of range, high 3. Review of patient test results reported on May 26, 2018 show 49 patient samples were tested and opiate test results were reported when controls were not acceptable. 4. Interview with testing personnel on July 9, 2018 at 12:45 PM confirmed opiate patient test results were reported when control results were not in the acceptable range as defined by the laboratory. Item 2: Based on surveyor review of laboratory procedures, quality control (QC) records, and patient reports, and interview with testing personnel, ethyl alcohol results were reported for 39 patients on March 9, 2018 when the high control results did not meet the laboratory's criteria for acceptability. Findings include: 1. Review of the laboratory's "Quality Control Guidelines" revealed the following statement, "Quality Controls must be run, and in control to begin testing the daily patient samples. If the control is "out", DO NOT run samples until determining what causes the control to be out, and solving the irregularity." 2. Review of the QC Data Summary for the high ethyl alcohol control show the control was tested once on March 9, 2018 at 1:54 PM. The acceptable range identified on the report is 240 - 360 mg/dL. The result obtained was 237.0. The result was flagged as out of range. There is no evidence the control was repeated on March 9, 2018. 3. Review of patient test reports shows ethyl alcohol results were reported on 39 patients tested on March 9, 2018. 4. Interview with testing personnel on July 9, 2018 at 12:45 PM confirmed ethyl alcohol patient test results were reported when control results were not in the acceptable range as defined by the laboratory.
D6181	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(6) Each individual performing high complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

	This STANDARD is not met as evidenced by: Based on surveyor review of ethyl alcohol corrective action, quality control (QC), and calibration records, and interview with testing personnel, all corrective actions taken were not documented when alcohol controls were not acceptable on two days of testing, March 2 and March 6, 2018. Findings include: 1. Review of corrective action records for March 2018 show both alcohol controls were out of range on two consecutive testing days; March 2 and March 6, 2018. The corrective action record created by the laboratory shows: March 2, 2018: both alcohol controls were out of range, both were rerun and in acceptable range. March 6, 2018: both alcohol controls were out of range, both were rerun and in acceptable range. The corrective action record does not show calibration of the ethyl alcohol test was performed in March. 2. Review of QC Data Summary reports show controls were tested on March 2 at 9:55 AM and 2:36 PM and on March 6, 2018 at 11:00 AM and 11:51 AM. 3. Review of calibration records show the ethyl alcohol test was calibrated between the two QC runs on March 2, 2018 at 1:48 PM and March 6, 2018 at 11:47 AM. 4. Interview with testing personnel on July 9, 2018 at 12:45 PM confirmed the corrective action log does not include all the corrective actions taken when controls were not acceptable.