| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D2117256 | 03/09/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Access Recovery Mental Health Services (Armhs) | 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 |
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| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>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).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency test (PT) records, procedures and previous survey plan of correction, and interview with the general supervisor, the laboratory did not evaluate non-consensus PT scores for opiates in one of three events in 2019. Findings include: 1. Review of PT records showed UD1 result for opiate was identified as non-consensus for 2019 event one. Further review showed no evidence of evaluation on the non-consensus score to verify accuracy of the opiate test results. 2. Review of the "Proficiency Testing" procedure stated, "Non-consensus or non-graded results from a proficiency test must be internally verified". 3. Review of the plan of correction submitted by the laboratory to address this same deficiency identified during the July 9, 2018 survey plan of correction showed the laboratory updated their procedure and assigned responsibility for monitoring the corrective actions to the general supervisor. 4. Interview with the general supervisor on March 9, 2020 at 9:28 AM confirmed the laboratory did not evaluate the accuracy of the UD1 result and the laboratory did not follow the "Proficiency Testing" procedure per the plan of correction. This is a repeat deficiency from July 9, 2018. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory |

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| | must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review and comparison of procedures and maintenance checklists, review of the previous survey plan of correction and interview with the general supervisor, the laboratory has not documented required maintenance for the Mindray BS 200 in 2019. Findings include: 1. Review of the laboratory's "Maintenance-Mindray BS 200" procedure showed requirements for daily, weekly, monthly, every three-month and every six-month tasks for the laboratory. 2. Review of the "Daily /Weekly Laboratory Checklist" showed requirements for daily, weekly, monthly and semi-annual tasks. Further review of the maintenance checklist showed the laboratory was not using the updated checklist from their previous survey plan of correction for their maintenance documentation. 3. 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: Ensure power cords are secured in the socket Check to ensure probe is not bent, dirty, containing remaining liquid or clogged Check sample/reagent syringe Weekly: Clean analyzer unit panels Clean sample/reagent compartment Every six months: Replace water tank filter assembly Clean analyzer dust screens Replace cuvettes, if necessary 4. Review of the plan of correction submitted by the laboratory to address this same deficiency identified during the July 9, 2018 survey showed the laboratory implemented a new maintenance checklist that includes all required maintenance, and the general supervisor is responsible for ensuring maintenance is completed. 5. Interview with the general supervisor on March 9, 2020 at 11:15 AM confirmed that not all tasks required in the procedure are included on the checklist and documentation was not available to show the laboratory completed the required maintenance. Further interview confirmed the laboratory did not implement the updated checklist per the previous survey plan of correction. This is a repeat deficiency from July 9, 2018. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of test reports, laboratory procedures and quality logs, and interview with the general supervisor, the laboratory did not follow the written procedure to monitor, assess and correct problems identified for one of five patients during comparison of internal and external reports in the June 2019 monthly quality assessment. Findings include: 1. Review of test reports for Patient 5 showed the amphetamine result reported by this laboratory and the reference laboratory are different. Internal laboratory report showed a positive amphetamine result. Reference laboratory report showed a negative amphetamine result. 2. Review of "Individual Quality Control Procedure" revealed each month the general supervisor gathers five to ten random finished tests from the laboratory records and checks off eight different parameters to ensure the testing quality. Further review revealed the laboratory is to log each result on to the spreadsheet and document corrective action for any |

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| | discrepancies. 3. Review of the June 2019 quality logs revealed the general supervisor reviewed the records to include Patient 5 and did not identify the discrepant results. Further review revealed no documentation of corrective action for the discrepant results. 4. Interview with the general supervisor on March 9, 2020 at 11:10 AM confirmed the laboratory did not document patient results on the quality log for five of five patients during the June 2019 quality review to include Patient 5 and did not identify the discrepant results. Further interview confirmed the laboratory did not document corrective action for the discrepant results. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of patient charts and interview with the general supervisor, the laboratory did not ensure delivery of test results to the final report destination for six of seven test reports in January and February 2020. Findings include: 1. Review of two patient charts showed the following test reports were not in the chart: Patient 1: five of five Patient 2: one of two Further review revealed two additional patient charts, Patient 3 and Patient 4, were not available. 2. Interview with the general supervisor on March 9, 2020 at 11:35 AM confirmed six of seven test reports were not available in Patient 1 and Patient 2 charts. Further interview confirmed Patient 3 and Patient 4 charts were unavailable. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Item 1 Based on surveyor review of patient reports and interview with the general supervisor, the laboratory did not ensure the test report included a patient identification number in addition to the patient name. Findings include: 1. Review of ten random patient test reports from February 2020 showed no evidence of a patient identification number on the patient reports. 2. Interview with the general supervisor on March 9, 2020 at 11:05 AM confirmed the test report did not have a patient |

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| | identification number in addition to the patient name. Item 2 Based on surveyor review of patient reports and test procedures and interview with the general supervisor, the laboratory did not ensure the test report contained the correct units of measure for five of six analytes in February 2020. Findings include: 1. Review of ten random patient test reports from February 2020 showed the units of measure as nanograms per deciliter (ng/dL) for opiate, cocaine, amphetamines, tetrahydrocannabinol (THC) and benzodiazepine. 2. Review of the opiate, cocaine, amphetamines, THC and benzodiazepine procedures showed the units of measure as nanograms per milliliter (ng/mL). 3. Interview with the general supervisor on March 9, 2020 at 11:05 AM confirmed the units of measure on the patient report were not accurate for five of six analytes. |