Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2128477	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Psychological Addiction Services Llc	3113 E Washington Ave, Madison, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's instructions, patient result reports, and interview with the technical consultant, the laboratory did not follow manufacturer's instructions for confirming positive toxicology test results. Findings include: 1. Review of Siemens Syva Emit II Plus Opiate Assay package insert states: "The Emit II Plus Opiate Assay provides only a preliminary test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result." 2. Review of patient reports show results of "Positive" with no confirmatory testing performed. 3. Interview with the technical consultant on December 5, 2018 at 2:30 PM confirms that toxicology results are reported as positive and confirmatory testing is not always performed as required by the manufacturer.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on surveyor review of Siemens V-Twin Operator Manual, laboratory policies, maintenance logs, and interviews with lab testing personnel, the laboratory has not monitored and documented room temperature and humidity as required. Findings include: 1. Review of Siemens V-Twin Operator Manual states that room temperature must be between 15-32 degrees Celsius, and humidity between 0-80%. 2. Review of laboratory "Quality Assurance Policy" states that room temperature and humidity must be monitored to assure acceptable levels according to manufacturer requirements. 3. Review of laboratory maintenance logs show no documentation of room temperature or humidity. 4. Interview on December 5, 2018 at 3:30 PM with two of two testing personnel confirms the laboratory does not monitor or document room temperature and humidity as required to ensure manufacturer requirements are met.
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 review of laboratory records and interview with lab testing personnel, the laboratory does not have a mechanism to document reagent, calibrator, and control lot number in-use dates to ensure expired supplies are not used for patient testing. Findings include: 1. Review of "Laboratory Reagent/Calibrator/Control Lot Numbers" log shows no record of dates when controls and calibrators are put into use. 2. Further review of "Laboratory Reagent/Calibrator/Control Lot Numbers" log show no reagents for the Siemens V-Twin chemistry analyzer are documented on the log. 3. Interview with both lab testing personnel on December 5, 2018 at 3:30 PM confirms that reagents, calibrators and controls for the Siemens V-Twin chemistry analyzer are not documented when they are put into use, therefore there is no mechanism to ensure expired reagents are not used for patient testing.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records of toxicology testing and interview with the technical consultant, the laboratory utilized calibration material of the same concentration and lot number used to calibrate the Siemens V-Twin chemistry analyzer as quality control material. Findings include: 1. Review of quality control records show the following calibrators were used on April 5, 2018 as control

	materials: *Calibrator Level 0 used for QC for Cocaine, Methadone, and Opiates analytes. *Calibrator Level 1 used for QC for Amphetamines analyte. *Calibrator Level 2 used for QC for Benzodiazepine, Opiates, and Tetrahydrocannabinol (THC) analytes. *Calibrator Level 3 used for QC for Amphetamines, Cocaine, and Methadone analytes. *Calibrator Level 4 used for QC for Benzodiazepine and THC analytes. *Calibrators 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine (EDDP) Low 225 and EDDP High 375 used for QC for EDDP analyte. *Calibrators 6-Acetyl Morphine (6 AM) Level 1 and 6 AM Level 3 used for QC for 6 AM analyte. 2. Interview with the technical consultant on December 5, 2018 at 3:00 PM confirms the laboratory used calibration material of the same concentration and lot number used to calibrate the Siemens V-Twin chemistry analyzer as quality control material.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of performance verification and proficiency testing records, and interview with the technical consultant, the laboratory director has not provided overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. Performance verification records were not approved before the start of patient testing. See D6013. 2. Proficiency testing reports were not reviewed to evaluate the laboratory's performance and identify problems. See D6018. 3. The laboratory did not have a qualified individual to provide technical oversight services to the laboratory for six months after patient testing began. See D6028.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of performance verification records and interview with the technical consultant, the laboratory director failed to ensure the verification procedures were adequate for the Siemens V-Twin chemistry analyzer prior to implementation for patient testing on March 29, 2018. Findings include: 1. Review of performance verification records for the Siemens V-Twin analyzer show no evidence the lab director approved, signed, or dated the verification of performance specifications for the test system prior to implementation for patient testing on March 29, 2018. 2. Interview with the technical consultant on December 5, 2018 at 11:00

	AM confirms the lab director did not evaluate and approve the accuracy, precision, reportable ranges, and reference intervals as part of the performance verification for the Siemens V-Twin analyzer.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory director did not review PT reports for the second toxicology event in 2018 to evaluate the laboratory's performance and identify any problems that require corrective action. Findings include: 1. Review of PT results for the second toxicology event of 2018 for specimen UD-3 shows the laboratory scored 50%, with an unacceptable result for 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine (EDDP). The acceptable result was negative and the lab reported the result as positive. 2. Review of PT records show result submission due date was May 18, 2018. The laboratory director did not review and sign the PT results until November 11, 2018. 2. Interview with the technical consultant on December 5, 2018 at 10:00 AM confirms the laboratory director did not review the proficiency testing report before November 11, 2018 to evaluate the laboratory's performance and identify needed corrective actions.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on surveyor review of laboratory patient test results, quality control, proficiency testing and competency assessment records, and interview with testing personnel and the technical consultant, the laboratory director did not employ a qualified technical consultant to provide technical oversight for six of nine months in 2018. Findings include: 1. Review of patient test results show patient testing began March 29, 2018. 2. Review of quality control, proficiency testing, and competency assessment records show no evidence of review before November 1, 2018. 3. Interview with two of two testing personnel and the technical consultant on December

	5, 2018 at 3:30 PM confirms the technical consultant was hired October 1, 2018, and there was no qualified technical consultant available to provide technical consultation services since patient testing began on March 29, 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of competency assessment records, patient test records, quality control records, proficiency testing results, and maintenance records, and interview with the technical consultant and testing personnel, the laboratory did not have a qualified individual to provide technical oversight in accordance with 493.1413 of this subpart for six of nine months in 2018. Findings include: 1. The laboratory did not have a qualified individual to review quality control records, proficiency testing results, or maintenance records for six months after patient testing began. See D6036. 2. The laboratory did not have a qualified individual to evaluate the competency of testing personnel before implementation of a new test system. See D6053.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant and testing personnel, the technical consultant has not provided technical oversight of the laboratory for six of nine months in 2018. Findings include: 1. Review of QC records, PT results, maintenance logs, and the Siemens V-Twin chemistry analyzer performance verification records shows no documented review of the records from March 29, 2018 through November 1, 2018. 2. Interview with the technical consultant and two of two testing personnel on December 5, 2018 at 2:00 PM confirms the review of QC records, PT records, maintenance logs, and the Siemens V-Twin chemistry analyzer performance verification records had not been documented for six of nine months in 2018; and technical and scientific oversight of the laboratory had not been provided.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor review of patient test records and competency assessment

	evaluations, and interview with the technical consultant, the technical consultant did not evaluate and document the performance of testing individuals at least semiannually during the first year of patient testing. Findings include: 1. Review of patient test records show patient testing began March 29, 2018. Review of competency assessment records for two out of two testing personnel show no documentation of initial competency assessment. The technical consultant performed the initial competency assessment on November 28, 2018. 2. Interview with technical consultant on December 5, 2018 at 9:30 AM confirms an initial competency assessment for the lab testing personnel was not performed.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and interview with the technical consultant, the monthly maintenance for the Siemens V Twin chemistry analyzer was not documented as performed for four out of nine months in 2018. Findings include: 1. Review of the Siemens V-Twin maintenance logs shows no documentation of monthly maintenance performed for July, August, September and November 2018. 2. Interview with the technical consultant on December 5, 2018 at 3:30 PM confirms the monthly maintenance for the Siemens V Twin chemistry analyzer was not documented as being performed for four of eight months in 2018.