

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2128477	<b>(X3) Date Survey Completed</b>  12/16/2020
<b>Name of Provider or Supplier</b>  Psychological Addiction Services Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2011</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory director, the laboratory's procedure for proficiency testing (PT) did not specify the samples may be used to assess competency and did not specify discussing results with additional staff at another laboratory after the submission deadline to prevent referral of proficiency testing. Finding include: 1. Review of the "Quality Assessment Policy" under Proficiency testing showed the following statements: a. "In addition, results may not be discussed with staff at another laboratory until results have been submitted to the PT agency". b. "Residual PT specimens may be used to assess the competency of testing personnel". 2. Interview with the laboratory director on December 16, 2020 at 10:45 AM confirmed the procedure was not specific in referencing the submission deadline to prevent referral of proficiency testing.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory did not maintain documentation of their calibrator lots on the "PAS Calibrator Lot Log" to ensure expired supplies are not used for patient testing from April 2019 through December 2020. Findings include: 1. Review of the "PAS Calibrator Lot Log" showed the laboratory did not document: a. Specialty Drug Calibrator one through four after Start date of September 15, 2019 with an expiration date of October 24, 2020. b. Drugs of Abuse (DAU) Calibrator Level two after Start date of April 26, 2019 with an expiration date of July 5, 2019. c. Drugs of Abuse (DAU) Calibrator Level five after Start date of April 26, 2019 with an expiration date of July 24, 2019. d. Methadone metabolite (EDDP) Calibrator two after Start date of January 8, 2020 with an expiration date of March 31, 2020. 2. Interview with the laboratory director on December 16, 2020, at 10:45 AM confirmed the laboratory did not maintain documentation of the calibrator lots from April 2019 through December 2020. This is a repeat deficiency from December 5, 2018.