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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>05D0642561   | <b>(X3) Date Survey Completed</b><br>11/02/2021 |
| <b>Name of Provider or Supplier</b><br>Psychemedics Corporation  | <b>Street Address, City, State</b><br>5832 Uplander Way, Culver City, CA |   |
| 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>   |
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| <b>D5801</b>              | <p>TEST REPORT<br/>CFR(s): 493.1291(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on Surveyor review of laboratory's policy &amp; procedure, patients test records /reports and interview with the laboratory technical consultant on November 2, 2021 at 11:50 am, the laboratory failed to report the test results of 1 patient out of 3 patients, reviewed. The findings include: 1. The laboratory's urine screening daily worksheet showed it performed urine drug screen testing for patient # 710017233 using an automated MGC-240 instrument on March 03, 2021. The test results showed that the patient sample was positive for Opiates and THC. However, the laboratory reported the results as unable to complete. Therefore, the laboratory's failure to report test results accurately might had caused patient harm. 2. The laboratory technical consultant on November 2, 2021 at 11:50 am, affirmed that the laboratory reported the test results as unable to complete. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/29/2021, stated that the laboratory performs 125 tests, annually.</p> |
| <b>D6004</b>              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(a)(b)</p>   |

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, patients test records /reports and interview with the laboratory technical consultant on November 2, 2021 at 11:50 am, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D5801.

**D6068**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, patients test records /reports and interview with the laboratory technical consultant on November 2, 2021 at 11:50 am, the laboratory testing person #1 failed to report the test results for patient # 710017233. The findings include: See D5801.