

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2110381	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Ideal Option, Pllc	Street Address, City, State 2685 Palmer Street Suite D, Missoula, MT	
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
D0000	Based on an on-site initial survey conducted on 8/29/18, deficiencies were cited for Ideal Options PLLC in Missoula, MT.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign approval of four policies and procedures from 11/2/17 through 8/29/18. The findings include: 1. A review on 8/29/18 at 9:50 a.m. of the Ideal Options policies and procedures on the computer included four not signed by the Laboratory Director. a. Quality Improvement. b. Quality Management. c. Proficiency Testing. d. Equipment Preventive Maintenance Program. 2. On 8/29/18 at 11:15 a.m., staff member C stated the policies and procedures should be signed by the Lab Director.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the laboratory failed to establish accuracy through the entire reportable range for six of nine new analytes. The findings include: 1. On 8/29/18 at 8:00 a.m., a Siemens V-twin analyzer was observed in the laboratory. 2. A review on 8/29/18 at 9:25 a.m. of the Siemens V-twin validation binder included a Method Comparison Concordance Table, which compared the accuracy of the V-twin positive and negative results to the Beckman Coulter AU640 chemistry analyzer. Six analytes lacked documentation of the accuracy of either the positive or negative reference range. a. Barbiturates lacked accuracy verification of positive results. b. Benzodiazepines lacked accuracy verification of positive results. c. Buprenorphine lacked accuracy verification of negative results. d. Cocaine metabolite lacked accuracy verification of positive results. e. Methadone lacked accuracy verification of both positive and negative results. f. Oxycodone lacked accuracy verification of positive results. 3. On 8/29/18 at 11:10 a.m., staff member C stated known patient samples were used to verify the entire reportable range and if the laboratory did not have both positive and negative samples, they did not run them.

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 record review and interview, the technical consultant failed to evaluate competency semiannually for two of two testing personnel. The findings include: 1. A review on 8/29/18 at 8:40 a.m. of the competency evaluations for staff members A and B lacked documentation of a six month competency assessment after initial training. 2. On 8/29/18 at 8:50 a.m., staff member C stated the competency was missing because only one staff member is present for testing at a time.