

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2133733	(X3) Date Survey Completed 10/29/2019
Name of Provider or Supplier Ideal Option Plc	Street Address, City, State 265 Mill Street Suite 100, Hagerstown, MD	
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
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> <p>This STANDARD is not met as evidenced by: A. Based on record review, the laboratory did not have the laboratory director review and approve verification studies for pH and buprenorphine precision studies. The precision study worksheets for these two analytes included a place to document the laboratory director review and approval of the study results and the "accepted by" line on the worksheet was not filled in. B. Based on record review, the laboratory did not have the laboratory director review and approve verification studies for pH and creatinine method validation studies. The method validation study worksheets for these two analytes included a place to document the laboratory director review and approval of the study results and the "accepted by" line on the worksheet was not filled in.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must</p>

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on record review, the laboratory did not take corrective action as described in the laboratory written procedure. Findings: 1. On August 1, 2019, July 31 and 3, 2019, the creatinine quality control failed to meet the laboratorys criteria for acceptability; 2. The laboratory director approved the test run, even though the quality control results failed to meet the laboratorys criteria for acceptability for creatinine; and 3. The laboratorys written procedure instructs staff to perform troubleshooting procedures and document these actions, these troubleshooting steps were not documented and instead the laboratory director determined that the quality control reagent was substandard and accepted the failed quality control results prior to patient testing.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on observation, the laboratory technical consultant did not perform a six month competency check on Testing Person #1. Findings: 1. Testing Person #1 was trained and approved to perform testing in July 2018; and 2. The laboratory did not have a record of a competency check performed at six months.