

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2039314	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier E. Carwile Leroy, Jr., Md, Inc.	Street Address, City, State 6594 N First St, Ste 103, Fresno, CA	
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:</p> <ul style="list-style-type: none"> . Based on observation of the Siemens Syva Viva Jr toxicology analyzer (serial number 148825), review of the laboratory document titled, "Accuracy / Precision" (approved August 2018), and test records; the lack of records, and interview with laboratory personnel, it was determined that the laboratory failed to verify test performance specifications and the establishment of Cutoff Concentrations for Ethanol (EtOH), 6-AcetylMorphine (6-AMorphine), Amphetamine, Benzodiazepines, Cocaine, Methadone, Opiate, and THC. Findings included: a. The laboratory tested EtOH Low Control for which the manufacturer stated the Concentration as 36 - 44 mg /dL. Although the laboratory obtained results within the stated range of concentrations, only 6 out of 27 results reported as Positive with the remaining 21 reported as Negative. b. The laboratory used Level 4 to verify Positive results for 6-AcetylMorphine (6-AM), and Level 5 to verify Postitive results for Amphetamine and Benzodiazepines. No testing was performed to verify the Accuracy and Precision of obtaining Positive results for the following drugs: Cocaine Methadone Opiate THC c. The document failed to address the determination of all Cutoff Concentrations stated on patients Urine Drug Testing Reports for reporting results as Negative or Positive. d. Although the laboratory failed to completely demonstrate that it could perform testing comparable to the manufacturer's performance specifications, it began

reporting patients test results in December 2018. And thus, the reliability and quality of results reported could not be assured. Based on the stated annual tests volume, the laboratory reported approximately 133,333 results from December 2018 to present (8 /14/19). A few examples are as follows: Date ID ----- 12/03/18 HF 12/04/18 RG 12/05/18 LD 1/07/19 JD 2/04/19 SS 3/25/19 ES .

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 survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure that test verification procedures were adequate to determine the assay cutoffs, accuracy, and precision of negative and positive results for each drug test. See D5421.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
. Based on survey findings and deficiency cited, the Technical Consultant is herein cited for deficiency in responsibility for providing technical and scientific oversight of toxicology testing, specifically verifying that testing personnel can obtain reliable negative and positive results for all drug tests with accuracy and precision (reproducibility) comparable to the test performance specifications established by the manufacturer. See D5421.