| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 19D2108253 | 03/01/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Stone Clinical Laboratories, Llc | 615 Baronne St, Ste 100, New Orleans, LA | |

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** | A REVISIT Survey was performed at Stone Clinical Laboratories, LLC, CLIA ID # 19D2108253, on through March 1, 2018. Stone Clinical Laboratories, LLC was found not in compliance with the follo LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 42 CFR CONDITION: Analytic Systems 42 CFR 493.1409 CONDITION: Laboratories performing moderate Technical Consultant 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testi Director<br><br>11040 A Validation/Complaint Survey was performed at Stone Clinical Laboratories, LLC - CLIA 19 9, 2017 through May 12, 2017. Stone Clinical Laboratories, LLC was found not in compliance with t CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patien laboratory: 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1250 CONDITION: A CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director CONDITION: Laboratories performing high complexity testing, Technical Supervisor 42 CFR 493.1 Laboratories performing high complexity testing, General Supervisor 42 CFR 493.1487 CONDITION performing high complexity testing, Testing Personnel 42 CFR 493.1771 CONDITION: Inspection |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I c approved by HHS. The laboratory must enroll in an approved program or programs for each of the sp subspecialties for which it seeks certification. The laboratory must test the samples in the same manne specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) p 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on F |

through March 1, 2018. Based on observation, record review, and interview with personnel, the labor
in a HHS approved proficiency testing program for Chemistry and Immunology testing. Findings: 1. (
surveyors during laboratory tour on February 28, 2018 revealed the laboratory utilizes the following i
Chemistry and Immunology testing: a) Siemens Dimension Vista 500: utilized for testing of Sodium,
Chloride, Carbon Dioxide, Blood Urea Nitrogen, Creatinine, Glucose, Total Calcium, Total Protein, A
Bilirubin, Direct Bilirubin, Alkaline Phosphatase, Aspartate Aminotransferase, Alanine Aminotransfe
Glutamyltransferase, Magnesium, Phosphorus, Uric Acid, Total Cholesterol, Triglycerides, High Den
Low Density Cholesterol, Total Creatine Kinase, Iron, Total Iron Binding Capacity, Ferritin, Vitamin
A1c, High Sensitivity C-Reactive Protein, Total Testosterone, Beta Human Chorionic Gonadotropin,
Hormone, Follicle-Stimulating Hormone, Progesterone, Prolactin, Thyroid Stimulating Hormone, Fre
(T3) , Free Thyroxine (T4), Thyroid Uptake, Rheumatoid Factor, Apolipoprotein A1, Apolipoprotein
terminal pro-Brain Natriuretic Peptide, Cardiac Troponin I, C-Reactive Protein, Amylase, Lipase, Tra
Immunoglobulin A, Immunoglobulin E, Immunoglobulin G, Immunoglobulin M, Complement C3, C
Lithium, Carbamazepine, Phenytoin, Digoxin, Random Urine Creatinine, Random Urine Total Protei
Urine Microalbumin. b) Siemens Centaur XP: Vitamin D, Cortisol, Dehydroepiandrosterone sulfate,
Homocysteine, Prostate Specific Antigen, Intact Parathyroid Hormone, Sex Hormone-Binding Globu
Thyroid Peroxidase Antibody, Thyroglobulin Antibody, and Cyclic Citrullinated Peptide Antibody Ig
laboratory's proficiency records for 2018 revealed the laboratory did not have documentation of enrol
interview on February 28, 2018, Personnel 10 stated the laboratory's payment for proficiency testing
College of American Pathologists (CAP) was submitted February 16, 2018. Personnel 10 further state
with CAP a confirmation letter for enrollment will not be issued until payment has been processed. 4.
March 1, 2018 at 10:44 am, Personnel 2 stated the laboratory began patient testing on the Siemens Di
Centaur instruments on December 1, 2017.