Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2108253	11/16/2018
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to follow their laboratory policy to verify the accuracy of all non-regulated analytes at least twice annually. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed the following: a) The laboratory will enroll in PT for every regulated analyte performed in-house and for every unregulated analyte performed in-house if PT is readily available. b) The laboratory will perform split sample analysis twice yearly for unregulated analytes when PT is not available. 2. Review of the laboratory's Task 1 and 3 Form submitted to surveyors on November 13, 2018 revealed the laboratory performed Urine Toxicology Confirmation testing which includes: 6-MAM, 7-Aminoclonazepam, Alpha hydroxyalprazolam, Amitriptyline, Amphetamine, Benzoylecgonine, Buprenorphine, Carisoprodol-SOMA, Citalopram, Codeine, Cyclobenzaprine, Desmethyldoxepin, Duloxetine, EDDP, Fentanyl, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Ketamine, Lorazepam, MDA, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Mirtazapine, Morphine, Naloxone, Naltrexone, Norbuprenorphine, Nordiazepam, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone, Nortriptyline, O-Desmethyl-Cis-Tramadol, Oxazepam, Oxycodone, Oxymorphone, Paroxetine, Phencyclidine-PCP, Phentermine, Pregabalin, Propoxyphene, Sertraline, Tapentadol, Temazepam, THC-11-Nor-Delta-9-Carboxy, Tramadol, Venlafaxine, Zolpidem, 2-hydroxyethylflurazepam, 6-Beta-Naltrexol, 7-AminoFlunitrazepam, Carbamazepine, Desipramine, Diazepam, Hydroxybuproprion, Imipramine, MDEA, MDPV, Mephedrone, Mitragynine, N-Demethyltapentadol, Ritalinic Acid, Zaleplon, Zopiclone, EtG, EtS, Amobarbital, Butabarbital, Butalbital, Pentobarbital,

	Phenobarbital,, and Secobarbital. 3. Interview with Personnel 3 and 15 on November 16, 2018 revealed the laboratory had written policies and procedures for performing split sample testing twice a year for Urine Toxicology Confirmation Testing. Personnel 15 also revealed the laboratory had not implemented the twice a year testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. I. Based on observation, record review, and interview with personnel, the laboratory failed to have performance specification verification studies for the BioFire FilmArray system. Findings: 1. In interview on November 13, 2018, Personnel 15 stated the laboratory installed a BioFire and began patient testing on April 24, 2018. 2. Observation by surveyors on November 13, 2018 revealed the laboratory utilizes the following: a) BioFire FilmArray Respiratory Panel 2 (RP2) for identification of the following: Adenovirus, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A (including subtypes H1, H1-2009, and H3), Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma, pneumoniae. b) Gastrointestinal (GI) Panel for identification of the following: Campylobacter (jejuni, coli, and upsaliensis), Clostridium difficile (toxin A/B), Plesiomonas shigelloides, Salmonella, Yersinia enterocolitica, Vibrio (parahaemolyticus, vulnificus, and cholerae). Vibrio cholerae, Enteroaggregative E. coli, Enterpathogenic E. coli, Enterotoxigenic E. coli, Shiga-like toxin-producing E. coli, E.coli 0157, Shigella/Enteroinvasive E. coli, Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (I, II, IV, and V). 3. Review of the laboratory's BioFire records revealed the laboratory did not have documentation of performance verification studies: to include accuracy, precision (run-to-run, day-to-day, within run, and operator variance), reportable and reference range studies, acceptability criteria and Laboratory Director's signature of approval. 4. In interview on November 16, 2018, Personnel 8 stated the previous Laboratory Director had the validation studies for the BioFire. Personnel 8 confirmed the laboratory did not have performance verification studies for the BioFire. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 315,000 respiratory and 330,000 GI testing annually. II. Based on record review and interview with personnel, the laboratory failed to have complete performance specification verification studies for valproic acid. Findings: 1. In interview on November 16, 2018 at 10:11 am, Personnel 16 stated the laboratory added valproic acid to the Siemens Dimension Vista 500 on October 4, 2018. 2. Review of the laboratory's validation records for valproic acid did

	not include the following: a) accuracy, reportable range, and reference range studies b) Laboratory Director's approval/signature 3. In interview on November 16, 2018, Personnel 8 confirmed the laboratory did not include the identified items in their validation records. 4. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 12,000 valproic acid tests annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on observation, record review and interview with personnel, the laboratory failed to perform a positive and negative control each day of patient testing for the Biofire Filmarray Gastrointestinal (GI) Panel and Respiratory Panel (RP) performed on the Biomereaux BioFire Filmarray Analyzer for thirty one (31) days of thirty one (31) days reviewed. Findings: 1. Observation by surveyor on November 13, 2018 revealed the laboratory utilized the Biomereaux Biofire System for the reporting of 2 Panels: a) GI Panel for: Campylobacter (jejuni, coli, and upsaliensis), Clostridium difficile (toxin A/B), Plesiomonas shigelloides, Salmonella, Vibrio (parahaemolyticus, vulnificus, and cholerae), Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt /st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E.coli O157, Shigella /Enteroinvasive E coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F 40/41, Astrovirus, Norovirus GI/ GII, Rotavirus, and Sapovirus. b) Respiratory Panel for: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H3, Influenza A/H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza virus 3, Parainfluenza 4, and Respiratory Syncytial Virus (RSV). 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures for Quality Control for the GI and RP Panels performed on the Biomereaux BioFire Filmarray Analyzer. 3. Review of Patient Test Records from July 13, 2018 through November 12, 2018 revealed the following fifty one (51) patient samples were tested and reported on twenty nine (29) patient test days without performing a positive and negative control each day of patient testing. a) For the GI Panel: On July 13, 2018 Patient 1. On July 18, 2018 Patient 2. On July 20, 2018 Patient 3. On July 23, 2018 Patient 4. On July 26, 2018 Patients 6 and 11. On August 1, 2018 Patient 8. On August 2, 2018 Patients 7 and 15. On August 10, 2018 Patients 9 and 14. On August 14, 2018 Patient 5. On August 15, 2018 Patient 13. On August 17, 2018 Patient 12. On August 31, 2018 Patient 16. On September 18, 2018 Patient 10. b) For the Respiratory Panel: On July 19, 2018 Patients 18, 20, 21, 22, 23, and 38. On July 20, 2018 Patient 42. On July 24, 2018 Patients 19, 30. On July 27, 2018 Patient 24. On July 31, 2018 Patients 32, 33, 34, 35, 36, 46, 47, and 48. On August 2, 2018 Patient 37. On August 21, 2018 Patient 31. On August 25, 2018 Patient 43. On September 11,

	2018 Patients 40, 49, 50, and 51. On September 18, 2018 Patients 17, and 39. On September 25, 2018 Patient 27. On September 26, 2018 Patient 26. On October 18, 2018 Patient 41. On October 27, 2018 Patients 25, and 29. On November 2, 2018 Patient 28. On November 12, 2018 Patients 44, and 45. 4. Interviews with Personnel 8, 15 and 16 revealed after the installation studies were completed on the Biomerieux BioFire Filmarray Analyzer on April 24, 2018 and that the laboratory has performed no external Quality Control. Personnel 8, 15 and 16 confirmed that all patients were tested and reported for GI or RP Panel performed on the BioFire Filmarray Analyzer without having any external quality control performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on review of the laboratory's Plan of Correction (POC), observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022.
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: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421 I and D5421 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform a positive and negative control each day of patient testing for the Biofire Filmarray Gastrointestinal (GI) Panel and Respiratory Panel (RP) performed on the Biomereaux BioFire Filmarray Analyzer for thirty one (31) days of thirty one (31) days reviewed. Refer to D5449. 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing for twenty four (24) of twenty four (24) lot numbers as required by the manufacturer. Refer to D5469 II.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on review of the laboratory's Plan of Correction (POC), observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: A REVISIT Survey was performed at Stone Clinical Laboratory LLC, CLIA ID # 19D2108253, on November 13, 2018 through November 16, 2018. Based on record review and interview with personnel, the Technical Supervisor failed to evaluate and document the performance of individuals at least semi-annually during the first year

	for twelve (12) of twelve (12) testing personnel reviewed. Findings: 1. Review of the laboratory's"Evaluation & Competency" policy revealed the each new employee is evaluated semi-annually for the first year. 2. Review of personnel records revealed the laboratory did not have documentation of performance of a semi-annual competency assessment for the following twelve (12) personnel: Personnel 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13 and 14. 3. Interviews with Personnel 3, 8, and 15 on November 16, 2018 confirmed the laboratory did not perform a semi-annual competency assessment for the personnel cited above.