Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0699865	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Spectra Clinical Laboratory	5160 Campus Dr, Newport Beach, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of proficiency testing enrollment/report and interviews with technical consultants (on 5/25/2018, at 10:00 A.M.), the laboratory failed to enroll in an approved proficiency testing program for the analyte creatinine. Findings include: a. The laboratory did not have proficiency enrollment/report for their creatinine test. b. Two technical consultants affirmed that the laboratory was not enrolled in a HHS approved proficiency testing program for the creatinine test. c. The laboratory receives approximately 50,000 urine samples/annually for toxicology testing. Each urine sample is testsed for creatinine and the result is reported, even though the laboratory failed to enroll in a HHS approved proficiency testing program.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the procedure manual and interview with technical consultants (on 5/25/2018, at 10:45 A.M.), the laboratory failed to identify the specific laboratory in which peer comparison studies for the laboratory's pH and specific gravity tests would be compared with. Findings included: a. The laboratory procedure manual described the procedural steps for the pH and specific gravity tests. The participating laboratory was not named. b. The technical consultant affirmed that the name of the peer laboratory (Genex Laboratories, Inc.) was not documented in their procedure manual. c. The laboratory annually tests approximately 50,000 urine specimen for pH and specific gravity tests, even though no laboratory was identified in their procedure manual as the one used to verify the accuracy of the these tests.
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: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of proficiency testing records and interview with technical consultants, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For the analyte, creatinine, the laboratory failed enroll in a HHS approved proficiency testing program. (See D2000)