Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2139769	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vivo Spectrum Laboratory	1050 Iron Point Rd, Ste 200, Folsom, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the technical consultant and the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Sysmex SX 1000i hematology analyzer to perform Completed blood Cells count (CBC) including WBC (White blood cell count) with automated cell differentials including Basophiles (Ba). Eosinophiles (Eo), Lymphocytes (Ly), Monocytes (Mo) and Neutrophiles (Ne). b. The laboratory enrolled its CBC with American Proficiency Institute (API) PT programs. c. The laboratory attained scores of 0 % for differentiate cells, Ba, Eo, Ly, and Ne in the 3rd 2017 PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory attained scores of 40 % for differentiate cell, Mo in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event. e. The laboratory performed in approximately 400 patient samples monthly. f. The laboratory affirmed (10/23/2018 @ 12:30 PM) that the laboratory failed to attain scores of at least 80 percent of acceptable responses for each WBC cell differentials in the 3rd 2017 testing event were unsatisfactory analyte performance for the testing event.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the facility, review of the laboratory's records, written policies and procedures (P&P), and interview with the technical consultant, and the testing personnel, it was determined that the laboratory failed to understand the the features of the digital thermometer functions, and temperature settings and failed to follow its written policies and procedures. The findings included: a. The laboratory established and set the acceptable/optimal temperature ranges to store the laboratory reagents, patient samples, and laboratory supplies at 2 -8 oC and 0 to -20 oC for the refrigerator and the freezer, respectively. b. The laboratory used digital thermometers equipped the following features which offer the following temperature information: current, a "Min and Max" mode for the temperature sometime past, a "Lo and Hi" mode for the setting of range, so it will trigger the alarm to set off to warn, if the current temperature outside of the acceptable ranges. c. A setting of the acceptable temperature range noted for a freezer on the chart was -10 to -20 oC, which is inconsistent with the setting in the written P&P, (0 to -20 oC). d. A Max temperature shown in a digital thermometer was -2 oC which was outside of the -10 to -20 oC setting, but not out according to written P&P (0 to -20 oC), at the time of the survey (10/23/18 @ 12:15 PM) e. A setting of the acceptable temperature range for a refrigerator was 10 oC for Lo, 30 oC for Hi were noted f. The laboratory turned off the "Alarm" feature to "Off" position, so no alarm could constantly ring, when out of the acceptable range.
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: Based on review of the laboratory's validation of the new instrument, and interview with the laboratory consultant and the testing personnel, it was determined that the laboratory failed to be responsible and demonstrate that it could verify the performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy, (B) Precision, (C) Reportable range of test results for the test system, (D) to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings included: a. The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results. b.

	Based on review of the validation records for the Sysmex XS 1000i, a Completed Blood Cells Count analyzer, the validations were performed by the manufacture representative. c. The validation data for accuracy and precision evaluation were obtained and performed from a manufacturer's representative and within one day run only by using commercial materials. d. Since the validation was verified by manufacturer's representative, the laboratory must demonstrate that this verification correlates with its in-house test performance.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of the facility, review of the laboratory documents, and interview with the technical consultant, and the testing personnel, it was determined that the laboratory failed to be 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. The findings included: See D-5413, D-5421 and D-6016
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 the laboratory's proficiency testing (PT) result reports, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2121