Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2094015	03/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vedanta Laboratories, Inc	1020 Calle Recodo, San Clemente, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory records, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to select and perform temperature monitoring system in the blood storage freezer, and an incubator in testing systems. The findings included: a. In the sample processing area, a freezer was assigned for blood sample storage, the acceptable temperature for the storage condition was set between - 10 to - 20 oC. b. At the time of the survey @ 10:45 AM, a digital thermometer by Fisher had seen the records with Min - 22 while Max -14 oC which indicated that at some ago, there was a storage condition (-22 oC) was out of the acceptable temperature range of - 10 to - 20 oC. c. There was no indication of the laboratory had taken actions to correct or remedial the problems. d. The laboratory technical consultant affirmed (03/01/18 @ 10:50 am) that the out of range condition was not noticed. e. An incubator was used for glucuronization procedure. A digital and a traditional thermometer were used to monitor the temperature of the incubator. f. The digital thermometer has features of "out" and "in" temperatures. f. The digital thermometer for the incubator at the time of survey (@ 3:15 PM) had numbers shown 54 for "out" and 24 for "in". g. The laboratory staff can not explain what these numbers, 54 and 24 oC are, but stated that the two thermometer probes were install reversibly.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff and the technical consultant, it was determine that the laboratory failed to use different lot number of the same calibration materials when preparing a control material. The findings included: a The laboratory purchased its calibration materials from Cerillien and prepared its calibration and control materials out of the Cerillient product. b. The laboratory prepared both the calibrators and quality controls out of the the same lot number. c. The laboratory failed to use different lot of the calibration material or purchase the quality control materials from different vendors. d. The laboratory consultant affirmed that the laboratory did not use different lot number to prepare for calibration and quality control materials.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, or instruments, and document all test result comparison activities. The findings included: a. The laboratory used Sysmex XS-1000i to provide WBC with automated cell differential, RBC, Hemoglobin, Hematocrit and platelet count. b. The laboratory established a criteria of WBC and other parameters to perform a MANUAL WBC cell differentials. c. There was no evidence that the laboratory had established the written policies and procedures to perform "Comparison of test results" and documented all test result comparison activities.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on observations, review of the laboratory's records, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to document all corrective actions taken when test systems, thermometers, do not meet the laboratory's verified or established performance specifications. The findings included: See D-5411
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's requisition forms, and patient test result reports, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to provide consistent result reports with the patient medical history provided by the ordering physicians. The findings included: a. The laboratory's requisition form does provide area for the ordering physicians to provide patient medical history. b. The laboratory did not enforce that the order physician provide complete medical history pertaining the medical prescribed. c. The laboratory's patient test result reports provide the test results and interpretation with "consistence" or "inconsistence". d. Review with 3 patient results reports, no patient prescribed medication were provided by the ordering physicians. e. Without the provided patient prescribed medications, how can the laboratory indicated that the test results were "consistence" or "inconsistence".
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) result reports, and interview with the laboratory staff and the technical consutant, it was determined that the laboratory director failed to ensure and review all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings included: a. The laboratory used a Beckman AU 640e to perform the validity of the urine specimen as well as ETG (gluconized ethyl alhocol). b. The laboratory employeed three units of

	Aligilant 6460, LC/MS/MS for direct urine screen and confirmation when any drug analyte was detected and confirmed with concentration. c. In order to ensure the accuracy of their testing systems at least twice annually, the laboratory electected to enroll UT and DMPM PT testing offered by CAP (College of American Pathologists) and API (American Proficiency Institute) PT programs, as well as using alternative methods to evaluate with other CLIA certified laboratory for result comparisions. b.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5411, D-5467, D-5778, D-5781 and D-5805