Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2053446	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Us Specialty Labs	11578 Sorrento Valley Rd Ste 27, San Diego, 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
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 laboratory staff and QA 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 was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed endocrinology testing including T3 Uptake, Triiodothyroxine (T3). b. In order to ensure and verify the accuracy of the testing systems, the laboratory enrolled its PT with CAP (College of American Pathologists) PT program for endocrinology testing. c. The laboratory attained a score of 40% for T3 Uptake in the 1st 2016 PT challenge, which was unsatisfactory analyte performance for the PT event. d. The laboratory attained a score of 0% for T3 in the 3rd 2017 PT challenge, which was unsatisfactory analyte performance for the PT event d. The laboratory performed T3 Uptake and T3 in approximately 13 patient samples each month, respectively. e. The laboratory staff and the QA personnel affirmed (01/30/18 @ 12:45 PM) that the laboratory attained scores less than 80% in the 1st 2016 and 3rd 2017 PT events, were unsatisfactory analyte performance for the testing events.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory information system (LIS) performance, review of the laboratory's quality control (QC) records, and interview with the laboratory staff and QA personnel, it was determined that the laboratory failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance and document all control procedures performed. The findings included: a. The laboratory performed urine drug screen with confirmation of any drug compound detected by LC/MS/MS and reported with a concentration of that drug. b. Observed and reviewed in its LIS data of Levy Jenney (LJ) chart from 09/01 /2017 thru 1/26/2018 (total of 48 runs) for THC (Cannobinoid). c. During that time frame identified on (b) above, the majority (about 40 runs) of the runs were on positive side of the LJ for both QC levels, i.e. above its mean (indicated by 0, 1 and 2 SD). d. There were no documents available to indicate that the laboratory evaluate and monitor any shift or trend of daily QC results.
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 laboratory staff and QA personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2098
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 observation of the laboratory information system (LIS) performance, review of the laboratory's quality control (QC) records, and interview with the laboratory

	staff and QA personnel, 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-5441