Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2103284	12/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Us Lab Inc	3194-A Airport Loop Dr, Ste A, Costa Mesa, 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
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 touring and observation the laboratory facility and instrumentation operations, review of the laboratory quality control (QC) records, and Levy Jennings (LJ) charts, and interview with the testing personnel (TP) and the laboratory director, it was determined that the laboratory TP failed to follow its QC policies and procedures (P&P) to monitor over time the accuracy and precision of its LC/MS/MS performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. The findings included: a. The laboratory used Thermo Tandem LC/MS/MS (two Quantiva Triple Quads, one Altis Triple Quads) to perform urine drug confirmations quantitatively. b. Review the laboratory's "QC REVIEW SUMAMARY REPORT" records and its LJ charts covered from 2/8/20 thru 2/29/20 for the following drugs: Cocaine, Carisoprodol and Norhydrocodone. c. The laboratory failed to be responsible for having control procedures that detect immediate errors, 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 failed to document all control procedures performed. d. The laboratory uses two levels of QC, lo QC1 and hi QC2. e. The LJ for Cocaine lo QC1 indicated a positive bias shift between 2/3/20 thru 2/28/20, while hi QC2 some daily control data were missing between 2/2/20 and 2/14/2020. f. The LJ for Carisoprodol lo QC1 indicated a shift between 2/18/20 and 2/28/20. e. The LJ for Norhydrocodone indicated a shift between 2/18/2020 and 2/28/2020, while hi QC2 indicated negative bias starting on 2/6/2020 ad 2/14/2020, some of the QC results were exceeded -3SD. g. There were no evidences of the laboratory personnel marks of concerns where the shift or out of 3 SD QC results on the copies of these three drugs QC records. h. The laboratory personnel attested reviews on the records of "QC REVIEW SUMMARY REPORT" sheet indicated no comments for "WEEK 1 REVIEW" and "WEEK 2 REVIEW". while made comments for "WEEK 3 REVIEW" and "WEEK 4 REVIEW" to identify the "MAJOR ISSUES(S)" and "ROOR CAUSE" and "SOLUTION".
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on touring and observation of the laboratory facility and instrumentaion operations, review of the laboratory quality control (QC) records, and Levy Jenning (LJ) charts, and interview with the testing personnel (TP) and the laboratory director, it was determined that the laboratory failed to meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability. The findings included: a. The laboratory used Thermo Tandom LC/MS/MS (two Quantiva Triple Quads, one Altis Triple Quads) to perform urine drug confirmations quantitatively. b. Review the laboratory's "QC REVIEW SUMAMARY REPORT" records and its LJ charts covered from 2/8/20 thru 2/29/20 for the analyte of Cocaine, Carisoprodol, and Norhydrocodone, the laboratory failed to document any QC results which were out of the laboratory's test system criteria for acceptability, see D-5441.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on touring and observation the laboratory facility and instrumentaion operations, review of the laboratory quality control (QC) records, and Levy Jenning (LJ) charts, and interview with the testing personnel (TP) and the laboratory director, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.The findings included: a. The laboratory used Thermo Tandon LC/MS/MS testing system to perform urine drug confirmation qauntitatively. b. Review of the laboratory's "QC REVIEW SUMAMARY REPORT" records and its LJ charts covered from 2/8/20

	thru 2/29/20 for the following drugs: Cocaine, Carisoprodol and Norhydrocodone. c. There were QC results bias and/or shift in the LJ charts between 2/3/20 thru 2/2/8 /2020 for the above drugs mentioned in item (b), see D-5441 and D-5481
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on touring and observation the laboratory facility and instrumentaion operations, review of the laboratory quality control (QC) records, and Levy Jenning (LJ) charts, and interview with the testing personnel (TP) and the laboratory director, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified. The findings included: a. Review of the laboratory's "QC REVIEW SUMAMARY REPORT" records and its LJ charts covered from 2/8/20 thru 2/29/20 for the following drugs: Cocaine, Carisoprodol and Norhydrocodone, the laboratory failed to follow its quality control policies and procedure to monitor over time the accuracy and precision of test performance and failed to document all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, see D-5481