Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2065640	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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 review of the laboratory quality control (QC) testing documents, and interview with the laboratory technical consultant by phone (TC), the laboratory supervisor and the testing personnel (TP), it was determined that the laboratory failed to select appropriate QC materials to detect immediate errors and 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. The findings included: a. The laboratory implemented V-Twin instrument by Siemens to perform qualitative analyses of urine drug screen, and report either Negative (Neg) or Positive (Pos) result. b. The laboratory performed a total of 12 drugs including 6-Acetylmorphine (6AM) , Amphetamine (AMP), Barbiturate (Bat), Bezodiazepine (Ben), Buprenorphine (Bun), Cocaine (Coc), Ecstasy (Esy), Methadone (Met), Opiate (Opt), Oxycodone (Oxy), Phencyclidine (PCP), Cannabinoid (THC). c. The laboratory established the Neg or Pos results criteria by the individual cutoff concentrations (Con) of the drugs. d. The following is a table of partial listed individual drug, its cutoff and QC Con for Negative and Positive results.

	Benzoylecgonine = Ben (Cocaine metabolite) Cutoff in ng/mL . Neg* = 0 ng/mL, Low QC Concentration, EMIT Drug Free Urine Pos* = High QC Concentration in ng /mL Drug Neg* Cutoff Pos* 6-AM 0 10 20 Amp 0 500 2000 Ben 0 150 1000 Esy 0 500 1000 e. For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. f. The control procedures must be able to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance, and be able 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. g. The laboratory concluded in its summary of "Validation/Verification Result" for Precision and Accuracy: (2) (b) All results indicated less than 20 % CV. h. Both Low and High QC materials with the concentrations of each QC materials the laboratory selected and used failed to reflect that the laboratory was able to detect immediate errors and/or 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.
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 patient final result report, and interview with the laboratory supervisor and the testing personnel (TP), it was determined that the laboratory's final test result report format failed to indicate the test report date. The findings included: a. Review of a final patient test result report of Sample ID 1, Date of Birth; 7/8/1957; Collection date: 8/13/2019 Measurement Date: 8/13/2019 Measurement Time: 11:04:09 AM b. The laboratory used "Measurement" which indicated that the patient samples tests were performed or run, not to indicate that was a "final" result report been generated. c. The date of the test report is the date results were generated as a final report and must not change on copies generated at a later date. d. The laboratory faailed to indicate the test "Report Date" in its final patient test result report.
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 review of the laboratory's patient final result report, and interview with the laboratory supervisor and the testing personnel (TP), it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory to assure compliance with the applicable CLIA regulations. The findings included: a. The laboratory failed to meet the format of the patient test result report to include the test report date indicating that the date results were generated as a final report and must not change on copies generated at a later date. b. See D-5805.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) testing documents, and interview with the laboratory supervisor and the testing personnel (TP), it was determined that the laboratory director failed to establish the quality control policies and procedures properly and effectively, and to use appropriate QC materials to monitor and to ensure the accuracy of the testing systems. The findings included: a. The laboratory used EMIT Drug Free Urine as Low QC (Neg) and High QC (Pos) materials failed to reflect that the laboratory was able to detect immediate errors and /or 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. b. See D-5441.