Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2125123	03/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Family Services	5801 Executive Center Drive, Suite 103, Charlotte, NC	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and technical consultant (TC) and testing personnel (TP) interview 3/13/19, the laboratory's procedure manual was not complete and current for the testing performed. The laboratory performs creatinine testing for adulteration detection on urine toxicology specimens. Review of laboratory procedure "Adulterant Failures" revealed "Should any one of the adulterants tested with each specimen not be within the "normal" range as expected, thus denoting that the drug test specimen may have been altered or compromised, the supervisor should

	be notified and the patient asked to re-collect another specimen. Results will not be used or patients will not be treated if the specimen is suspected of being altered in any way." The procedure fails to specify which adulterant the laboratory is testing, and fails to state what the criteria for "not within the "normal' range as expected" is. Review of laboratory procedure "Adulteration Detection" revealed the procedure states 5 ways in which the laboratory detects adulteration; for example "Means to detect adulteration by the collector and/or laboratory include the following: 1. Specimen Temperature...2. Urine Appearance and Odor....3. Creatinine.....4. PH.....5. Visible Blood" Review of laboratory procedure "Adulteration Detection" revealed under section "3. Creatinine: ..."Normal" random urine specimens will generally have urine creatinine levels of greater than 20 mg/dL, while specimens with creatinine levels between 10 and 20 mg/dL may be due to increased liquid consumption....Urine specimens with creatinine levels between 2 and 10 mg/dL are usually a result of ingestion of large volumes of water....Urine creatinine levels below 2.0 mg/dL are usually the result of "dipping"....". The procedure fails to specify what specific creatinine values the laboratory has established for determining specimen adulteration. Interview with TC and TP at approximately 12:00 p.m. confirmed the laboratory only performs creatinine testing for adulteration detection. The interview also confirmed that the TP was unaware that a urine specimen should be recollected if creatinine values were "not within the "normal" range as expected", and she was also unsure of what the criteria for a "normal" range would be.
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 laboratory records, review of reagent package inserts, review of random patient test reports and technical consultant (TC) interview 3/13/19, the laboratory failed to include required interpretation information on the patient test report. Review of laboratory records revealed the laboratory performs Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methadone, Opiate and Cannabis urine toxicology testing on the Easy RA chemistry analyzer using Medica reagents. Review of Medica reagent package inserts for all analytes tested revealed the following statement; "The assay provides only a preliminary analytical result. A more specific alternative analytical chemistry method must be used in order to obtain a confirmed analytical result." Review of 2 random patient test reports, #T-C-94, and #L-C-171, revealed the test reports failed to include a statement indicating that test results were considered preliminary and another analytical chemistry method must be used to confirm the test result. Interview with TC at approximately 12:00 p.m. confirmed the patient test reports did not include a statement to indicate the test results were preliminary and must be confirmed.