Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2125123	03/11/2026
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 review of reagent package inserts (PI), review of policies and procedures, and interview with the Technical Consultant (TC) on 3/11/26, the laboratory failed to follow manufacturer instructions for 4 of 6 assays performed on urine samples on the Horiba Pentra C400 analyzer. Findings: The laboratory's test menu consists of 6 assays. Review of the reagent PI for each assay revealed the following: 1. The PI titled ABX Pentra Creatinine 120 CP explained the reagent "should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise." Under the section titled Specimen on page 2, the manufacturer lists sample types, including serum, plasma, and "Fresh centrifuged urine." 2. Three PIs titled DRI Ethyl Alcohol Assay, DRI Opiate Assay, and DRI Cannabinoid Assay each instructed ," Samples within a pH range of 3 to 11 are suitable for testing with this assay." 3. The PIs titled DRI Benzodiazepine Assay and DRI Cocaine Metabolite did not include a statement concerning a suitable pH. Review of the "Patient Test Management and Specimen labeling/handling and retention" policy revealed the following: 1. Absence of steps which include centrifuging urine prior to performing the Creatinine assay. 2. Absence of steps which include obtaining urine pH to determine sample suitability for performing Ethyl Alcohol, Opiate, and Cannabinoid assays. During an interview at approximately 11:45 a.m., the TC confirmed the laboratory does not use a centrifuge

	to process its urine samples. They also confirmed the absence of a method to determine urine pH. The TC said the reagents have been in use since the Horiba Pentra C400 was installed in December 2024.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on review of reagent package inserts, lack of a centrifuge, lack of pH testing, and interview with the Technical Consultant (TC), the Lab Director failed to ensure personnel are performing the laboratory's test methods as indicated by the manufacturer to obtain reliable results. Findings: 1. Review of reagent package inserts revealed test method steps that were not being performed, including: a. Utilization of fresh centrifuged urine specimens for the Creatinine assay. b. Determination of urine pH to ensure results are within pH range 3 to 11 for Ethyl Alcohol, Opiate, and Cannabinoid assays. 2. During a tour of the laboratory at approximately 11:30 a.m., the surveyor did not observe a centrifuge or any test method to detect urine pH. 3. During an interview at approximately 11:45 a.m., the Technical Consultant (TC) confirmed there was no centrifuge or pH test available for use by testing personnel. See D5411.