

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D2125123 | (X3) Date Survey Completed 07/16/2025 |
| Name of Provider or Supplier Epiphany Family Services | Street Address, City, State 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 |
|---------------------------|---|
| D5311 | <p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, review of specimen logs, observation, and interview with testing personnel (TP) on 7/16/25, the laboratory failed to follow its policy for storing patient urine specimens prior to analysis on the Horiba Pentra 400. Findings: Review of the "Patient Test Management and Specimen labeling /handling and retention" policy revealed, "... If the specimen will not be tested within two hours it is placed in the refrigerator at 2-8 C for up to 3 days, if testing will be longer than three days the specimen is placed in the freezer at -20 C or colder. ..." Review of 2024 and 2025 specimen logs revealed patient urine specimens were collected and frozen on the same date, then tested on the Horiba Pentra 400 on a future date. For example, on 6/4/25, 13 of 13 patient specimens were collected and frozen, then thawed for "in-house" testing on 6/16/25. During a tour of the lab at approximately 11:30 a.m., the surveyor observed a thermometer in a black freezer indicating a temperature of -10 degrees Celsius (C). There were four empty, unlabeled boxes in the freezer. The freezer did not contain patient specimens at the time of the observation. During interview at approximately 3:40 p.m., TP #1 stated the boxes were used to store patient specimens if they cannot be tested on the date of collection. She stated the boxes sometimes get mixed up and newer specimens are tested before older ones.</p> |

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on lack of documentation in the Horiba Pentra 400 validation records, review of reagent assay sheets, and interview with the Technical Consultant (TC) on 7/16/25, the laboratory director failed to ensure all instrument validation requirements, specifically specimen stability studies, were met prior to patient testing. Findings: Review of the Horiba Pentra 400 validation records revealed no documentation of specimen stability studies. Review of assay sheets for tests performed on the Horiba Pentra 400, including Creatinine (CREA), Cocaine (COC), Alcohol (ETOH), Opioids (OPI), Tetrahydrocannabinol (THC), and Benzodiazepine (BENZO) revealed 5 of 6 assay sheets contained no information about specimen stability at freezing temperatures. The ABX Pentra Creatinine 120 CP assay sheet stated urine specimens are stable "... At -20 degrees C: 6 months. ..." During an interview at approximately 2:58 p.m., the TC verified that specimen stability studies were not performed during validation of the Horiba Pentra 400 analyzer.