Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2048814	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Corydon Pain Management Clinic	**Street Address, City, State** 2230 Edsel Ln Nw, Corydon, IN	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include time and date of urine specimen collection on drug screening requisitions for five (Pt#1-Pt#5) out of five patients reviewed in the sub-specialty of toxicology. Findings included: 1. Review of Progress Notes/Orders for Pt#1-Pt#5 revealed the collection dates and times of urine specimens was not documented. 2. Review of urine drug screen patient final reports for Pt#1-Pt#5 revealed the urine collection date and time were missing for the following: a. Pt#1 final report -missing date of urine collection and time. b. Pt#2 final report - missing a time for urine collection. c. Pt#3 - no final report document. d. Pt#4 final report -no urine collection time. e. Pt#5 final report - no urine collection time. 3. Review of Policy & Procedure Manual - "Section Specimen Collection", signed by the laboratory director on 8/23/2022, on page 26 states "All specimens are labeled by collection personnel with the following: Patient name (First

	& Last) Date of birth and/or patented# Date and Time of collection." 4. During interview on 08/24/2022 at 12:25 PM, SP#1 (Technical Consultant) and SP#2 (Owner) confirmed the laboratory failed to include time and date of urine specimens collection for drug chemistry screening on the requisitions for Pt#1-Pt#5. 5. Annual test volume for toxicology is 41,665.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the time and date urine specimen were received and documentation of the testing personnel performing the urine drug screenings for five (Pt#1-Pt#5) out of five patients reviewed in the sub-specialty of toxicology. Findings included: 1. Review of Urine Drug Screen patient final reports for Pt#1-Pt#5 revealed the time and date urine specimens were received and documentation of the testing personnel performing the tests was missing for the following: a. Pt#1 final report - no written date and time received and no written Tech ID b.Pt#2 final report -no written date and time received and no written Tech ID. c.Pt#3 - no final report just instrument print out. d.Pt # 4 final report- no written date and time received and no written Tech ID. e.Pt#5 final report - no written date and time received and no written Tech ID. 2. Review of Policy & Procedure Manual - Section 6 "Quality Systems Management", signed by the laboratory director on 8/23/2022, had no written procedure for what information should include on patient final reports and reviewed. 3. Review of Policy & Procedure Manual - Section 4 "Post-Analytic", signed by the laboratory director on 8/23/2022, had no written policy on how the laboratory develops final reports. 4. During interview on 08/24 /2022 at 12:25 PM, SP#1 and SP#2 confirmed the laboratory failed to record the time and date urine specimen were received and documentation of the testing personnel performing the urine drug screenings for Pt#1-Pt#5. 5. Annual test volume for toxicology is 41,665.