

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2175813	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Cincinnati Comprehensive Pain Center	Street Address, City, State 2816 Mack Road, Fairfield, OH	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: ITEM 1: Based on document review and interviews with the Technical Supervisor (TS) and the Laboratory Director (LD), the laboratory failed to follow the procedure manual for urine collection. This deficient practice had the potential to affect all patients tested under the subspecialty of toxicology from 02/22/2020 to 10/07/2020. Findings include: 1. Review of the laboratory's policy titled "Urine Collection with Patient Instructions", approved by the LD on 01/20/2020 found the following statement: "II...Containers containing patient specimens for testing are labeled as follows: o Time and date of collection" 2. Direct observation of two out of two labeled patient specimen containers, #11779 and #11286, revealed the label indicated a default specimen collection time of 12:00 AM for both specimens. 3. An interview with the TS and the LD on 10/07/2020 at 1:15 PM confirmed the collection times were automatic program default times and not accurate. ITEM 2: Based on document review and interviews with the Technical Supervisor (TS) and the Laboratory Director (LD), the laboratory failed to follow the procedure manual for urine collection. This deficient practice had the potential to affect all patients tested under the subspecialty of toxicology from 02/22/2020 to 10/07/2020. Findings include: 1. Review of the laboratory's policy titled "Urine Collection with patient Instructions", approved by the Laboratory Director on 01/20/2020 found the following statement: "III...The test requisition must include: o Source/type of specimen, when appropriate (e.g., anatomical site, urine)" 2. Review of four out of four test requisitions did not find any specimen source listed. 3. An interview with the TS and the LD on 10/07/2020 at 1:15</p>

PM confirmed the laboratory did not include the specimen source on the test requisition.

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 record reviews and interviews with the Technical Supervisor (TS) and the Laboratory Director (LD), the laboratory failed to include on the final test report the units of measure for patient toxicology results. All patients tested under the subspecialty of toxicology from 02/22/2020 to 10/07/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of two out of two of the laboratory's final test reports for patient toxicology results did not find any units of measure for toxicology patient results or cutoff values. 2. The TS and LD confirmed the laboratory did not include any units of measure for any patient toxicology toxicology test results on the final test report. The interviews occurred on 10/07/2020 at 1:30 PM.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on record review and an interview with Technical Supervisor (TS), the Technical Supervisor (TS) failed to include the review of intermediate test results or worksheets, quality control (QC) records, test accuracy verification (TAV), and preventive maintenance records in the evaluation of the competency of one out of one Testing Personnel (TP#1). This deficient practice had the potential to effect all patients tested by TP#1 under the subspecialty of toxicology from 02/22/2020 to 10/07/2020. Findings Include: 1. Review of the laboratory's competency assessment documentation for TP#1 did not find any indication that the assessments included the review of intermediate test results or worksheets, QC records, TAV, and preventive maintenance records in the evaluation of competency for TP#1. 2. The Surveyor requested the laboratory's competency assessment documentation that included the review of intermediate test results or worksheets, QC records, TAV, and preventive maintenance records in the evaluation of the competency of TP#1 from the TS. 3. The TS confirmed the laboratory did not include the review of intermediate test results or worksheets, QC records, TAV, and preventive maintenance records in the evaluation of the competency of TP#1 for toxicology testing and was unable to provide the

requested documentation on the date of the inspection. The interview occurred on 10/07/2020 at 12:00 PM.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Supervisor (TS), the Technical Supervisor (TS) failed to include the review of test performance in the evaluation of the competency of one out of one Testing Personnel (TP#1). This deficient practice had the potential to effect all patients tested by TP#1 under the subspecialty of toxicology from 02/22/2020 to 10/07/2020. Findings Include: 1. Review of the laboratory's competency assessment documentation for TP#1 did not find any indication that the assessments included the review of test performance in the evaluation of competency for TP#1. 2. The Surveyor requested the laboratory's competency assessment documentation that included the review of test performance in the evaluation of the competency of TP#1 from the TS. 3. The TS confirmed the laboratory did not include the review of test performance in the evaluation of the competency of TP#1 for toxicology testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/07/2020 at 12:00 PM.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Supervisor (TS), the Technical Supervisor (TS) failed to include the review of problem solving skills in the evaluation of the competency of one out of one Testing Personnel (TP#1). This deficient practice had the potential to effect all patients tested by TP#1 under the subspecialty of toxicology from 02/22/2020 to 10/07/2020. Findings Include: 1. Review of the laboratory's competency assessment documentation for TP#1 did not find any indication that the assessments included the review of problem solving skills in the evaluation of competency for TP#1. 2. The Surveyor requested the laboratory's competency assessment documentation that included the review of problem solving skills in the evaluation of the competency of TP#1 from the TS. 3. The TS confirmed the laboratory did not include the review of problem solving skills in the evaluation of the competency of TP#1 for toxicology testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/07/2020 at 12:00 PM.