

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2166587	(X3) Date Survey Completed 10/08/2021
Name of Provider or Supplier Premier Pain Solutions, Pllc	Street Address, City, State 9 Walden Ridge Drive Suite 10, Asheville, 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
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: Based on review of laboratory procedures, review of manufacturer's package insert, surveyor observation and interview with General Supervisor (GS) #2 10/08/21, the laboratory failed to follow the procedure for the storage of urine specimens for Ethyl Gluconoride (ETG) testing. Findings: Review of the laboratory procedure "Specimen Analysis for Ethyl Gluconoride Assay on the Indiko Plus Chemistry Analyzer Version 4" revealed "Use fresh urine specimen for the the test. To protect the integrity of the sample...store refrigerated at all times when not in use." Review of the manufacturer's package insert "DRI Ethyl Glucuronide Assay" "revealed "Urine samples must be stored refrigerated at all times when not in use." During tour of laboratory the surveyor observed urine specimens for ETG testing stored at room temperature. Interview with GS #2 at approximately 12:00 p.m. confirmed the laboratory failed to follow the procedure for storage of ETG urine specimens and also confirmed urine specimens were stored at room temperature when not in use.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 manufacturer's instructions and laboratory procedures for Amphetamines, Buprenorphine and Hydrocodone testing on the ThermoFisher Indiko Plus 10/8/21, the procedures failed to include the stability and storage requirements for quality control (QC) and/or calibration reagents once opened. 1. The laboratory procedure for Amphetamines failed to include the stability and storage of QC reagents once opened. Findings: Review of manufacturer's instructions for the Thermo Scientific MAS DOA Total Controls, DOAT-4 and DOAT-5, used for the Amphetamine testing revealed "Once opened, vials of controls are stable for 30 days when stored tightly capped at 2-8 Celcius (C)". Review of the laboratory procedure "Specimen Analysis for Amphetamines Assay on the Indiko Plus Chemistry Analyzer" revealed no reference to the stability and storage requirements for DOAT-4 and DOAT-5 once opened. 2. The laboratory procedure for Buprenorphine failed to include the stability and storage of QC and calibration reagents once opened. Findings: Review of manufacturer's instructions for the Cedia Buprenorphine Low Control, High Control and calibrators used for the Buprenorphine testing revealed "Store calibrators or controls at 2-8 C. Do not freeze. For stability of the unopened containers or controls, refer to the box or bottle labels for the expiration date. For stability of the opened calibrators or controls, 60 days or until the printed expiration date whichever comes first.". Review of the laboratory procedure "Specimen Analysis for Buprenorphine Assay on the Indiko" revealed no reference to the stability and storage requirements for the Cedia Buprenorphine Low Control, High Control and calibrators once opened. 3. The laboratory procedure for Hydrocodone failed to include the stability and storage of QC and calibration reagents once opened. Findings: Review of manufacturer's instructions for the DRI Hydrocodone Low Control, High Control and calibrators used for the Hydrocodone testing revealed "Once opened the calibrators and controls are stable for 60 days when stored at 2-8 C. Do not use calibrators or controls beyond the expiration date.". Review of the laboratory procedure manual for the "Specimen Analysis for Hydrocodone Assay on the Indiko" revealed no reference to the stability or storage requirements for the DRI Hydrocodone Low Control, High Control and calibrators once opened.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, review of reagent logs, and surveyor observation 10/08/21, the laboratory failed to label Cedia Buprenorphine High and Low QC reagents with correct expiration dates and failed to label Thermo Scientific MAS DOA Total Controls QC reagents with correct expiration dates. 1. The laboratory failed to label Cedia Buprenorphine High and Low QC reagents with correct expiration dates. Findings: Review of manufacturer's instructions for the Cedia Buprenorphine High and Low QC reagents for Buprenorphine testing revealed "For stability of the opened calibrators or controls, 60 days or until the printed expiration date whichever comes first.". Review of 2021 reagent logs revealed Cedia Buprenorphine Low Control, Lot #74312495, and Cedia Buprenorphine High Control, Lot #74312496 were listed with an open date of 10/04/21 and an expiration date of 01/31/2023. The expiration date listed is approximately 16 months after the open date. During surveyor inspection of reagents in the laboratory refrigerator, the surveyor observed one bottle of Cedia Buprenorphine Low Control, Lot #74312495, and one bottle of Cedia Buprenorphine High Control, Lot #74312496, labeled with an open date of 10/04/21 and expiration date of 01/31/2023. The expiration date listed is approximately 16 months after the open date. 2. The laboratory failed to label Thermo Scientific MAS DOA Total Controls used for multiple assays performed on the ThermoFisher Indiko Plus with correct expiration dates. Findings: Review of manufacturer's instructions for Thermo Scientific MAS DOA Total Control revealed "Once opened, vials of controls are stable for 30 days when stored tightly capped at 2-8 C.". Review of 2021 reagent logs revealed Thermo Scientific MAS DOA Total Controls, DOAT-2 Lot #23032 A, DOAT-3 Lot #23033 A, DOAT-4 Lot #23034 A and DOAT-5 Lot #23035 A, were listed with open dates of 10/04/21 and expiration dates of 03/31/2022. The listed expiration date is approximately 6 months after the open date. During surveyor inspection of reagents in the laboratory refrigerator, the surveyor observed one bottle each of Thermo Scientific MAS DOA Total Controls, DOAT-2 Lot #23032 A, DOAT-3 Lot #23033 A, DOAT-4 Lot #23034 A and DOAT-5 Lot #23035 A, labeled with open dates of 10/04/21 and expiration dates of 03/31/2022. The labeled expiration dates are approximately 6 months after the open date.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions and review of the laboratory's 2019, 2020, and 2021 temperature and humidity logs 10/8/21, the laboratory failed to ensure corrective action was taken and documented for refrigerator readings outside the acceptable range and failed to ensure the corrective actions taken had corrected the unacceptable readings. Findings: The manufacturer's instructions for the assays performed on the ThermoFisher Indiko Plus revealed a refrigerator storage range of 2-8 degrees C for reagents, calibrators, and controls. For example, the Buprenorphine Assay package insert states, "Storage Conditions: Store CEDIA Buprenorphine

reagents at 2-8 degrees C. DO NOT FREEZE." The CEDIA Buprenorphine Calibrators and Controls package insert states, "Storage and Stability: Store calibrators and controls at 2-8 degrees C. Do not freeze." 1. Review of the 2019 and 2020 temperature and humidity logs revealed refrigerator temperatures were below the acceptable range of 2-8 degrees C on the following days with no corrective action documented: a. 3 of 19 days in June 2019 - 6/4, 6/6, 6/10; b. 6 of 22 days in July 2019 - 7/18, 7/22, 7/23, 7/25, 7/30, 7/31; c. 10 of 22 days in August 2019 - 8/1, 8/5, 8/6, 8/7, 8/15, 8/26, 8/27, 8/28, 8/29, 8/30; d. 14 of 17 days in September 2019 - 9/9, 9/10, 9/11, 9/12, 9/13, 9/17, 9/18, 9/19, 9/20, 9/24, 9/25, 9/26, 9/27, 9/30; e. 17 of 22 days in October 2019 - 10/1, 10/3, 10/8, 10/9, 10/10, 10/11, 10/14, 10/15, 10/16, 10/21, 10/22, 10/23, 10/24, 10/28, 10/29, 10/30, 10/31; f. 15 of 19 days in November 2019 - 11/1, 11/4, 11/5, 11/6, 11/7, 11/8, 11/11, 11/12, 11/13, 11/14, 11/15, 11/20, 11/21, 11/25, 11/27; g. 12 of 17 days in December 2019- 12/3, 12/4, 12/6, 12/9, 12/10, 12/11, 12/13, 12/16, 12/17, 12/18, 12/19, 12/20; h. 15 of 22 days in January 2020 - 1/2, 1/3, 1/6, 1/7, 1/8, 1/9, 1/13, 1/15, 1/16, 1/17, 1/21, 1/22, 1/23, 1/24, 1/31; Instructions on the laboratory's temperature and humidity logs beginning February 2020 state, "Corrective Action must be noted for out of range readings." 2. Review of the March 2020 - December 2020 temperature and humidity logs revealed documentation that "QC was acceptable or QC passed" on the following days, but there was no documentation to indicate that any additional corrective action was taken to correct the problem when the refrigerator reading was below the acceptable range of 2-8 degrees C: i. 2 of 22 days in March 2020 - 3/2, 3/17; j. 1 of 20 days in May 2020 - 5/14; k. 1 of 18 days in June 2020 - 6/12; l. 1 of 23 days in July 2020 - 7/8; m. 1 of 20 days in October 2020 - 10/22; n. 2 of 19 days in November 2020 - 11/11, 11/23; o. 2 of 19 days December 2020 - 12/7, 12/22.