

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2013788	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Eastern Physical Medicine And Rehabilitation	Street Address, City, State 2470 Emerald Place, Suite D, Greenville, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of manufacturer's package inserts and interview with general supervisor (GS) 1/8/20, the laboratory's procedure manual was not complete and current for the testing performed. Findings: The laboratory performs urine toxicology qualitative analysis on the Diatron Pictus 700 analyzer using Thermo Scientific reagents. 1. Review of laboratory procedure manual and manufacturer's package inserts revealed the quality control (QC) procedure and manufacturer package inserts failed to specify the type of QC used for each analyte tested, the level of QC used for each analyte tested and the frequency of QC for</p>

qualitative assays. For example: a. Laboratory procedure "Quality Control Policy" revealed "Intended use/Summary...The following procedure outlines quality control protocols for the laboratory in general; for department-specific procedures, refer to the respective department manual...Procedure...A minimum of two levels of controls are used...For all tests performed on automated analyzers giving a numeric result, quality control material will be run at least daily or in accordance with the manufacturer's frequency recommendation...These results will be analyzed using accepted statistics... The quality control material used is commercially prepared material. Qualitative assays are evaluated by use of both a positive and negative control.". b. Thermo Scientific package insert for "DRI Oxycodone Assay" manufacturer's QC requirements revealed "Quality Control and Calibration...Qualitative analysis...use either the Oxycodone 100 Calibrator, or the Oxycodone 300 Calibrator, as a cut-off level...Use controls near the cutoff calibrator...Each laboratory should establish its own control frequency.". 2. Review of laboratory procedure manual revealed the laboratory utilizes manufacturer's package inserts for calibration procedures on the Diatron Pictus 700 analyzer. Review of manufacturer's package inserts revealed they failed to specify the type of calibrator used, the level of calibrator used for each analyte, the frequency of calibration, the laboratory's criteria for calibration acceptability and the corrective action to take if calibration fails to meet the laboratory's criteria for acceptability. For example: a. Manufacturer's package insert for "DRI Oxycodone Assay" revealed "Quality Control and Calibration...Qualitative analysis...use either the Oxycodone 100 Calibrator, or the Oxycodone 300 Calibrator, as a cut-off level...Use controls near the cutoff calibrator...Each laboratory should establish its own control frequency.". b. Manufacturer's package insert for "DRI Amphetamines Assay" revealed "Quality Control and Calibration...Each laboratory should establish its own calibration and control frequency...Qualitative Analysis...For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1 or 2...". Interview with GS at approximately 11:30 a.m. confirmed the laboratory procedures for quality control and calibrations were not complete. She stated she had written specific procedures for each analyte and was told by the technical consultant at the time that they were not needed and the package inserts and quality control procedure were sufficient.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation and interview with the general supervisor (GS) 1/8/20, the laboratory failed to discard supplies that exceeded their expiration dates. Findings:
During a tour of the laboratory at approximately 2:05 p.m., the surveyor observed the following expired supplies in a cabinet in the laboratory, available for use: 1. 1 box Calibration Set Control Solutions for Clinical Chemistry Analyzers lot #SLC0071214, expiration date 12/2016; 2. 1 bottle ISE Module Urine Diluent lot #15267, expiration date 8/2017; 3. 1 box ISE Module Cleaning Solution Kit lot #15303, expiration date 9/2017; 4. 1 box Calibration Set Control Solutions for Clinical Chemistry Analyzers lot #151120, expiration date 11/2017; 5. 1 box Cleaning Solution Cleaning kit for

Clinical Chemistry Analyzers lot #SLP0300518, expiration date 11/2019. During interview at approximately 2:10 p.m., the GS stated the expired supplies might have been left at the laboratory by instrument service representatives.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of instrument validation records for the Diatron Pictus 700 analyzer, review of patient test report and interview with general supervisor (GS) 1/8/20, the laboratory director failed to ensure that patient test reports included the pertinent information required for test result interpretation. Findings: The laboratory performs qualitative analysis on the Diatron Pictus 700 analyzer for the following analytes; Alcohol, Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone and Creatinine. Review of laboratory validation records for the Diatron Pictus 700 analyzer revealed the analytes are validated for only positive or negative qualitative test results based on cut-off values established for each analyte. Review of random patient test report, medical record number 213963145, revealed quantitative results were included on the patient test report for all qualitative analytes. Interview with GS at approximately 12:30 p.m. confirmed the validation records for the analytes were for qualitative results only, she also confirmed that the patient test report included quantitative test results.