Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2092862	05/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Maryland Pain And Wellness Ctr	2200 Defense Highway, Ste 203, Crofton, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to maintain copies of the signed attestation statements for six of seven PT events reviewed. Findings: 1. The records for seven PT events from 2020-2022 for urine drug screening (UDS) were reviewed. 2. Records for six of the seven PT events reviewed did not include the attestation statement signed by the TP and laboratory director or designee documenting that the PT samples were tested in the same manner as patient specimens. 3. During the survey on 05/31/2022 at 2:30 pm, the TC confirmed that attestation statements were not printed, signed, and maintained for six of seven UDS PT events.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical consultant (TC), the laboratory's procedure manual failed to reflect updated laboratory practices for urine specimen storage and failed to include urine specimen stability for toxicology testing. Findings: 1. The laboratory received urine specimens for drug screening testing that were received in collection containers and then aliquoted into smaller sample tubes for testing. 2. The laboratory's "Sample Collection Protocol" stated that original urine containers were to be placed on a marked tray and stored in the refrigerator for 15 days before disposal and that sample aliquot tubes were to be maintained for six months before disposal. 3. The TC confirmed that typically if the received urine specimens were not to be tested within 48 hours, they would be stored frozen and then thawed prior to testing. The TC also confirmed that the sample aliquot tubes were not stored. 4. The procedure did not state how long after specimen collection the urine specimen was stable for testing when stored at room, refrigerator, and freezer temperatures and how many freeze thaw cycles the urine specimen was stable for. 5. During the survey on 05/31/2022 at 2:30 pm, the TC confirmed that the procedure manual did not reflect current laboratory practice for urine specimen storage and did not contain urine specimen stability for toxicology testing.
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 review of the procedure manual and reagent records and interview with the technical consultant (TC) and testing personnel (TP), the laboratory failed to maintain records of reagent lot numbers, expiration dates, and dates in use for toxicology testing to ensure that reagents were not used beyond their expiration dates. Findings: 1. The laboratory performed urine drug screening testing using a Beckman Coulter AU480 chemistry analyzer. The analyzer was recently replaced in 05/2022 with an analyzer of the same make and model. 2. The TP confirmed that the reagents did not have a barcode, so the lot numbers and expiration dates had to be manually entered

	into the analyzer which was not performed on a consistent basis by both TP. 3. The TP and TC confirmed that any reagent lot numbers and expiration dates that might have been entered into the AU480 analyzer that was replaced in 05/2022 were not saved. 4. The laboratory's procedure manual included a reagent log template to document the lot numbers and expiration dates of the drug screening reagents. The TC confirmed that the reagent log was not in use and the reagent lot numbers and expiration dates were not being manually logged. 5. The laboratory had a binder with the packing slips for the most recent batches of drug screening reagents that included the lot numbers and expiration dates. The TP confirmed that all previous packing slips and product inserts were not retained for a minimum of 2 years. 6. During the survey on 05/31/2022 at 2:30 pm, the TC confirmed that the laboratory did not have a record of reagent lot numbers, expiration dates, and dates in use for the drug screening reagents used prior to those currently in use.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel report and personnel competency records and interview with the technical consultant (TC), the TC failed to document annual competency assessments of the testing personnel (TP) in 2020 and 2021. Findings: 1. The laboratory personnel report (form CMS-209) listed two TP. 2. The personnel files for both TP included competency assessments completed on 02/23/2022 but were missing competency assessments for 2020 and 2021. 3. During the survey on 05/31 /2022 at 2:30 pm, the TC confirmed that annual competency assessments for the two TP were not documented in 2020 and 2021.