Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2092862	12/15/2023
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory staff did not test PT samples in the same manner as patient samples. Findings: 1. The laboratory currently has 2 testing personnel (TP) listed on the "Laboratory Personnel Report" (CMS-209). A review of the attestation worksheets from five PT events in 2022 and 2023 showed that TP #2 performed the PT for the second event of 2022 ("UDS-B-2022") and the first event of 2023 ("UDS-A-2023"). The remaining three PT events were performed by TP #1. 2. Review of the PT instrument printouts showed that for five of five PT events, the printouts stated, "Run by (TP #1)," documenting that TP #1 ran and resulted the PT. 3. During an interview on 12/13/2023 at 11:46 AM, the TC stated that each TP should log in with their credentials before running the analyzer. They confirmed that the TP listed on the instrument printout was not the TP who performed the PT.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and record review and interview with the technical consultant (TC), the laboratory did not ensure that the procedure for documenting unacceptable specimens accurately reflected the current practice in the laboratory. Findings: 1. The laboratory performs urine toxicology testing. The "Sample Collection, Accessioning, Rejection, and Referral Protocol" procedure states, "If a specimen has a recoverable deficiency, the specimen will be accessioned and tested; however, no results will be reported until the deficiency is corrected with documentation. The specimens are logged into the Tests In Question (TIQ) log." The procedure includes a table, listing in which cases a patient specimen should be documented on the TIQ log. 2. Record review showed that the procedure did not include an example of the TIQ log and there were no TIQ logs available for review at the time of the survey. 3. During an interview on 12/13/2023 at 12:30 PM, the TC stated that the testing personnel document rejected specimens on a rejection log, which is not included in the procedure manual. The TC confirmed that the procedure did not reflect the actual practice in the laboratory and that it needed to be updated.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on room temperature and humidity log record review and interview with the technical consultant (TC), the laboratory failed to document corrective action when laboratory room humidity was out of range. Findings: 1. The laboratory performs urine toxicology testing on a Beckman AU480 chemistry analyzer. The procedure, "Precautions, Installation and Specifications," section "2.2.1 Installation Environment" "Temperature and Humidity Conditions When In Use" states, "Ensure that...The humidity is between 40% and 80% Relative Humidity (RH), and with no condensation." 2. Review of "Room Temperature Log: Room #1" logs from January through November 2023 shows that the "Acceptable range" for humidity in the laboratory is listed as "40% - 80% Humidity"; and 3. From January through November 2023 the humidity level in the laboratory was lower than the acceptable range 191 out of 191 times recorded. 4. There were no corrective actions documented for these dates. 5. The corrective action log for November 2023 showed that the TC reviewed the log and commented, "Humidity Not Applicable." 6. During an interview on 12/13/2023 at 1:40 PM, the TC confirmed that there were no corrective actions documented for the days that the laboratory humidity was out of range.

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on competency assessment record review, and interview with the technical consultant (TC), the laboratory director failed to ensure that the policies for monitoring the laboratory staff included the evaluation of the TC. Findings: 1. A review of competency assessment records from 2022 and 2023 showed that the documentation did not include an annual evaluation of the TC for the duties they perform as TC in 2022. 2. During an interview on 12/13/2023 at 12:35 PM, the TC confirmed that an annual competency assessment for the TC was not available.