Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 21D2092862	**(X3) Date Survey Completed** 10/27/2025
Name of Provider or Supplier Maryland Pain And Wellness Ctr	**Street Address, City, State** 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**
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 monthly quality assurance (QA) reviews, reagent packing lists, and monthly maintenance forms, and interview with the technical consultant (TC), the laboratory failed to ensure that phencyclidine (PCP) toxicology reagents were not used beyond their expiration dates. Findings: 1. The laboratory documented the lot numbers of reagents that were in use in the monthly QA reviews. 2. The expiration dates for the reagent lot numbers were contained in the packing lists from the received reagents. 3. The packing list for PCP reagent lot 75191188 showed an expiration date of 07/31/2025. The 08/2025 QA review showed that lot 75191188 was used at the beginning of the month and the next lot, 75251349, was put into use on 08/20/2025. Maintenance logs showed that patient testing was performed on 08/04/2025 and 08/05/2025, after the expiration date of lot 75191188 and before lot 75251349 was put into use. 4. The packing list for PCP reagent lot 75156792 showed an expiration date of 05/31/2025. The 06/2025 QA review showed that lot 75156792 was used at the beginning of the month and the next lot, 75191188, was put into use on 06/26/2025. Maintenance logs showed that patient testing was performed on 06/02/2025, 06/03/2025, 06/04/2025, 06/16/2025, and 06/25/2025, after the expiration date of lot 75156792 and before lot 75191188 was put into use. 5. During the survey on 10/27/2025 at 1:45 PM, the TC confirmed that PCP reagents were used beyond their expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of the procedure manual, instrument maintenance records, and quality assurance (QA) reviews, and interview with the technical consultant (TC), the laboratory failed to ensure that maintenance activities were performed with the frequency specified by the manufacturer. Findings: 1. Section "IV. Instrument Maintenance" of the procedure manual stated: a. "To maintain instrument integrity it is important to follow the manufacturer's instruction for (daily, weekly, monthly, quarterly, annually, and preventative, etc.) maintenance. Each analyzer will have maintenance logs that will require some form of documentation for each day of use." b. "Preventative Maintenance will be performed by the Instrument Service Tech" and stated that preventative maintenance for the Chemistry AU480 instrument was to be "performed annually." 2. The monthly maintenance logs included multiple monthly and quarterly maintenance tasks. 3. Maintenance logs were reviewed from 01/2024-10 /2025 for a total of 22 months. 4. None of the monthly maintenance activities were documented in nine of 22 months (01/2024, 02/2024, 03/2024, 05/2024, 06/2024, 11 /2024, 04/2025, 06/2025, and 08/2025). The monthly QA reviews dated 06/28/2024, 11/17/2024, 1207/2024, 05/20/2025, and 09/01/2025 did make note that monthly maintenance had not been performed and requested that the testing personnel (TP) begin documenting that maintenance was performed. The monthly QA reviews were written by the TC and signed by the laboratory director. There was no documentation that the TP reviewed the notes made on the QA monthly reviews. 5. At least one but not all monthly maintenance activities were documented as performed in seven of 22 months (04/2024, 07/2024, 08/2024, 09/2024, 03/2025, 07/2025, and 10/2025). 6. There were three quarterly maintenance tasks: a. The task to "Inspect and if needed Replace the DI Water Filter and Sample Probe Filter" wasn't documented as performed from 11/2024-03/2025 or from 04/2025-10/2025. b. The task "Replace the wash solution roller pump tubing" was only documented as performed in 10/2024 and 06/2025. 7. There were no records that the annual preventive maintenance was performed in 2024. 8. During the exit interview on 10/27/2025 at 3:25 PM, the TC confirmed that maintenance activities were not performed with the frequency specified by the manufacturer. II. Based on review of the procedure manual, instrument maintenance records, and quality control (QC) records, and interview with the technical consultant (TC), the laboratory failed to ensure that daily maintenance activities were performed on days when patients were tested. Findings: 1. Section "IV. Instrument Maintenance" of the procedure manual stated "To maintain instrument integrity it is important to follow the manufacturer's instruction for (daily, weekly, monthly, quarterly, annually, and preventative, etc.) maintenance. Each analyzer will have maintenance logs that will require some form of documentation for each day of use." 2. Daily maintenance was documented on the monthly maintenance forms. 3. The monthly QA reviews included the monthly QC results. Two levels of QC were tested each day of patient testing. 4. The following dates were when QC was tested, but daily maintenance activities were not documented: 01/31/2024, 06/12/2024, 06/20 /2024, 08/15/2024, 02/05/2025, 03/11/2025, 03/31/2025, and 05/14/2025. 5. During the exit interview on 10/27/2025 at 3:25 PM, the TC confirmed that daily maintenance was not documented as performed on each day that QC was run for patient testing.
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: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 12/15/2023 for not documenting corrective actions when humidity was outside the acceptable range. The laboratory's plan of correction stated that this would be corrected by 02/09/2024. Based on review of the procedure manual, review of temperature records, and interview with the technical consultant (TC), the laboratory failed to document corrective actions when humidity was outside the acceptable range in four of 20 months reviewed. Findings: 1. The "General Maintenance" procedure stated to "Record temperature on a daily basis. If temperature is out of the acceptable range, note on the daily temperature log, and complete the following corrective actions and document" and then listed "Check for the source of the problem," "Correct the error accordingly," and "Check the temperature at a later time in the same day." 2. The laboratory documented humidity on the monthly "Room Temperature Log: Room #1" (temp log). The second page of the temp log included a chart and the statement "Record corrective actions, corrected temperature, and responsible initials for all out of range temperatures." 3. Temp logs were reviewed from 02/2024-09/2025 for a total of 20 months. 4. Humidity values were outside the acceptable range in the following months: a. 04/2024: seven of 18 days recorded b. 06/2024: six of 16 days recorded c. 07/2024: 10 of 18 days recorded d. 09/2024: three of 16 days recorded 5. No corrective actions were documented on the second page of the temp log for any of the out of range humidity values listed above. 6. During the exit interview on 10/27/2025 at 3:25 PM, the TC confirmed that corrective actions were not documented when humidity values were outside acceptable range.