Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2258123	03/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Greater Maryland Pain Management	7845 Oakwood Rd Suite 201, Glen Burnie, 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
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 final reports, review of the procedure manual, and interview with the testing person (TP) and compliance specialist (CS), the laboratory did not have a procedure for adding a comment on the final report regarding possible adulteration for urine drug screening testing. Findings: 1. The report for patient "AUR-11" had a comment "Potential Adulterant" listed under the result for creatinine. 2. During the exit interview at 2:45 PM, the TP confirmed that the providers requested that a

	comment regarding potential adulteration be entered on patient final reports when creatinine results were less than 20 mg/dL and the CS confirmed that there was no procedure detailing how and when to add this comment on a final report.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the procedure manual and email communication with the compliance specialist (CS), the laboratory failed to document the condition and disposition of specimens that did not meet the laboratory's criteria for specimen acceptability. Findings: 1. Section "5.1.3 Specimen Submission, Handling, and Referral" of the procedure manual listed the "criteria used for the possible rejection of specimens" and stated "Health Care Providers will be contacted and informed when an unacceptable specimen is received and a new specimen is required. Record communication on specimen rejection log." 2. In an email received 03/27/2024 at 7:50 AM, the CS stated that "Concerning the rejection log, the Office Manager relays the message to the provider or makes a comment on the patient's next appointment, but she does not have a log" confirming that the laboratory was not documenting the condition and disposition of rejected patient specimens.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the "General Policies and Procedures" manual, laboratory records and interview with the compliance specialist (CS), the laboratory director (LD) failed to ensure that the technical consultant (TC) was reviewing the laboratory records on a routine basis to ensure that the new testing person (TP) was performing the test accurately and providing reliable test results. Findings: 1. The new TP started performing and releasing patient test results in October 2023. 2. The "Quality Control" section of the 3.2.3 Analytical Systems procedure within the "General Policy and Procedures" states "The quality control is reviewed monthly by the General Supervisor for any shifts and trends." and "Levey Jennings graphs are reviewed and signed monthly by the General Supervisor and quarterly by the Laboratory Director /Designee." Please note that the testing performed in this laboratory is moderate complexity, therefore, there is no need for a general supervisor. These duties are to be

	performed by the TC. 3. The "Monthly QC Review Form (Levy-Jennings)" records for November 2023 through February 2024 were reviewed. November and December 2023 showed that the testing person (TP) signed the review as the reviewer and the Laboratory Director/Designee. The TP who is not qualified as a TC cannot perform the review of the quality control and Levy-Jennings graphs. January and February 2024 showed no documented review by the TC or laboratory director/designee and the forms were pre dated as being reviewed on 01/31/24 and 03/01/24 with no signatures. 4. Section "5.2 Analytical" of the "General Policy and Procedures" manual states "There should be documentation that temperature and humidity charts are reviewed monthly by a lab supervisor to ensure that the temperature and humidity are being read, reported, and are within acceptable range." The temperature and humidity charts were not reviewed and the policies and procedures failed to identify the duties and responsibilities of a laboratory supervisor. 5. According to the CS the TC is part of the laboratory management system provided to the laboratory by SLP labs. The laboratory was assigned a temporary TC from October through December 2023 and then another TC was assigned starting in January 2024. Neither TC documented a review of the laboratory records as required by the "General Policy and Procedures" manual. 6. According to the TP, all the monthly laboratory records are to be sent electronically to the TC for review. This responsibility is not included in the job description of the TP. 7. During the exit interview at 2:45 PM, the CS was not able to provide electronic documentation showing that the monthly reviews were being documented; the procedure manual did not include the duties and responsibilities of a "lab supervisor"; and that the TP is to submit laboratory records electronically to the TC on a monthly basis for review.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: The technical consultant (TC) failed to ensure that oversight was provided to the laboratory on a monthly basis as defined in the "General Policy and Procedures." Cross refer to Tag D6014 for details.