

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2276616	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Map Rc Llc DbA Prime Regenerative And	Street Address, City, State 2565 Cowan Blvd, Fredericksburg, VA	
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
D0000	An announced CLIA recertification survey was conducted at MAP RC, LLC dba Prime Regenerative and Spine on April 1-2, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, maintenance documents, lack of documentation, and interviews, the laboratory failed to follow their establish policy to perform and document the annual function checks for the laboratory's centrifuge and incubator thermometer in calendar year 2024 The findings include: 1. Review of the laboratory's "Good Laboratory Practice" policy revealed the following instructions, "5.2 Verification and Equipment Calibration Activities, 5.2.1 Perform calibration checks...Thermometers and hygrometers (NIST traceable) should be checked and replaced on expiration." 2. Review of the laboratory's "QA (Quality Assurance) Policy and Forms" policy revealed the following statements, "The QA plan will be implemented by review of the following monitors at the frequency and method of review specified. Quality Assessment Forms for each monitor which are suitable for documenting the review...Analytical Checklist-Reagent Integrity and Instrument Maintenance, Calibration/Calibration Verification, QC Review: Analytical." Review of the above listed checklist revealed the following listing,</p>

"General-Annual maintenance performed as required " Pipettes Calibrated " Centrifuges Verified 3. Review of the laboratory's maintenance documentation from November 2023 until the date of the survey on April 1-2, 2025 revealed the following: One record of "Annual Centrifuge Verification Form" for the Hermle Z307 (serial # 872250012) dated as performed by the laboratory on 01/07/2025. One record of "Annual Incubator Temperature Check Form" for the LabNet Vortemp 56 Incubator (serial # 22010411) dated as performed by the laboratory on 01/07/2025. The surveyor requested to review the Centrifuge and Incubator Check Verification forms for calendar year 2024. The laboratory provided no documentation for review. 4. In an exit interview with the technical supervisors on April 2, 2025 at 9:15 AM, the above findings were confirmed.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, quality control (QC) records, and interview, the laboratory failed to follow their established policy to review Toxicology EIA Analyzer QC statistics monthly for six (6) of seventeen (17) months reviewed from November 2023 until the date of the survey on April 1-2, 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Control", with the statements "6.1 EIA Analyzer...6.1.2 Laboratory Director or Designee-Monthly identify failures, biases and trends for all QCs used in the screening with analyzer." 2. Review of the November 2023 to April 2023 Toxicology Indiko Plus EIA Analyzer QC records for Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Opiates, THC, Cocaine, Methadone, Alcohol /Ethanol, and Oxycodone revealed the following months lacked the laboratory director signature demonstrating the review of the QC Levy Jennings (LJ) charts for December 2023, January 2024, February 2024, March 2024, April 2024 and May 2024. A total of 6 of 17 months from November 2023 until April 2025. The surveyor requested to review the Laboratory Director reviewed QC documents for the above listed months. The laboratory provided no documents for review. 3. In an exit interview with the technical supervisors on April 2, 2025 at 9:15 AM, the above findings were confirmed.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory, review of Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS-116), laboratory's policies and procedures, toxicology records, and interviews, the laboratory failed to establish and follow a policy for the comparison of the toxicology testing performed on the laboratory's Indiko Plus EIA Analyzer and Agilent Technologies 6420 Triple Quad LC/MS from November 2023 until the date of the survey on April 1, 2025. The findings include: 1. In a tour of the laboratory at 9:10 AM on April 1, 2025, the surveyor noted an Indiko EIA Analyzer (Serial #864000094793) and Agilent Technologies 6420 Triple Quad LC/MS (Serial #14337001) in use in the laboratory for toxicology screening and confirmation testing. 2. Review of the laboratory's CMS-116 revealed two different analyzers, the Indiko Plus EIA Analyzer and Agilent Triple Quad LC/MS, were utilized for the detection of the following drugs in patient urine specimens: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Opiates, THC, Cocaine, Methadone, Alcohol /Ethanol, and Oxycodone. 3. Review of the laboratory's policies and procedures revealed a lack of a policy or procedure to perform and evaluate the twice annual result comparison between the Indiko EIA analyzer and Agilent Triple Quad LC/MS testing (see #2 for drug listing). 4. Review of the toxicology records from November 2023 up to the date of survey on April 1-2, 2025 revealed a lack of documentation of the result comparison/evaluation between the two (2) Toxicology analyzers listed above utilized in the detection of drugs in patient urine specimens (see #2 for drug listing). The surveyor requested documentation of the twice annual comparisons for the Indiko and Agilent analyzers for 2024. The laboratory provided no documentation to review. 5. In an exit interview with the technical supervisors on April 2, 2025 at 9: 15 AM, the above findings were confirmed.