

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2076684	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Recovery Services Of New Mexico, Llc	Street Address, City, State 901 3rd Street Nw, Albuquerque, NM	
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 onsite Validation survey conducted on January 30, 2025, at Baymark Health Srvcs/ Recovery Services of NM Lab found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, College of American Pathologist (CAP) proficiency testing (PT) drug master list, lack of documentation, and interview with the General Supervisor, the laboratory failed to verify the accuracy at least twice annually for 3 of 30 non-regulated analytes in 2023 and 2024. Findings included: 1. A review of the laboratory's test menu from 2023 and 2024 revealed the following non-regulated analytes the laboratory failed to verify the accuracy at least twice annually: - 2-hydroxyethylflurazepam - Alphahydroxymidazolam - Ritalantic Acid 2. A review of the CAP PT drug master list for the Urine Toxicology Survey kit in 2023 and 2024 revealed the 3 above analytes are not listed as analytes tested for by the CAP PT kit. 3. A request was made for documentation verifying the accuracy at least twice annually for the above 3 analytes. The laboratory failed to provide any documentation. 4. An Interview on 01/30/2025 at 10:16 am with the General Supervisor, confirmed the above findings. 5. The laboratory reported performing 459,756 toxicology tests annually.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p>

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of College of American Pathologist (CAP) proficiency testing (PT) records, lack of documentation, and interview with the General Supervisor, the laboratory failed to perform corrective actions for an unacceptable PT score for one of five PT samples tested for event 3 in 2023. Findings included: 1. A review of CAP PT records for event 3 in 2023 revealed the laboratory received a grade of unacceptable for PT sample UT-15 2. A request was made for documentation of corrective actions for the unacceptable PT score. The laboratory failed to provide documentation. 3. Interview on 01/30/2025 at 9:40 am with the General Supervisor confirmed the above findings. 4. The laboratory reported performing 459,756 toxicology tests annually.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(d)

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to have a policy for specimen storage and transportation requirements in 2023 and 2024. Findings include: 1. A request was made for policies with storage and transportation requirements for specimens. The laboratory failed to provide a policy. 2. During an interview on 01/30/2025 at 12:04 pm the TC stated specimens are received from multiple locations either through pickups by laboratory staff or FedEx, however there is no policy for storage requirements at collection facilities or during transport, confirming the above findings. 3. The laboratory reports performing 521,000 tests annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(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 review of the laboratory's Laboratory General Maintenance procedure, temperature logs, patient reports, and interview with the Technical Consultant (TC), the laboratory failed to follow its own procedure by failing to record daily temperatures and humidity for 4 days in 2024. Findings include: 1. Review of the facility's Laboratory General Maintenance procedure listed the following temperature and humidity monitoring frequency requirements: - Temperature will be checked and recorded daily for the following equipment. o Refrigerator (2-8C(Celsius)) o Freezer (-20C to no limit) o Room (20-36C) o Humidity (15%-85%) 2. Review of temperature logs revealed no temperature or humidity recordings for the following days in 2024: a. February 7,2024 b. September 13, 2024 c. September 23, 2024 d. September 29, 2024

3. Review of patient reports revealed that patient tests were reported without temperature or humidity monitoring: a. 68 patients on February 7, 2024 b. 30 patients on September 23, 2024 4. An Interview on 01/30/2025 at 1:23 pm with the TC confirmed the above findings. 5. The laboratory reports 512,000 tests annually.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of ThermoScientific DRI Fentanyl II Assay Instructions for Use (TS DRI IFU), lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to follow manufacturer's instructions for storage temperature requirements for urine samples in 2023 and 2024 by failing to verify sample temperature upon receipt. Findings include: 1. A review of the TS DRI IFU listed the following: - Cap the urine sample immediately, store refrigerated at 2-8C (Celsius) and assay within 7 days of collection. 2. A request was made for documentation that storage requirements were met for specimens at the collection facilities and during transport . The laboratory failed to provide documentation. 3. During an interview on 01/30/2025 at 11:06 am with the TC, they stated urine samples were collected offsite and transported in insulated bags, however specimens were not monitored for temperature storage requirements, which confirmed the above findings. 4. The laboratory reports performing 231,424 fentanyl tests annually.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the safety data sheet (MSDS) for methanol, and interview with the General Supervisor, the laboratory failed to monitor storage conditions for methanol in 2023 and 2024. Findings included: 1. During a tour of the laboratory room 2 on 01/30/2025 at 10:52 am 11 bottles of methanol were observed being stored. 2. A review of the MSDS for methanol listed the storage conditions as 2 - 30C (Celsius). 3. During an interview on 01/30/2025 at 12:00 pm with the general supervisor, they stated they are not currently monitoring the temperature in the room where the methanol is being stored. 4. The laboratory reported performing 459,756 toxicology tests annually.

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:

Based on review of manufacturer's user manual, maintenance logs, patient reports, and interview with the Technical Consultant (TC), the laboratory failed to perform required daily maintenance for the Thermo Scientific Indiko Plus for 7 days in 2024. Findings include: 1. Review of manufacturer's User Manual for the Thermo Scientific Indiko Plus (Serial Number 864000090107R) listed the following required daily maintenance : - Fill the water container with DI water. - Empty the waste water container. - Empty the cuvette waste bin. 2. Review of the laboratory's maintenance logs for the Thermo Scientific Indiko Plus in 2024 revealed daily maintenance was not performed on the following days: a. February 7, 2024 b. September 6, 2024 c. September 12, 2024 d. September 16, 2024 e. September 17, 2024 f. September 18, 2024 g. September 27, 2024 3. Review of patient reports revealed the following patients tested on days where daily maintenance was not performed: a. 68 patients on February 7, 2024 b. 49 patients on September 12, 2024 c. 110 patients on September 16, 2024 d. 31 patients on September 17, 2024 e. 90 patients on September 18, 2024 4. Interview on 01/30/2025 at 1:23 pm with the TC confirmed the above findings. 5. The laboratory reports performing 231,424 tests annually using the Indiko Plus analyzer.