

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 32D2163190	<b>(X3) Date Survey Completed</b> 01/09/2024
<b>Name of Provider or Supplier</b> New Mexico Treatment Services Llc	<b>Street Address, City, State</b> 123 Madera Drive Se, Albuquerque, NM	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite validation survey conducted at New Mexico Treatment Services on January 09, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, moderate complexity
<b>D5300</b>	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory records, laboratory test volume, Specimen Collection Policy, direct observation, review of patient reports, and interview the laboratory failed to meet the requirements for pre-analytic systems, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for the shipping and storage sample requirements for the ARK Fentanyl II Assay from July 2023 through October 2023. Refer to D5311 I 2. The laboratory failed to follow policies to ensure turbid specimens were not tested for 9 of 49 patient samples on January 8, 2024. Refer to D5311 II</p>
<b>D5311</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

I. Based on a review of manufacturer's instructions, laboratory policy, laboratory records, laboratory test volume, and staff interview, the laboratory failed to follow manufacturer's instructions for the shipping and storage sample requirements for 118 of 118 sample batches for the ARK Fentanyl II Assay testing from July 2023 through October 2023. Findings included: 1. Review of the manufacturer's instructions for the ARK Fentanyl II Assay (March 2020, 1600-1032-00 Rev 01) stated: "7. SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS Cap the urine sample immediately after collection, store refrigerated at 2-8C (36-46F) and assay within 7 days after collection." 2. Review of the laboratory's policy "Patient Test Management Policy" (signed by the laboratory director on 05/22/2019) stated: "Specimen Preservation, Transport, and Processing Preservation: Urines can be held seven days unrefrigerated and up to thirty days refrigerated. Transport: Urines can be transported at room temperature." The laboratory's policy failed to meet the manufacturer's preservation and shipping requirements for samples tested with the ARK Fentanyl II Assay. 3. Review of the laboratory's sample receipt log from clinic collection sites from July 2023 through October 2023 revealed 118 sample batches were received at ambient shipping conditions by the laboratory for testing. 4. Review of the laboratory's annual test volume revealed 120,000 tests are performed. 5. In an interview on 01/08/24 at 11:20 am, testing person number 1 stated samples are received in ambient conditions and may be stored up to 30 days before testing. After review of the above records, the findings were confirmed. Word Key: C = Degrees Celsius F = Degrees Fahrenheit 48884 II. Based on review of Specimen Collection Policy, direct observation, review of patient reports, and interview, the laboratory failed to follow policies to ensure turbid specimens were not tested for 9 of 49 patient samples on January 8, 2024. Finding Included: 1. Review of Specimen Collection Policy stated under specimen rejection criteria, "Turbid specimens will not be tested. The specimen can be recollected or canceled." 2. Observation on 1/8/2024 at 11:30 am of the laboratory testing area noted the following turbid patient samples waiting to be tested. 1. 3164-2 2. 1762-1 3. 3086-1 4. 1361 5. 3012 6. 3039 7. 1372-2 8. 1388 9. 3339 3. Review of patient reports on 1/9/2024 showed the samples for the patients listed were tested, confirming that turbid samples were run and not recollected or canceled. 4. Interview on 01/08/2024 at 11:30 am with testing person #1 confirmed the findings.

**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 review of Benzodiazepines Reagents procedure, Quality Control (QC)

Policy, calibration reports, and interview, the laboratory failed to follow procedures for running duplicate calibration for benzodiazepines for 8 of 8 events in January of 2023. Findings included: 1. Review of the procedure for Benzodiazepines on the V-series Using Syva Emit II Plus Reagents, stated "for qualitative analysis calibration should be run in duplicate". 2. Review of Quality Control Policy showed calibration is to be done once a week with no mention of running in duplicate for any analyte, contradicting the previously stated procedure. 3. Review of calibration reports showed calibrations for benzodiazepines were not being run in duplicate. 4. Interview on 01/08/2024 at 11:20 am with testing person #1 confirmed the discrepancy between the benzodiazepines reagent procedure and QC policy and confirmed testing personnel were only following the QC policy.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's test menu, review of laboratory policy, and staff interview, the laboratory failed to perform calibration verification every 6 months for 4 of 4 events on the Siemens Viva E analyzer in 2022 and 2023. Findings included: 1. A review of the laboratory's test menu revealed the following analytes were tested on the Siemens Viva E analyzer in 2022 and 2023: Amphetamines Barbiturate Benzodiazepine Buprenorphine Cocaine Metabolite Opiate Methadone Oxycodone EDDP (Methadone Metabolite) Fentanyl Creatinine 2. Review of the laboratory's policy titled "Quality Control Policy" (signed by the laboratory director on 05/22/2019) stated: "G. Semi Annual Calibration Verification - Both Complexities: Calibration Verification is not required for qualitative; absorbance based testing according to CLIA/COLA regulations." 3. The laboratory was asked to provide documentation of performing Calibration Verification every 6 months in 2022 and 2023. No documentation was provided. 4. In an interview on 01/08/2024 at 11:20 am, after review of the above records, testing person number 1 confirmed the findings.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of manufacturer's instructions, laboratory policies, laboratory records, direct observation, and staff interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed ensure an effective quality assurance plan was established and maintained. Refer to D6021.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on manufacturer's instructions, laboratory policies, laboratory records, direct observation, and staff interview, the Laboratory Director failed to have an effective quality assurance program in place as evidenced by: 1. The Laboratory Director failed to ensure sample storage, shipping, and rejection requirements were met prior to performing patient testing. Refer to D5311. 2. The Laboratory Director failed to establish calibration verification procedures. Refer to D5439.