

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1104004	(X3) Date Survey Completed 02/18/2026
Name of Provider or Supplier Neuromedical Center Clinic, The	Street Address, City, State 10101 Park Rowe Avenue Suite 200, Baton Rouge, LA	
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	A Recertification survey was performed at The Neuromedical Center Clinic, CLIA ID 19D1104004, on February 18, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with personnel, the laboratory failed to ensure the Testing Personnel signed the attestation statement for one (1) of four (4) proficiency testing events reviewed. Findings: 1. Review of the laboratory's 2024 and 2025 American Proficiency Institute (API) proficiency testing records revealed the Testing Personnel did not sign the attestation statement for 2024 Chemistry - Miscellaneous - 2nd Event. 2. In interview on February 18, 2026 at 12:30 p.m., Testing Personnel 1 confirmed he did not sign the attestation statement.</p>
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:</p>

Based on review of the laboratory's test menu, policy and procedure manual, and proficiency testing records; as well as interview with personnel, the laboratory failed to verify the accuracy of urine drug screen testing for ecstasy at least twice annually in 2024 and 2025. Findings: 1. Review of the laboratory's test menu revealed the laboratory performed urine drug screen testing for ecstasy on the Indiko Plus analyzer. 2. Review of the laboratory's policy "MC General SOP" section "Proficiency Testing Procedures" revealed "...the lab is enrolled in approved external Proficiency Testing programs for all regulated analytes that can be tested by an approved proficiency testing program...In addition, we perform split-sample analysis with other CLIA-certified laboratories as an external validation of all regulated and non-regulated analytes not included in our approved proficiency testing programs." 3. Review of the laboratory's 2024 and 2025 American Proficiency Institute (API) proficiency testing records and twice year verification records revealed the laboratory did not verify the accuracy of urine drug screen testing for ecstasy in 2024 and 2025 through proficiency testing or split sample analysis. 4. In interview on February 18, 2026 at 11:12 a.m., Testing Personnel 1 confirmed the laboratory did not have documentation of twice a year verification of urine drug screen testing for ecstasy as identified above. 5. Review of the laboratory's test menu revealed the laboratory performs 6,301 urine drug screens for ecstasy 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 observation, review of manufacturer's instructions and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory from February 2024 through January 2026. Findings: 1. Observation by surveyor during the laboratory tour on February 18, 2026 at 10:07 a.m. revealed the laboratory stored the following urine specimen tubes in the laboratory: * BD Vacutainer Urinalysis Urine Tube - Manufacturer's storage requirements: 4 - 25 degrees Celsius (C) 2. Review of the laboratory's temperature records from February 2024 through January 2026 revealed the laboratory defined the acceptable room temperature limits as 18 to 30 degrees Celsius which exceeded the manufacturer's upper limit. 3. In interview on February 18, 2026 at 10:20 a.m., Testing Personnel 1 confirmed the laboratory's acceptable limits exceeded the manufacturer's limits as identified above.

D5439

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

(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 observation; review of the laboratory's policy and procedure manual, calibration verification records, and test menu; as well as interview with personnel, the laboratory failed to perform calibration verification procedures on the Indiko Plus analyzer utilized for urine drug screen (UDS) testing at least once every six (6) months in 2024 and 2025. Findings: 1. Observation by surveyor during the laboratory tour on February 18, 2026 at 10:07 a.m. revealed the laboratory utilized the Indiko Plus analyzer for testing of the following analytes on urine specimens: Creatinine, pH, Ethanol (ETOH), Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cannabinoid, Ecstasy, Hydrocodone, Methadone, Opiate, and Oxycodone. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for performing calibration verification at least every six (6) months. 3. Review of the laboratory's calibration records revealed the laboratory did not have documentation of performance of calibration verification at least every six (6) months in 2024 and 2025. 4. In interview on February 18, 2026 at 1:24 p.m., Testing Personnel 1 stated the laboratory performs a two (2) point calibration at least weekly and performs two (2) levels of quality control each day of patient testing. He further stated he was unaware of the requirement for calibration verification at least every six (6) months. He confirmed calibration verification was not performed as identified above. 5. Review of the laboratory's test menu revealed the laboratory performs 88,214 urine drug screen tests annually.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

(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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of urine drug screen testing for ecstasy at least twice annually in 2024 and 2025. Refer to D5217. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory from February 2024 through January 2026. Refer to D5413.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D2009.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5439.