Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1104004	01/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Neuromedical Center Clinic, The	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	An Initial survey was performed at The Neuromedical Center Clinic, CLIA ID 19D1104004, on January 24, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instructions, temperature logs, and interview with personnel, the laboratory failed to ensure urine human chorionic gonadotropin (hCG) test kits were stored at 15 degrees Celsius to 30 degrees Celsius per the manufacturer's requirements. Findings: 1. Observation by surveyor on January 24, 2024 at 9:46 am, on the third floor in the room where urine hCG test kits were stored, revealed the laboratory utilizes SAS Ultimate hCG test kits for urine pregnancy testing. Surveyor did not observe a thermometer monitoring the room temperature. 2. Review of the manufacturer's package insert revealed the following storage requirement: "Store at 15 degrees Celsius to 30 degrees Celsius." 3. Review of the laboratory's temperature logs revealed the laboratory did not have a temperature log for the room where the urine hCG kits were stored. 4. In interview on January 24, 2024 at 1:28 pm, the Director of Clinical Systems confirmed the laboratory did not monitor the room temperature where the urine hCG kits were stored.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of 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: Based on observation by surveyor, review of the laboratory's policies, patient test logs, and interview with personnel, the laboratory failed to reject five (5) of thirty-seven (37) randomly selected patient samples, from test dates January 8, 2024 through January 11, 2024, that exceeded the laboratory's 24 hours sample stability criteria. Findings: 1. Observation by surveyor in the laboratory during the tour on January 24, 2024 at 9:30 am revealed the laboratory utilized the Indiko Plus analyzer for UDS testing of the following drugs and analytes: alcohol, amphetamines, barbiturates, benzodiazepines, buprenorphine, cocaine, ecstasy, hydrocodone, methadone, opiate, oxycodone, cannabinoid, pH and creatinine. 2. Review of the laboratory's "Specimen Collection, Storage & Transport" and "Specimen Rejection" policies revealed the following: a) "If the samples are not analyzed immediately, specimens may be stored refrigerated at 2-8 degrees Celsius for up to 24 hours." b) Specimen Rejection: "Specimens that do not adhere to our laboratory stability standards for storage at refrigerated temperature. Urine Stability: Refrigerated: 24 hours." 3. Review of random selection of patient test logs from test dates January 8, 2024 through January 12, 2024 revealed the following five (5) of thirty-seven (37) patients reviewed were not rejected based on the laboratory's 24 hours sample stability criteria: Patient 129121: Collected: January 2, 2024; Received: January 9, 2024 Patient 116485: Collected: January 5, 2024; Received: January 9, 2024 Patient 153253: Collected January 8, 2024; Received: January 11, 2024 Patient 134703: Collected January 8, 2024; Received: January 10, 2024 Patient 81760: Collected: January 9, 2024; Received: January 11, 2024 4. In interview on January 24, 2024 at 1:33 pm, the Testing Personnel confirmed the identified patient samples were not rejected based on the laboratory's 24 hours sample stability criteria.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(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 review of the laboratory's policies and interview with personnel, the laboratory failed to provide written instructions for specimen handling, transport, and stability to providers at satellite clinics for urine drug screen (UDS) testing. Findings: 1. In interview on January 24, 2024 at 9:27 am, the Testing Personnel stated the laboratory receives samples from their satellite clinics located in Zachary, Slidell, and Hammond. 2. Review of the laboratory's policies revealed the laboratory had written "Specimen Collection, Storage, & Transport" and "Specimen Rejection" policies. 3. In interview on January 24, 2024 at 12:53 pm, the Director of Clinical Systems, stated the satellite clinics did not have access to the written instructions for specimen

	collection, handling, and rejection. The Director of Clinical Systems stated the laboratory has the only copy of the instructions; if satellite clinics have questions they would have to contact the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 observation by surveyor, review of maintenance logs, and interview with personnel, the laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for one (1) of four (4) months in 2023 reviewed. Findings: 1. Observation by surveyor in the laboratory during the tour on January 24, 2024 at 9:30 am revealed the laboratory utilized the Indiko Plus analyzer for UDS testing of the following drugs and analytes: alcohol, amphetamines, barbiturates, benzodiazepines, buprenorphine, cocaine, ecstasy, hydrocodone, methadone, opiate, oxycodone, cannabinoid, pH and creatinine. 2. Review of the "Indiko Plus Maintenance Checklist" logs revealed the following monthly procedures were not performed in December 2023: a) "Decontaminate all reservoirs and tubing" b) "Clean cuvette incubator" 3. In interview on January 24, 2024 at 12:04 pm, the Testing Personnel confirmed performance of the monthly maintenance procedures for December 2023 was not documented.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy, quality control (QC) records, corrective action logs, and interview with personnel, the laboratory failed to evaluate patient test results since the last acceptable test run when quality control and calibration failed to meet the laboratory's acceptability for one (1) of fifty-five (55) testing days reviewed for Urine Drug Screens (UDS). Findings: 1. Observation by surveyor in the laboratory during the tour on January 24, 2024 at 9:30 am revealed the laboratory utilized the Indiko Plus analyzer for UDS testing of the following drugs and analytes: alcohol, amphetamines, barbiturates, benzodiazepines, buprenorphine, cocaine, ecstasy, hydrocodone, methadone, opiate, oxycodone, cannabinoid, pH and creatinine. 2. Review of the laboratory's "Quality Control Policies and Procedures for Screening Instrumentation" for daily control acceptability revealed the following actions to take for unacceptable results: a) "Repeat controls b) If repeated controls are still beyond the established range, re-calibrate and rerun the controls c) When controls

	are within the established range, patients can be tested, and results released d) Document all corrective actions taken Weekly reviews of quality controls must be documented: e) To assure control materials are not deteriorating f) If a control is repeatedly out of range, replace with a new bottle of control material g) Assess if there is any trending or shifting of the target value/mean h) Document the weekly review on the maintenance log for the instrument Monthly reviews of quality controls must be documented: i) To determine if there are any trends or shifts in the target value or mean j) Review any documentation of control materials for out of range for proper corrective actions" 3. Further review of the laboratory's QC policy revealed the laboratory did not include written instructions for an evaluation of patient results to determine impact for repeated QC and calibration failures. 4. Review of quality control records and corrective action logs for December 2023 revealed on December 13, 2023 the "DOAT 4" control for benzodiazepines was tested a total of seven (7) times before it passed and thirty-six (36) patients were reported. The laboratory's documented corrective actions included re-run of the control, re-calibration twice, and use of a new control. 5. In interview on January 24, 2024 at 12:19 pm, the Testing Personnel confirmed the laboratory did not have a policy or documentation of an evaluation of patient test results since the last acceptable test run.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instructions, random selection of patient final test reports, test menu, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer for three (3) of three (3) patients reviewed. Findings: 1. Observation by surveyor in the laboratory during the tour on January 24, 2024 at 9:30 am revealed the laboratory utilized the Indiko Plus analyzer with Thermo Scientific DRI assay reagents for UDS testing. 2. Review of Thermo Scientific package insert under "Intended Use" revealed "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 3. Review of the following random selection of patients with UDS testing revealed the laboratory did not include the identified preliminary result comment: Patient 98866 Patient 80329 Patient 81760 4. In interview on January 24, 2024 at 12:08 pm, the Testing Personnel confirmed the laboratory did not report the urine drug screen results as preliminary as required by the manufacturer. 5. Review of the laboratory's test menu revealed the laboratory performs 163,800 UDS tests annually.

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of random selection of patient final test reports, test menu, and interview with personnel, the laboratory failed to include the normal qualitative value on patient final reports for Urine Drug Screen (UDS) testing for three (3) of three (3) patients reviewed. Findings: 1. Observation by surveyor in the laboratory during the tour on January 24, 2024 at 9:30 am revealed the laboratory utilized the Indiko Plus analyzer with Thermo Scientific DRI assay reagents for UDS testing. 2. Review of patient final test reports for UDS testing revealed the laboratory reports qualitative (positive/not detected) results; however, the laboratory did not include the normal qualitative value on the patient final test reports. 3. Further review of patient final test reports for UDS testing revealed the laboratory did not report the normal qualitative value on patient final reports for the following three (3) patients: Patient 98866 Patient 80329 Patient 81760 4. In interview on January 24, 2024 at 12: 08 pm, the Testing Personnel confirmed the laboratory did not report the normal qualitative value for UDS testing. 5. Review of the laboratory's test menu revealed the laboratory performs 163,800 UDS tests annually.
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 observation by surveyor, review of records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to reject five (5) of thirty-seven (37) randomly selected patient samples, from test dates January 8, 2024 through January 11, 2024, that exceeded the laboratory's 24 hours sample stability criteria. Refer to D5311. 2. The laboratory failed to provide written instructions for specimen handling, transport, and stability to providers at satellite clinics for urine drug screen (UDS) testing. Refer to D5317.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required monthly maintenance for one (1) of four (4) months in 2023 reviewed. Refer to D5429.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5783.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information for three (3) of three (3) patients reviewed. Findings: 1. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer for three (3) of three (3) patients reviewed. Refer to D5805. 2. The laboratory failed to include the normal qualitative value on patient final reports for Urine Drug Screen (UDS) testing for three (3) of three (3) patients reviewed. Refer to D5807.