Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2139173	03/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinicore	800 North Causeway, Suite 300, Mandeville, 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 on March 25, 2024 at Clinicore, CLIA ID # 19D2139173. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 test menu and client services manual as well as interview with personnel, the laboratory failed to include instructions for specimen handling, transport, and stability requirements for molecular microbiology and toxicology testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory performed molecular microbiology and toxicology testing. 2. In interview on March 25, 2024 at 3:56 p.m., the Technical Supervisor stated the laboratory began testing molecular microbiology in March 2024 and toxicology in October 2023. 3. Review of the laboratory's client services manual revealed the laboratory did not include the testing identified above. 4. In interview on March 25, 2024 at 3:56 p.m., the Technical Supervisor confirmed the laboratory's client services manual was not updated to include molecular microbiology and toxicology requirements.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's package inserts, and interview with personnel, the laboratory failed to document the open expiration date for chemistry quality control (QC) material as required. Findings: 1. Observation by surveyors on March 25, 2024 at 10:15 a.m. revealed the following thawed chemistry quality control vials in the Insignia refrigerator. - BioRad Liquicheck Immunoassay Plus Control, Level 1, Lot: 85321, manufacturer's expiration date: 5/31/2024, Quantity: two (2) bottles - BioRad Liquicheck Immunoassay Plus Control, Level 2, Lot: 85322, manufacturer's expiration date: 5/31/2024, Quantity: one (1) bottle - BioRad Liquicheck Immunoassay Plus Control, Level 3, Lot: 85323, manufacturer's expiration date: 5/31/2024, Quantity: two (2) bottles - BioRad Liquicheck Specialty Immunoassay Control, Level 1, Lot 64991, manufacturer's expiration date: 5/31/2026: Quantity: one (1) bottle - BioRad Liquicheck Specialty Immunoassay Control, Level 3 Lot 64993, manufacturer's expiration date: 5/31/2026: Quantity: one (1) bottle 2. Further observation of the QC materials identified above revealed the bottles did not have an open expiration date documented. 3. Review of the manufacturer's package insert for BioRad Liquicheck Immunoassay Plus Control revealed the following storage and stability requirements: a) This product will be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius. b) Thawed Unopened: When thawed and stored unopened at 2 to 8 degrees Celsius, this product is stable as follows: - All Analytes: 30 days Except: - Androstenedione: 25 days - Prolactin, PSA (Free) and PSA (Total): 14 days - Estradiol: 8 days - Folate: 4 days Date of thaw should be noted. c) Thawed opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: - All Analytes: 14 days Except: - Estradiol: 5 days - Folate: 4 days 4. Review of the manufacturer's package insert for BioRad Liquicheck Specialty Immunoassay Control revealed the following storage and stability requirements: a) This product will be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius. b) Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: - All Analytes: 30days Except: - PTH (Intact): 7 days c) Thawed Unopened: When thawed and stored unopened at 2 to 8 degrees Celsius, this product will be stable as follows: - All Analytes: 30days Except: - PTH (Intact): 7 days 5. In interview on March 25, 2024 at 10:45 a.m., the Technical Supervisor confirmed the laboratory did not document the open expiration date for the thawed QC materials identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: **Repeat deficiency from previous survey conducted on May 25, 2022.** Based on observation by surveyors and interview with personnel, the laboratory failed to ensure reagents did not exceed expiration dates. Findings: 1. Observation by surveyor on March 25, 2024 at 10:15 am during the laboratory tour revealed the following expired

	items: a) Panasonic refrigerator: UTAK SSRI 7 Plus MR Serum Control, lot C8454, Expiration date: 2024-02-29, Quantity: one (1) bottle Drugs of Abuse Level 1 Whole Blood Control, lot C7674, Expiration date: 2023-11-30, Quantity: one (1) bottle PM 100 Whole Blood Control, lot C4306, Expiration date: 05/2022, Quantity: one (1) bottle UTAK SSRI 7 Plus MR Serum controls, lot 5704, Expiration date: 2024-02-29, Quantity: one (1) bottle Tricyclics VI MR Serum control, lot C8012, Expiration date: 2023-07-31, Quantity: one (1) box Applied Biosystems Array Card Spectral Calibration Dye Kit, Expiration date: 2022-12-13, Quantity: one (1) box Located in blue plastic bin labeled "UTI and STI In Use:" TaqMan Fast Advanced Master Mix, Expiration date: 2022-05-31, Quantity: one (1) bottle Located in blue plastic bin labeled "UTI and STI In Use:" More Diagnostics Clinical Chemistry Controls EV/Rap /Tac/CsA controls 1-4, lot 9148, Expiration date: 2023-05-27, Quantity: one (1) box b) pHcbi Freezer located in blue plastic bin labeld "UTI/STI opened:" Applied Biosystems TaqMan Vaginal Microbiota Amplification control, Expiration date: 2022-05-07, Quantity: one (1) vial Applied Biosystems TaqMan Open Array Real-Time PCR Master Mix, 2022-01-31, Quantity: one (1) vial c) Insignia refrigerator: Access TPO Antibody Calibrators, Lot 389818, manufacturer's expiration date: 7/23/2024, open expiration date: 3/22/2024, Quantity: one (1) open box 2. In interview on March 25, 2024 at 10:48 am, the Technical Supervisor confirmed the identified items were expired.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's performance specification studies, test menu, patient final reports, and interview with personnel, the laboratory failed to define the normal values (cut-offs) for therapeutic drug monitoring (TDM) testing. Findings: 1. Observation by surveyors during the laboratory tour on March 25, 2024 at 10:15 am and review of the laboratory's test menu revealed the laboratory utilizes the LCMS 8060 CC for TDM testing of the following drugs: Morphine, Acetaminophen, Oxymorphone, Hydromorphone, Cotinine, Amphetamine, Naloxone, Norhydrocodone, Codeine, 6-MAM, Norhydrocodone, MDA, Methamphetamine, O-desmethyltramadol, Oxycodone, Phetermine, Olanzapine *, Aripiprazole *, Hydrocodone, MDMA, Caffeine, Lamotrigine, Norfentanyl, Tapentadol, Benzoylecgonine, Tramadol, Meprobamate, Methylphenidate, Normeperidine, Meperidine, Bupropion, 7-Aminoclomazepam, Norbupropion, Citalopram, Fentanyl, Carisoprodol, Buprenorphine, Fluoxetine, PCP, Quetiapine, Desipramine, Imipramine, Cyclobenzaprine, Nortriptyline, EDDP, Amitriptyline, Lorazepam, Clonazepam, Oxazepam, Sertraline, Methadone, Alpha-OH-Alprazolam, Nordiazepam, Alprazolam, Temazepam, Diazepam, Zolpidem-

	COOH, THC-COOH, Phenobarbital, Butalbital, and 7-OH-Mitragynine. *-only reported in blood samples 2. Review of the laboratory's performance specification studies for TDM testing revealed the laboratory did not include the cut-off values for the identified drugs. 3. In interview on March 25, 2024 at 5:33 pm, the Technical Supervisor stated the low cut-off values listed on the "TM2 Toxicology AMR" document were the same as the ones included on their patient final reports. The Technical Supervisor provided Surveyor 2 the "TM2 Toxicology AMR" document at the time of the interview. 4. Review of the "TM2 Toxicology AMR" document and random patient final test reports for blood and urine TDM testing revealed the cut-offs for Methamphetamine, Benzoylecgonine, Desipramine, Nortriptyline, Amitriptyline, and Lorazempam differed. Olanzapine, Aripiprazole, and Gabapentin were not included on the "TM2 Toxicology AMR" list. 5. In further interview on March 25, 2024 at 5:45 pm, the Technical Supervisor confirmed the laboratory's performance specification studies did not define the normal (cut-off) values that were in use by the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and maintenance records, observation, and interview with laboratory personnel, the laboratory failed to perform pipet calibrations annually as required by the laboratory. Findings: 1. Review of the laboratory's policy "Maintenance and Safety" revealed the following: a) The following pipettes are used at CliniCORE: - Gilson Pipetman L P8X200L Multichannel pipette - Gilson Pipetman L P1000L 100 - 1000 uL - Gilson Pipetman L P200L 20 - 200 uL - Gilson Pipetman L P20L 2 - 20 uL b) Each pipette must be calibrated every year and the pipette calibration report/certificate must be stored in the Certificate of Analysis book. 2. Observation by surveyors during the laboratory tour on March 25, 2024 at 10: 15 a.m. revealed the pipettes had stickers stating calibration was due in June 2024. 3. Review of the laboratory's maintenance records revealed the laboratory did not have documentation of pipette calibrations performed in 2023. 3. In interview on March 25, 2024 at 6:13 p.m., the General Supervisor stated an outside vendor performed the calibrations. He confirmed the laboratory did not have documentation the pipet calibrations were performed in 2023.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable limits per laboratory policy for twenty four (24) of 253 days reviewed. Findings: 1. Review of the laboratory's "Quality Assurance Plan" under the "Temperatures" section revealed "If temperatures fall outside the specified limits, corrective action is instituted and recorded on the log sheets." 2. Review of the laboratory's temperature logs for 2023 revealed the acceptable temperature range for the pBHCI freezer was -20 degrees Celsius to -30 degrees Celsius. 3. Further review of the laboratory temperature logs for 2023 revealed the pBHCI freezer temperatures were documented as outside of acceptable range without corrective actions for the following twenty four (24) days: January 3, 2023: documented temperature of -11 degrees Celsius January 6, 2023: documented temperature of -11 degrees Celsius January 19, 2023: documented temperature of -15 degrees Celsius February 8, 2023: documented temperature of -17 degrees Celsius February 17, 2023: documented temperature of -11 degrees Celsius February 20, 2023: documented temperature of -13 degrees Celsius February 28, 2023: documented temperature of -17 degrees Celsius April 7, 2023: documented temperature of -19 degrees Celsius April 11, 2023: documented temperature of -19 degrees Celsius April 17, 203: documented temperature of -19 degrees Celsius April 18, 2023: documented temperature of -17 degrees Celsius April 20, 2023: documented temperature of -17 degrees Celsius April 25, 2023: documented temperature of -17 degrees Celsius May 2, 2023: documented temperature of -18 degrees Celsius May 8, 2023: documented temperature of -17 degrees Celsius May 9, 2023: documented temperature of -11 degrees Celsius May 11, 2023: documented temperature of -15 degrees Celsius May 18, 2023: documented temperature of -17 degrees Celsius May 23, 2023: documented temperature of -18 degrees Celsius May 24, 2023: documented temperature of -18 degrees Celsius July 11, 2023: documented temperature of -18 degrees Celsius July 19, 2023: documented temperature of -17 degrees Celsius July 21, 2023: documented temperature of -17 degrees Celsius July 25, 2023: documented temperature of -17 degrees Celsius 4. In interview on March 25, 2024 at 4:42 pm, the Technical Supervisor confirmed the laboratory did not have documentation of performance of corrective actions for unacceptable temperatures for the identified days.
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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

	The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5415.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 surveyors and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to include instructions for specimen handling, transport, and stability requirements for molecular microbiology and toxicology testing. Refer to D5317. 2. The laboratory failed to ensure reagents did not exceed expiration dates. Refer to D5417.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 the establishment of maintenance procedures as required. Refer to D5435.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)

	The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5785.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight of the laboratory. Findings: 1. The laboratory failed to include instructions for specimen handling, transport, and stability requirements for molecular microbiology and toxicology testing. Refer to D5317. 2. The laboratory failed to ensure reagents did not exceed expiration dates. Refer to D5417. 3. The laboratory failed to perform pipet calibrations annually as required by the laboratory. Refer to D5435.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies. Refer to D5423.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785.