Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D2128775	**(X3) Date Survey Completed** 03/12/2019
Name of Provider or Supplier Mcleod Addictive Disease Center Laboratory	**Street Address, City, State** 515 Clanton Road, Charlotte, NC	

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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the GS (general supervisor) 3/12/19, the laboratory failed to establish and follow written policies and procedures for evaluating the competency of the general supervisor. Review of policies and procedures revealed the laboratory did not have a written policy for evaluating the competency of the GS for the performance of supervisory responsibilities. Review of personnel records revealed the GS had competency evaluations in October 2017 and April - June 2018 for test performance. The competency evaluations did not include supervisory responsibilities. During interview at approximately 6:00 p.m., the GS confirmed competency evaluations conducted in 2017 and 2018 did not include supervisory responsibilities.
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 review of manufacturer's instructions and interview with staff 3/12/19, the laboratory failed to follow the manufacturer's instructions for the preparation of specimens for testing on the AU5800. Review of manufacturer's product inserts revealed the manufacturer specifies turbid specimens should be centrifuged before analysis. Examples: a. The product insert for the Thermo Scientific CEDIA Cocaine Assay states "... Specimen Collection and Handling... Centrifuge specimens with high turbidity before testing. ..." b. The product insert for the Thermo Scientific DRI Ethyl Alcohol Assay states "... An effort should be made to keep pipetted samples free from gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. ..." c. The product insert for the Syva Emit II Plus Cannabinoid Assay states "... 5 Specimen Collection and Preparation ... Specimens with high turbidity should be centrifuged before analysis. ..." During interview at approximately 3:10 p.m., the laboratory director and the general supervisor stated they don't usually receive turbid specimens. They stated they do not have a centrifuge and they do not centrifuge specimens before testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and review of random patient test reports 03 /12/19, the laboratory procedures for potential of hydrogen (PH) and creatinine do not reflect the normal ranges on the patient test report. Review of laboratory procedures for PH and creatinine revealed the following normal ranges: 1. "pH between 4.7 - 7.8" 2. "Creatinine concentration of 80-200 mg/dL" Review of random patient test reports, #061932 and #2025360, revealed the following normal ranges: 1. pH - "4.5 -9.0" 2. Creatinine - "20.0 - 400.0 mg/dL"
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 surveyor observation, review of manufacturer package inserts and testing personnel (TP) interview 03/12/19, the laboratory failed to label expiration dates on opened and in use quality control (QC) and calibration material. At approximately 5:00 p.m. surveyor observed 2 large cardboard box tops, labeled "in use", in laboratory's reagent storage refrigerator. The cardboard box tops contained over 30 bottles of various QC and calibration material that were open and available for use. The QC and calibration bottles were all labeled with a receipt date and an open date. The QC and calibration bottles were not labeled with expiration dates. Review of manufacturer package inserts revealed QC and calibration material have expiration dates that change once the bottle of material is opened. For example: 1. Package insert for Bio-Rad Quantify Control Levels 1 and 2 states "This product will be stable until the expiration date when stored unopened at 2 to 8 degrees C. Once opened, this product will be stable for 31 days when stored tightly capped at 2 to 25 degrees C..." 2. Package insert for Cedia Propoxyphene/Methadone Calibrators states "Stability prior to opening the bottle: up to the printed expiration date. Stability after opening the bottle: 60 days or until the printed expiration date, whichever comes first." 3. Package insert for Cedia Buprenorphine Calibrators and Controls states "For the stability of the opened calibrators or controls, 60 days or until the printed expiration date, whichever comes first." Interview with TP#2 at approximately 5:00 p.m. confirmed the QC and calibration bottles observed by the surveyor were open and in use.
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 review of laboratory validation records for the AU5800 chemistry analyzer, review of manufacturer product bulletin, review of Federal Food and Drug Administration (FDA) website and laboratory director (LD) and general supervisor (GS) interview 3/12/19, the laboratory failed to establish and/or document analytical specificity that included interfering substances for analytes that did not have FDA approval prior to performing patient testing. The laboratory began patient testing on the AU5800 on 5/17/17. Review of AU5800 validation records, review of ThermoFisher Scientific Product Bulletin, dated 9/21/18, and review of FDA website revealed the laboratory uses the following reagents on the AU5800 chemistry analyzer

	which are not FDA approved: 1. CEDIA Amphetamine Assay reagent 2. CEDIA Barbiturate Assay reagent 3. CEDIA Benzodiazepine Assay reagent 4. CEDIA Cocaine Assay reagent 5. CEDIA Methadone Metabolite (EDDP) Assay reagent 6. CEDIA Methadone Assay reagent 7. DRI Ethylglucuronide Assay reagent 8. CEDIA Opiate Assay reagent 9. CEDIA Phencyclidine (PCP) Assay reagent Review of validation records for the AU5800 chemistry analyzer revealed the laboratory had documented and established accuracy, precision, analytical sensitivity and reportable range performance characteristics for the non-FDA approved analytes. The validation records failed to reveal the establishment and/or documentation of analytical specificity that included interfering substances for the non-FDA approved analytes. Interview with LD at approximately 1400 revealed the LD was not aware that all the testing performed on the AU5800 was not FDA approved. She stated she became the LD after the installation of the AU5800 and assumed all testing except for Ethylglucuronide was FDA approved. At approximately 1420, she confirmed the validation performed on the AU5800 did not include interfering substances. Interview with GS at approximately 1700 confirmed that patient testing on the AU5800 began on 5/17/17.
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 review of random patient test reports and interview with the LD (laboratory director) 3/12/19, the laboratory director failed to ensure patient test reports included pertinent information for all analytes that did not have Food and Drug Administration (FDA) approval. The laboratory performs the following testing on the AU5800 chemistry analyzer that is not FDA approved (see D5423). 1. CEDIA Amphetamine Assay reagent 2. CEDIA Barbiturate Assay reagent 3. CEDIA Benzodiazepine Assay reagent 4. CEDIA Cocaine Assay reagent 5. CEDIA Methadone Metabolite (EDDP) Assay reagent 6. CEDIA Methadone Assay reagent 7. DRI Ethylglucuronide Assay reagent 8. CEDIA Opiate Assay reagent 9. CEDIA Phencyclidine (PCP) Assay reagent Review of random patient test reports, #061932 and #2025360, revealed the test reports included a disclaimer indicating that the performance characteristics of Ethylglucuronide testing were established by the laboratory and have not been cleared or approved by the FDA. The test reports failed to include this disclaimer for all analytes that were not cleared or approved by the FDA (see test list above). Interview with LD at approximately 1400 revealed the LD was not aware that all the testing performed on the AU5800 was not FDA approved. She stated she became the LD after the installation of the AU5800 and assumed all testing except for Ethylglucuronide was FDA approved