Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2137666	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Community Behavorial Services Lab	2216 West Meadowview Road, Suite 111, Greensboro, 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
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory procedures, review of 2019 American Proficiency Institute (API) proficiency testing (PT) records, review of patient records, review of manufacturer's instructions, interview with sales representative and surveyor observation 9/24/19, the laboratory failed to meet all specified requirements for the performance of urine drug screen testing on the Diatron Pictus 500 chemistry analyzer. Findings: The laboratory performs urine toxicology screen testing on the Diatron Pictus 500 chemistry analyzer for the following analytes; Amphetamines (AMPH), Cocaine (COC), Opiate (OPI), Oxycodone (OXY) and Cannabinoid (THC). Urine specimens are then frozen and later sent out to a reference laboratory for confirmation testing. 1. The laboratory failed to participate in the 2019 API 1st PT event for Chemistry-Miscellaneous to verify the accuracy of the urine drug screen testing. See D5217. 2. The laboratory failed to establish and/or follow policies and procedures for specimen storage, the conditions for specimen transportation, the criteria for specimen acceptability and rejection, procedures for specimen processing, and the criteria for specimen referral. See D5311. 3. The laboratory failed to monitor, document and/or define the correct criteria for the room temperature and humidity, and the refrigerator and freezer temperatures used to store and freeze urine specimens before they are sent out for drug confirmation testing. See D5413. 4. The laboratory failed to discard supplies that had exceeded their expiration date. See D5417. 5. The laboratory failed to establish performance specifications for interfering substances for the testing performed on the Diatron Pictus 500 chemistry analyzer. See D5423.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of 2019 American Proficiency Institute (API) proficiency testing (PT) records, absence of documentation, review of patient records, and observation 9 /24/19, the laboratory failed to participate in a system to verify accuracy of the urine drug screen test results. Findings: Review of the 2019 API Order confirmation revealed the laboratory enrolled in PT for Urine Drug Screen and Urine Adulteration Test on 3/20/19. The API order confirmation revealed the 1st PT event for Chemistry-Miscellaneous shipped to the facility on 4/22/19. There was no documentation present that the 1st PT event was tested. During tour of the lab at approximately 11:15 a.m., surveyor observed the unopened API PT samples in the laboratory's refrigerator. Review of patient records revealed patient testing was performed in January, February, March and April, 2019.
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 laboratory procedures, review of manufacturer's instructions, review of "Urine Test Request" forms, surveyor observation and interview with service representative 9/24/2019, the laboratory failed to establish and/or follow policies and procedures for specimen storage, the conditions for specimen transportation, the criteria for specimen acceptability and rejection, procedures for specimen processing, and the criteria for specimen referral. Findings: 1. The laboratory failed to establish procedures for urine specimen storage that meet all manufacturer's instructions for each analyte. Review of laboratory procedure manual revealed copies of manufacturer's instructions for each analyte. Review of manufacturer's instructions revealed the analytes tested in the urine drug screen have different refrigeration requirements for the length of time in which urine specimens can be stored. For example: a. The manufacturer's instructions for the analyte COC, "Thermo Scientific DRI Cocaine Metabolite Assay", state "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigerator unit at 2 to 8 degrees celcius (C) for up to two months.". b. The manufacturer's instructions for the analyte THC, "Thermo Scientific DRI Cannabinoid Assay", state "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigerator unit at 2 to 8 degrees C for up to 4 weeks." 2. The laboratory failed to establish procedures for the conditions required for specimen transport. Review of laboratory procedure, "Standard Operations Manual for Lab" revealed "(name of

reference lab) will handle all training for shipping of specimen for confirmation to their laboratory prior to shipping any specimen. See shipment guidelines provided by (name of reference lab) for shipment." The name of the reference laboratory in the procedure is not the same name as the reference laboratory on the test order slip used by the facility for confirmation drug testing. The procedure manual did not include shipment guidelines. Interview with service representative at approximately 11:00 a. m. confirmed the laboratory sends urine specimens to the reference laboratory listed on the test order slip for confirmation drug testing and not the reference laboratory noted in the laboratory procedure. Review of reference laboratory web site and test order slip from reference lab revealed no instructions or guidelines for the transportation of urine specimens for confirmation drug testing. 3. The laboratory failed to establish criteria for specimen acceptability and rejection. a. Review of laboratory procedure, "Standard Operations Manuel for Lab" revealed the procedure explains methods used to detect adulterated urine specimens, but does not state what should be accepted or what should be rejected. Also, many methods listed in the procedure as a means for detecting adulterations are not used by the laboratory. For example: a. The procedure states "Adulteration &(and) Dilution Detection...Means to detect adulteration by the collector and/or the laboratory include the following: 1. Specimen Temperature...2. Urine Appearance and Odor...3. Creatinine...4. Specific Gravity...5. PH (potential of Hydrogen)...6. Visible Blood..." and "Creatinine:..." Normal" random urine specimens will generally have urine creatinine levels of greater that 20 milligrams per deciliter (mg/dl)...levels below 2.0 mg/dl are usually a result of "dipping"...". The procedure does not state what should be accepted or rejected. b. Review of manufacturer's package inserts for opiate and cannabinoid assays revealed "Samples within a pH range of 3 to 11 are suitable for testing with this assay." Review of laboratory records revealed the laboratory performs specimen temperature testing only and does not perform creatinine, specific gravity, or pH testing. Interview with service representative at approximately 11:00 a.m. confirmed the laboratory does not perform creatinine, specific gravity or pH testing and also confirmed the laboratory performs specimen temperature testing as a means of detecting adulteration of the urine specimen. 4. The laboratory failed to follow and/or establish procedures for specimen processing. a. Review of laboratory procedure "Standard Operations Manual for Lab" revealed "Urine Collection Procedure...6. Upon receipt of the specimen from the donor, immediately apply the temperature strip (if applicable) to the outside of the bottle. If using a drug screen test request form, record the urine temperature on the form. NOTE: Urine temperature should be measured within (4) four minutes of collection and should read between 90-100 degrees Fahrenheit...1. Specimen Temperature...The urine temperature should be noted on Urine Test Request form.". Review of random "Urine Test Request" forms, sample identification numbers 211 and 131, revealed no urine temperatures were documented. b. Review of manufacturer's package inserts for all analytes tested revealed "It is recommended that grossly turbid specimens be centrifuged before analysis." Surveyor observation revealed the laboratory does not have a centrifuge. Interview with service representative at approximately 11:00 a.m. confirmed the laboratory does not have a centrifuge and does not have a policy for the acceptance or rejection of turbid specimens. 5. The laboratory failed to establish criteria for the referral of urine drug screen confirmation testing. a. Review of laboratory procedure manual revealed no policy or procedure defining the criteria the laboratory has established for urine drug screen confirmation referrals. Phone interview with owner and provider at approximately 1:15 p.m. confirmed all urine drug screens were sent out for confirmation testing. b. Review of laboratory procedure manual revealed the laboratory had not established a system for tracking urine drug screens that were sent out for confirmation drug testing. For example; there was no log in which specimens

	sent out for drug confirmation testing were recorded and no system for verifying whether the confirmation report was received and reviewed by the provider.
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 procedure manual, review of operator's manual, and review of manufacturer's package inserts 9/24/19, the laboratory procedure manual was not complete and current for the testing performed. Findings: 1. Review of laboratory procedure manual, review of Diatron Pictus 500 operator's manual and review of manufacturer's package inserts revealed the laboratory's quality control (QC) procedures failed to include what type of QC material was used for each analyte, the frequency of QC, the criteria used to determine if QC results were acceptable, and the corrective action to take when QC results were not acceptable. For example: a. Review of laboratory procedure manual revealed no documentation of quality control procedures. b. Review of operator's manual for Diatron Pictus 500 analyzer revealed "4.7 Quality control...The quality control system is based on the use of Control Sets. A control set is a vial of a given brand and lot containing all the desired analytes with their respective admissible ranges. Control sets from different brands and levels can be defined." c. Review of manufacturer's package inserts for all analytes tested revealed "Quality Control and Calibration...Use controls near the cutoff calibrator to validate the calibration. Control results must fall within the established ranges, as determined by laboratory procedures and guidelines....Each laboratory should establish its own calibration and control frequency.". 2. Review of laboratory procedure manual revealed no documentation of the established cut-off values (reference ranges) established for each analyte tested. 3. Review of laboratory procedure manual, review of Diatron Pictus 500 operator's manual and review of manufacturer's package inserts revealed the laboratory's calibration procedures failed to include what type of calibration material is used for each analyte, the frequency of calibration, the criteria used to determine if calibration results are acceptable, and the corrective action to take when calibration results are not acceptable. For example: a. Review of laboratory procedure manual revealed no documentation of calibration procedures. b. Review of operator's manual for Diatron Pictus 550 analyzer revealed

	"4.5 Calibration...To enter a new calibration or define a calibrator set, press button... 4.5.1 Calibrator sets...Calibrations are conducted by means of calibrator sets. A calibration set represents the cluster of methods a commercial calibrator can be used for." c. Review of manufacturer's package inserts for the all analytes tested revealed for example "use the DRI Multi-Drug Calibrator 1 or 2", or "use the 300 nanograms per milliliter (ng/mL) or 2000 ng/mL calibrator...". And "Each laboratory should establish its own calibration and control frequency.". 4. Review of laboratory procedure manual revealed no procedure for entering results in the patient record and no procedure for the reporting of patient results to the provider. 5. Review of laboratory procedure manual revealed no procedure for the course of action to take if the Diatron Pictus 500 analyzer becomes inoperable.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor observation, review of manufacturer's instructions, and review of laboratory temperature and humidity logs 9/24/19, the laboratory failed to monitor, document and/or define the correct criteria for the room temperature and humidity, and the refrigerator and freezer temperatures used to store and freeze urine specimens before they are sent out for drug confirmation testing. Findings: During tour of laboratory at approximately 11:15 a.m., the surveyor observed patient urine specimens stored in the freezer. Review of manufacturer's instructions for all analytes tested revealed "For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at - 20 degrees Celcius (C)." Review of laboratory temperature and humidity logs revealed the laboratory failed to document room temperature, humidity, refrigerator and freezer temperatures for November and December of 2018. Review of 2019 laboratory temperature and humidity logs revealed the laboratory began documenting room temperature, humidity, and refrigerator temperatures in 2019, but failed to document freezer temperatures. Review of temperature logs revealed the laboratory failed to define the correct criteria for freezer storage of urine drug screen specimens. The log revealed a freezer range of 2 degrees C or colder. Manufacturer's instructions state freezer storage of -20 degrees C.
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:

	Based on surveyor observation 9/24/19, the laboratory failed to discard supplies that had exceeded their expiration date. During a tour of the laboratory at approximately 11:15 a.m., the surveyor observed 1 bottle of THC 50 ng/ml Urine Calibrator (lot #73207055, expiration date: 2019-08) on the middle shelf of the refrigerator, available for 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 the laboratory's policies and procedures and review of instrument validation records for the Diatron Pictus 500 analyzer 9/24/19, the laboratory failed to establish performance specifications for interfering substances. Review of the "DIATRON P700, P400 DRUGS OF ABUSE VALIDATION PROCEDURE (DRAFT 9-8-15)" revealed the procedure included instructions for establishing performance specifications for the following: specificity, sensitivity, precision, and linearity/accuracy/reportable range. The procedure did not include instructions for validating interfering substances. Review of Diatron Pictus 500 validation records revealed the validation performed in December 2018 did not include interfering substances.
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 manufacturer's instructions, review of instrument validation records and review of random patient test reports 9/24/19, the patient test report failed to include the following: 1. The patient test report failed to indicate that the test results are presumptive and confirmation testing is required. Findings: a. Review of manufacturer package inserts for all analytes tested 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.". b. Review of random patient test reports, Sample #163 and Sample #211, revealed the test reports failed to indicate that the test results were presumptive (preliminary analytical test result) and a specific method must be used in order to obtain a confirmed result. 2. The patient test report includes numerical (quantitative) values in the "result" column of the test report instead of a positive or negative result as validated by the laboratory. Findings: a. Review of instrument validation records for the drug screen testing performed revealed the drug analytes tested are validated for qualitative testing only. Qualitative testing produces either a negative or positive test result. b. Review of random patient test reports, Sample #169 and Sample #131, revealed quantitative results in units of nanograms per milliliter (ng/mL) on the patient test report in addition to Negative and Positive results.
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 laboratory procedures, review of laboratory records and interview with sales representative 9/24/19, the laboratory director failed to provide overall management and direction for the laboratory services provided. Findings: 1. The laboratory director failed ensure the establishment of procedures for specimen storage, specimen transportation, specimen acceptability and rejection, specimen processing, and specimen referral. See D6082. 2. The laboratory director failed to ensure performance verification procedures were established and adequate to determine the accuracy and precision of the testing performed on the Diatron Pictus 500 analyzer. See D6086. 3. The laboratory director failed to ensure quality control procedures and calibration procedures were established to assure the quality of the testing performed on the Diatron Pictus 500 analyzer. See D6093. 4. The laboratory director failed to ensure quality assessment policies and procedures were established and maintained to assure the quality of the laboratory services provided. See D6094. 5. The laboratory director failed to ensure patient test reports included all information required for interpretation. See D6098. 6. The laboratory director failed to ensure the establishment of competency policies and procedures. See D6103. 7. The laboratory director failed to ensure an approved procedure manual was available to all personnel. See D6106.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of manufacturer's instructions, review of "Urine Test Request" forms, surveyor observation and interview with

	service representative 9/24/2019, the laboratory director failed ensure the establishment of procedures for specimen storage, specimen transportation, specimen acceptability and rejection, and specimen referral. Findings: See D5311.
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 review of the laboratory's policies and procedures, review of 2019 American Proficiency Institute (API) proficiency testing (PT) records, and review of instrument validation records for the Diatron Pictus 500 analyzer 9/24/19, the laboratory director (LD) failed to ensure performance verification procedures were established and adequate to determine the accuracy and precision of the testing performed on the Diatron Pictus 500 analyzer. Findings: 1. The laboratory director failed to ensure the laboratory participated in the 2019 APT 1st PT event for Chemistry-Miscellaneous to verify biannual accuracy of the Diatron Pictus 500 analyzer. See D5217. 2. The laboratory director failed to ensure the validation of the Diatron Pictus 500 analyzer included performance specifications for interfering substances. See D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of operator's manual, and review of manufacturer's package inserts 9/24/19, the laboratory director failed to ensure quality control procedures and calibration procedures were established to assure the quality of the testing performed on the Diatron Pictus 500 analyzer. Findings: See D5403.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and review of laboratory records 9/24 /19, the laboratory director failed to ensure quality assessment policies and procedures were established and maintained to assure the quality of the laboratory services provided. Findings: Review of laboratory procedure manual revealed no quality assessment procedures were established for the pre-analytical, analytical and post-

	analytical assessment of the laboratory services provided. For example, there were no quality assessment procedures to assess if urine drug screens were assessed for temperature, if urine specimens were being stored appropriately, if quality control and calibrations were performed as required and within range, if performance verifications were performed as required, if patient test results correlated to the patient's clinical picture, if patient test reports for urine drug confirmation were received and reviewed by providers, and if patient test results were entered correctly into the patients medical record. Review of laboratory records revealed no documentation that quality assessments were performed for pre-analytical, analytical and post-analytical laboratory services from the time testing began in November of 2018 until time of survey, a period of approximately 11 months.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of instrument validation records and review of random patient test reports 9/24/19, the laboratory director failed to ensure patient test reports included all information required for interpretation. Findings: See D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with sales representative 9/24/19, the laboratory director failed to ensure the establishment of competency policies and procedures that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Findings: Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Review of laboratory procedure manual revealed no policies or procedures for

	the assessment of testing personnel. Interview with sales representative at approximately 9:30 a.m. confirmed the laboratory procedure manual had no procedures for the assessment of testing personnel competency.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of manufacture's package inserts, and interview with sales representative 9/24/19, the laboratory director failed to approve, sign and date the procedures in use by the laboratory. Findings: Review of laboratory procedures including "Standard Operations Manuel For Lab", "Diatron P700, P400 Drugs of Abuse Validation Procedure" and manufacture's package inserts used as procedures by the laboratory revealed no documentation the laboratory director had approved, signed and dated the procedures before patient testing began in November of 2018. Interview with sales representative at approximately 9:30 a.m. confirmed the laboratory began testing in November of 2018.