Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2086064	07/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cary Behavioral Health, Pc	160 Ne Maynard Road, Suite 200, Cary, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on review of 2018 American Proficiency Institute (API) proficiency testing (PT) records and interview with technical supervisor (TS) 07/23/18, the laboratory director and testing personnel failed to sign attestation statements for the PT performed. Review of 2018 API remedial kit PT records revealed no attestation statement for the PT performed. Review of 2018 API - 2018 Chemistry - Miscellaneous - 1st Event PT records revealed no attestation statement for the PT performed. Interview with TS at approximately 2:30 p.m. confirmed the testing personnel and the laboratory director did not sign attestation statements for the PT performed.
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 laboratory records, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with technical supervisor (TS) 07/23/18, the laboratory failed to verify the accuracy of all testing performed on the Mindray BS 200 at least twice annually as required. 1. Review of laboratory records

	revealed the laboratory failed to verify the accuracy of the following testing performed on the Mindray BS 200 at least twice annually from September 2016 until January 2018, a period of approximately 15 months. a. Alcohol b. Amphetamines c. Benzodiazepines d. Cannabinoids e. Cocaine Metabolites f. Methadone g. Opiates h. Propoxyphene Review of 2018 API PT records revealed the laboratory had participated in 2 API PT events in 2018; an API remedial event, approximately January 23, 2018, and the API PT 2018 Chemistry - Miscellaneous - 1st Event for the above named analytes. Both events were scored acceptable. 2. Review of laboratory records revealed the laboratory failed to verify the accuracy of creatinine testing performed on the Mindray BS at least twice annually from September 2016 until time of survey 7/23/18, a period of approximately 22 months. Interview with TS at approximately 10:30 a.m. confirmed the laboratory failed to verify the accuracy of all testing performed on the Mindray BS 200 at least twice annually as required.
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 procedure manual review and interview with TP (testing personnel) 7/23/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory's procedure for reporting patient test results did not reflect the laboratory's current practice. The "Patient Test Management And Specimen labeling and handling" procedure states "... After the specimen is tested, the analyzer generates a printable lab report with all required elements on the report - name and address of testing facility, patient normal values, units of measure and the result is reported as 'pos' or 'neg' for the drug panel and values for adulterants. The instrument printout is placed on the patient's chart for review by the provider. (If EHR /EMR is used, then the copy of the instrument printout is scanned into the electronic medical record. ...)" During interview at approximately 12:05 p.m., TP #1 stated that patient test results are uploaded to a flash drive on the medical assistant's computer and then uploaded from the flash drive to the patients' electronic medical records. She stated the office manager is notified of abnormal results, the office manager notifies the provider, and then informs the TP what to do next. 2. The laboratory's procedure for quality control was incomplete. The "Quality Control Drug Testing" procedure

	states "Two levels of controls must be tested and acceptable prior to patient testing. ... Analyzer - Drug Testing: Test controls each day of patient testing. At least two levels must be within acceptable limits prior to patient. Acceptable limits = established mean +/- 2 std dev or assayed control ranges. ..." The procedure did not indicate the quality control material used or how many controls are tested for each test. During interview at approximately 11:40 a.m., TP #1 stated that the analyzer tells you what controls to run. She stated she also has it written down in her training notebook. She stated she runs DOA Total Level 4 and Level 5 for all drugs except alcohol. She stated alcohol uses ETOH Level 1 and Level 2. She also stated she runs four controls for pH and three controls for creatinine.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and interview with TP (testing personnel) 7/23/18, the laboratory failed to follow manufacturer's instructions for performance of urine drug screens. The Thermo Scientific DRI product inserts include instructions for centrifugation of turbid specimens prior to testing. For example, the product insert for the Thermo Scientific DRI Cannabinoid Assay states, "Specimen Collection and Handling ... An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. ..." During interview at approximately 12:15 p.m., TP #1 stated she tests turbid specimens in the same manner as other specimens are tested. She stated turbid specimens are not centrifuged prior to testing. She stated the laboratory does not have a centrifuge.
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 records, review of Federal Food and Drug Administration (FDA) web site, review of manufacturer's package insert, review of laboratory procedures, review of validation documentation and interview with technical supervisor (TS) 07/23/18, the laboratory failed to validate all performance

	specifications for the high complexity testing of potential hydrogen (PH) on the Mindray BS 200 chemistry analyzer before reporting patient test results. Review of laboratory records revealed the laboratory began performing PH testing using Thermo Scientific Dri-pH-Detect test reagent on the Mindray BS 200 chemistry analyzer in January of 2018. Review of FDA web site and manufacturer's package insert revealed the Thermo Scientific Dri-pH-Detect test reagent used on the Mindray BS 200 chemistry analyzer has not been FDA approved. The PH testing is considered a laboratory developed test (LDT) and high complexity. Review of laboratory procedure "Performance Specification Verifications - (When implementing a new test, reagent, or instrument)...Laboratories are now required to verify the manufacturer's performance specifications provided in the package insert for: Accuracy, Precision, Reportable Range, Reference Range,.....Specificity and Sensitivities.....Verification should be done prior to patient testing." Review of laboratory records revealed the laboratory failed to validate the accuracy, precision, analytical specificity, reportable range and reference intervals for PH testing on the Mindray BS 200 chemistry analyzer before performing patient testing in January 2018, a period of approximately 7 months in which patient testing of PH was performed. Interview with TS at approximately 12:30 p.m. confirmed the laboratory had failed to validate all performance specifications for PH testing on the Mindray BS 200 chemistry analyzer before beginning patient testing in January 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of manufacturer's package insert, review of laboratory calibration records and interview with technical supervisor (TS) 07/23/18, the laboratory failed to perform calibration verification at least once every 6 months as required for Ethyl Alcohol (ETOH). The laboratory began patient testing for ETOH in September of 2016. Review of Thermo Scientific-Dri Ethyl Alcohol reagent package insert revealed "Quality Control and Calibration.....Both negative and 100 mg/dl alcohol calibrators should be used to calibrate the assay." Review of laboratory calibration records

	revealed the laboratory performs a 2 point calibration with the negative and 100 mg/dl ETOH calibrators as required per package insert. The laboratory failed to perform a 3 point calibration verification at least once every 6 months from September 2016 until time of survey 7/23/18, a period of approximately 22 months. Interview with TS at approximately 12:30 p.m. confirmed the laboratory had failed to perform 3 point calibration verifications as required from September 2016 until time of survey 7/23 /18.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of policies and procedures and review of 2017 and 2018 daily maintenance logs 7/23/18, the laboratory failed to follow corrective action policies and procedures for humidity readings outside the acceptable limits. The laboratory's "Quality Control Drug Testing" policy states "... INSTRUMENTS AND DAILY: Temperature and Humidity: Daily temperatures and humidity are recorded and must be within acceptable limits each day. When temperature is outside acceptable limits, make adjustment and recheck within 2 hours. Record adjusted temperature. If adjustment did not resolve the problem, move reagents, calibrators, controls, etc to another refrigerator/freezer that is within range. Suspend testing until room temperature and humidity read within acceptable limits. (Note: Humidity adjustment may require a humidifier or dehumidifier.) Record all corrective actions. ..." Review of 2017 and 2018 daily maintenance logs revealed documented humidity readings were consistently below the acceptable range of 35% - 80% from June 2017 - January 2018 with no corrective action documented. Humidity readings recorded were below 35%: 1. 10 of 10 days in June 2017; 2. 5 of 10 days in July 2017; 3. 14 of 14 days in August 2017; 4. 9 of 10 days in September 2017; 5. 8 of 8 days in October 2017; 6. 8 of 8 days in November 2017; 7. 10 of 10 days in December 2017; 8. 4 of 9 days in January 2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records 7/23/18, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure performance specifications were established and validated for the performance of PH (potential hydrogen) testing on the Mindray BS 200 chemistry analyzer prior to the initiation of patient testing (see D6086). 2. The laboratory director failed to ensure that a quality control program was established and maintained to assure the quality of urine toxicology testing performed on the Mindray BS 200 analyzer (see D6093). 3. The laboratory director failed to ensure that a quality

	assessment program was established and maintained from September 2016 until January of 2018 (see D6094). 4. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for urine toxicology testing performed on the Mindray BS 200 analyzer (see D6095). 5. The laboratory director failed to ensure that patient urine toxicology test reports included pertinent information required for interpretation (see D6098).
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 laboratory records and interview with the TS (technical supervisor) 7/23/18, the laboratory director failed to ensure performance specifications were established and validated for the performance of PH (potential hydrogen) testing using Thermo Scientific Dri-pH-Detect test reagent on the Mindray BS 200 chemistry analyzer. Review of laboratory records revealed the laboratory began performing PH testing using Thermo Scientific Dri-pH-Detect test reagent on the Mindray BS 200 chemistry analyzer in January of 2018. Review of laboratory records revealed the laboratory failed to establish and validate the accuracy, precision, analytical specificity, reportable range and reference intervals for PH testing on the Mindray BS 200 chemistry analyzer prior to the initiation of patient testing. During interview at approximately 12:30 p.m., the TS confirmed the laboratory had not established and validated all performance specifications for PH testing on the Mindray BS 200 chemistry analyzer before beginning patient testing in January 2018 (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 the laboratory's policies and procedures, review of laboratory records, and interview with staff 7/23/18, the laboratory director failed to ensure that a quality control program was established and maintained to assure the quality of toxicology testing performed on the Mindray BS 200 analyzer. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have a detailed, complete quality control procedure which included the quality control material used or how many controls are used for each test (see D5403). 2. Review of 2017 and 2018 quality control records available for review revealed the records were daily instrument printouts and did not include manufacturer's assay sheets with acceptable ranges for each lot number of MAS DOA TOTAL Liquid Assayed Drugs of Abuse Control material used. During interview at approximately 1:15 p.m., the TS (technical supervisor) and TP (testing personnel) #1 stated they did not document in-use dates for the quality control material, and they had not retained assay sheets for all

	lot numbers. They confirmed there was no way to tell whether quality control results were acceptable each day of testing (see D8103).
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 records and interview with technical supervisor (TS) 7 /23/18, the laboratory director failed to ensure a quality assessment program was established and maintained from September 2016 until January of 2018. Review of laboratory records revealed the laboratory began patient testing in September of 2016. Review of laboratory records revealed the laboratory hired a technical supervisor in January 2018. The TS began to establish a quality assessment program for the laboratory in January 2018. Review of laboratory records revealed no documentation that a quality assessment program was established and maintained to ensure the quality of laboratory services provided from September of 2016 until January of 2018, a period of approximately 15 months. Interview with TS at approximately 10:30 a.m. confirmed the laboratory director had not established or maintained a quality assessment program. She stated she began the establishment of the quality assessment program when she was hired in January of 2018.
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 review of manufacturer's instructions, review of laboratory records, and interview with staff 7/23/18, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for urine drug screens on the Mindray BS 200 analyzer. Findings: 1. Review of manufacturer's instructions for the Thermo Scientific DRI Cocaine Metabolite, Opiate, Amphetamines, Cannabinoid, Propoxyphene, Ethyl Alcohol, Benzodiazepine, and Methadone assays revealed instructions for centrifugation of turbid specimens prior to testing. During interview at approximately 12:15 p.m., testing personnel #1 stated the laboratory does not have a centrifuge (see D5411). 2. Review of 2016, 2017, and 2018 calibration records revealed the laboratory failed to perform a 3 point calibration verification for Ethyl Alcohol (ETOH) at least once every 6 months from September 2016 until the date of the survey 7/23/18, a period of approximately 22 months. During interview at approximately 12:30 p.m., the technical supervisor confirmed the laboratory had failed to perform 3 point calibration verifications as required from September 2016 until time of survey 7/23/18 (see D5439). 3. Review of 2017 and 2018 daily maintenance logs revealed the laboratory failed to document corrective action for humidity readings outside the acceptable limits. Review of daily maintenance logs

	revealed documented humidity readings were consistently below the acceptable range of 35% - 80% from June 2017 - January 2018 with no corrective action documented (see D5779).
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: Review of manufacturer's instructions, review of the laboratory's policies and procedures, and review of a random patient test report (#59006) 7/23/18 revealed the laboratory director failed to ensure that patient test reports included pertinent information required for interpretation. Findings: Review of manufacturer's product inserts revealed the assays should be used to determine the presence or absence of the analyte tested, and should not be used to quantify the amount of analyte. Examples: 1. The product insert for the Thermo Scientific DRI Methadone Assay states "Intended Use ... The 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. ... Quality Control and Calibration Qualitative analysis For qualitative analysis of samples, use the 300 ng/mL calibrator as a cutoff level. The DRI Calibrator 2, which contains 300 ng/mL methadone, is used as a cutoff reference for distinguishing 'positive' and 'negative' samples. Semiquantitative analysis For semiquantitative analysis, use all calibrators. ... Results and Expected Values Qualitative results A sample that exhibits a change in absorbance value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value lower than the value obtained with the cutoff calibrator is considered negative. Semiquantitative results A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve. Limitations 1. A positive result from this assay indicates only the presence of methadone and does not necessarily correlate with the extent of physiological and psychological effects. ..." 2. The product insert for the Thermo Scientific DRI Cocaine Metabolite Assay states "Intended Use ... The 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. ... Quality Control and Calibration Qualitative analysis For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1, which contains 150 ng/mL benzoylecgonine, or DRI Multi-Drug Calibrator 2, which contains 300 ng/mL benzoylecgonine as a cutoff level. The cutoff calibrator is used as a reference for distinguishing 'positive' from 'negative' samples. Semi-quantitative Analysis For semiquantitative analysis of samples, use all calibrators: Negative Calibrator, Multi-Drug Calibrator 1, 2, 3 and 4 to create a standard curve to analyze the results. Results and Expected Values Qualitative Analysis A sample that exhibits a change in absorbance value equal to or greater than the value obtained with the cutoff calibrator is considered a 'positive' result. A sample that exhibits a change in absorbance value lower than the value obtained with the cutoff calibrator is considered a 'negative' result. ... Semi-quantitative Analysis A rough estimate of drug concentration in the samples can be obtained by running a standard curve with calibrators and then quantifying samples off that curve. ... The semi-quantitation of

	positive results enables laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS. ... Limitations 1. A positive result from this assay indicates only the presence of cocaine metabolite and does not necessarily correlate with the extent of physiological and psychological effects. ..." The laboratory's "LAB PROTOCOLS AND PROCEDURES" document states on page 3 "VII. Confirmations ... lab results that require further, more precise information, will be sent to another lab for confirmation, metabolites, or quantitative measures (our testing is referred to as screening, and yields only qualitative measures; ie: results are interpreted as positive or negative only). ..." Random review of a patient test report (#59006) revealed the laboratory reported a numerical result in ng/mL (nanograms per milliliter) for each of the drugs tested. The test report also included numerical values for creatinine and pH. A "Reference" value for each substance tested was also included on the patient report. A column labeled "Flag" on the report listed an interpretation of "POSITIVE" or "NEGATIVE" for each drug as well as for creatinine and pH.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 quality control records and interview with staff 7/23/18, the laboratory failed to provide all records needed by the surveyors to determine compliance with the quality control requirements of part 493. 2017 and 2018 quality control records available for review were daily instrument printouts and did not include manufacturer's assay sheets with acceptable ranges for each lot number of MAS DOA TOTAL Liquid Assayed Drugs of Abuse Control material used. The following assay sheets were available for review during the survey: 1. lot # DAT 15071, 15072, 15073, 15074, 15075, 15076 - expiration date 7/31/15; 2. lot # DAT 19051, 19052, 19053, 19054, 19055, 19056 expiration date 5/31/19. During interview at approximately 1:15 p.m., the TS (technical supervisor) and TP (testing personnel) #1 stated they did not document in-use dates for the quality control material, and they had not retained assay sheets for all lot numbers. They confirmed there was no way to tell whether quality control results were acceptable each day of testing.