| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 34D2086064 | 01/28/2022 |
| **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 |
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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2020, 2021 and 2022 toxicology calibration records, review of calibration records retained on the Diatron 500 analyzer, interview with technical consultant (TC) and interview with testing personnel (TP#1) 1/28/22, the laboratory failed to retain all records needed to document calibration performed on the Diatron 500 analyzer in 2020, 2021 and 2022. 1. The laboratory failed to document dates of calibrations and lot numbers of reagents calibrated for all toxicology calibrations performed in 2020. Findings: a. Review of 2020 calibration records revealed the records had the date in which the calibration was printed from the Diatron 500 analyzer and the lot number of quality control in use. The records failed to include the date the calibration was performed and also failed to indicate the lot number of reagent calibrated. b. Review of Diatron 500 analyzer record database revealed the analyzer failed to retain the toxicology calibrations for 2020. c. Interview with TC at approximately 1:30 p.m. confirmed the laboratory failed to document the date calibrations were performed and lot number of the reagent calibrated. She also stated the previous TP would have downloaded the calibration records from the Diatron 500 analyzer but they were unable to locate the database file in the laboratory's computer system. 2. The laboratory failed to document the reagent lot number for all toxicology calibrations performed in 2021 and 2022. a. Review of 2021 and 2022 toxicology calibration records revealed the records failed to include the lot number of reagent calibrated. b. Interview with TP #1 at approximately 1:30 p.m. confirmed the records failed to include the lot number of reagent calibrated. He stated the analyzer does not have the capability to allow entry of the reagent lot number. |

**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 procedure manual, review of manufacturer's instructions, review of "lab inventory" form and interview with TP#1 and GS 1/28/22, the laboratory procedure manual was not complete and current for the testing performed. 1. The procedure manual failed to include a procedure/package insert for the analyte Tetrahydrocannabinol (THC). Findings: a. Review of procedure manual revealed the laboratory utilizes package inserts for reagents as procedures for each analyte. b. Review of procedure manual revealed no package insert for the analyte THC. 2. The laboratory procedure "Quality Control Drug Testing" is not current for the testing performed. Findings: a. Review of "Quality Control Drug Testing" procedure revealed "The following controls are used for the BS Mindray analyzer:" The laboratory performs testing on the Diatron 500 analyzer. b. Interview with GS at approximately 2: 30 p.m. confirmed the laboratory performs testing on the Diatron 500 analyzer. 3. The procedure manual failed to include the type and levels of quality control and calibrators used for each analyte tested on the Diatron 500 analyzer. Findings: The laboratory performs testing for Amphetamine (AMPH), Benzodiazepine (BENZ), Buprenorphine (BUP), Cocaine (COC), Opiates (OPI), Potential Hydrogen (PH), Tetrahydrocannabinol (THC), and Urine Creatinine (CREA) on the Diatron analyzer. a. Review of laboratory procedure "Quality Control Drug Testing", review of reagent package inserts and review of "lab inventory" form revealed the procedure, package inserts and "lab inventory" failed to specify the type and levels of quality control and calibrator used for each analyte tested on the Diatron 500 analyzer. For example: The laboratory procedure "Quality Control Drug Testing" states "DOAT 4 and DOAT 5 (NEG AND POS) ...Calibration Requirements...there are three calibrators that are used for each drug when calibration is needed." The procedure fails to specify the type and level of QC and calibrators used for each analyte. The manufacturer's instructions for AMP reagent "DRI Amphetamines Assay" states "Quality Control and Calibration...All quality control requirements should be performed in conformance with local, state, and/or federal regulations....Qualitative Analysis...use the DRI Multi-Drug Urine Calibrator 1 or 2. The package insert fails to specify the type and level of QC and calibrators used. The "lab inventory" form lists quality control reagents used

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| | by the laboratory but it fails to state what analytes MAS DOA 4, MAS DOA 5, PRIMARY LOW, PRIMARY HIGH, CLINICAL LOW, CLINICAL HIGH are for and what level of QC for each analyte is verified. The form also lists calibrators used by the laboratory but fails to state what analytes are calibrated using MULTI 2, MULTI 4, DOA LOW and DOA HIGH and what level of calibration is measured for each analyte. b. Interview with TP #1 at approximately 2:00 p.m. confirmed the procedures do not specify the type and levels of quality control and calibrator used for each analyte tested. He stated he refers to the inventory form and the loading directions on the analyzer. 4. The procedure "Quality Control Drug Testing" is not current for the calibration frequency performed. a. Review of "Quality Control Drug Testing" procedure revealed "Calibration requirements:...With change of reagent lot number if controls do not work." b. During interview at approximately 2:00 p.m. TP #1 stated since he began employment in 2021 he has been calibrating all analytes weekly. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Food and Drug Administration (FDA) database, review of laboratory performance verification records and interview with general supervisor (GS) 1/28/22, the laboratory failed to perform stability verification for the potential hydrogen (PH) testing performed on the Diatron 500 analyzer. Findings: The laboratory began testing on the Diatron 500 analyzer in February 2019. Review of FDA database revealed the Thermo Scientific PH assay is not approved for use on the Diatron 500 analyzer. Review of performance verification records for the Diatron 550 analyzer revealed no documentation the laboratory had performed a stability verification study for PH testing. Interview with GS at approximately 10:25 a.m. confirmed the laboratory failed to perform a stability verification study for PH testing. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2020 and 2021 calibration records, review of 2020 and 2021 calibration verification records and interview with general supervisor (GS) 1/28/22, the laboratory failed to perform a 3 point calibration verification every 6 months for the creatinine (CREA) testing performed on the Diatron 500 analyzer. Findings: Review of CREA calibration records revealed the laboratory performs 2 point calibrations with each new lot number. Review of CREA calibration verification records revealed the laboratory performed a calibration verification in December of 2020 that was unsuccessful. The next calibration verification performed was in November of 2021, approximately 11 months after the unsuccessful calibration verification and 17 months since the last successful calibration verification in June of 2020. Interview with GS at approximately 12:00 p.m. confirmed the laboratory failed to perform a 3 point calibration verification every 6 months for the CREA testing from June of 2020 until November of 2021, a period of 17 months. |