Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2095725	02/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bald Mountain Behavioral Medicine	1445 S Lapeer Road Suite 200, Lake Orion, MI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to retain quality control (QC) records for the chemistry toxicology testing for 5 (October 2019 to February 2020) of 5 months reviewed. Findings include: 1. Record review of the laboratory's QC records revealed a lack of documentation of the QC testing between October 2019 to February 2020 for the following days of testing when patient final reports were generated: a. 10/17/2019 b. 11/12/2019 c. 11/13/2019 d. 12/12/2019 e. 12/16/2019 f. 12/17/2019 g. 12/19/2019 2. During the interview on 2/18/2020 at approximately 1:30 pm, the TC confirmed that all QC records had not been retained.
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 record review and interview, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to establish a

	written procedure for corrective action to take when calibrations and/or control results are not acceptable and the interpretation of patient results when a instrument flag is generated. Refer to D5403. 2. The laboratory failed to monitor and document the room temperature and humidity of the laboratory each day of patient testing. Refer to D5413. 3. The laboratory failed to perform quality control as required for the toxicology testing. Refer to D5445. 4. The laboratory failed to establish a procedure to include the patient's scanned final report into the electronic medical records. Refer to D5805.
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: A. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to establish a written procedure for corrective action to take when calibrations and/or controls do not meet acceptable criteria for 5 (October 2019 to February 2020) of 5 months of operation. Findings include: 1. Record review of "Bald Mountain Behavioral Medicine" laboratory procedure manual revealed a lack of a procedure for the corrective action to take when calibrations and/or controls fail to meet acceptability criteria as follows: a. 12/10/2019 - H-Trol 2 (positive) - resulted as negative for Barbiturates (BAR), Benzodiazepine (BZO), and Cocaine (COC) b. 1/18 /2020 H-Trol 1 (negative) - resulted as positive for Opiates (OPI) c. 1/18/2020 H-Trol 2 (positive) - resulted as negative for Amphetamines (AMP) and COC 2. During the interview on 2/18/2020 at approximately 12:30 pm, the TC confirmed a written procedure was not established for corrective action to take when calibrations and/or controls do not meet acceptable criteria. B. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to establish a written procedure for interpretation of results when a instrument flag was generated for 5 (October 2019 to February 2020) of 5 months of operation. Findings include: 1. Record review of "Bald Mountain Behavioral Medicine" laboratory procedure manual revealed a procedure was not established for the interpretation of patient laboratory results when an instrument flag is generated. 2. Record review for 4 (#4, #6-#8) of 11 patient charts audited revealed an instrument generated flag was reported on the patient's test report as follows: a. Patient #4 - High absorbance (HA) on Barbiturates (BAR) b. Patient #6

	- Reaction Rate Noise (RN) on Cocaine (COC), High Reaction Rate Noise (HN) for Methadone (MTD) and Oxycodone (OXY) c. Patient #7 - HN for Benzodiazepine (BZO) d. Patient #8 - System Error or Ended by User (SE) for Opiates (OPI) 3. Further review of 60 patients tested from 10/17/2019 to 12/30/2019 the final reports had the following instrument generated flags for the following tests: a. 10/17/19 - HA flag for Buprenorphine (BUP) for 1 patient b. 10/21/19 - HA flag for BUP for 1 patient c . 11/7/19 - i. RN flag for COC, BAR, BZO, and MTD for 1 patient, Amphetamines (AMP) and OXY for 2 patients, and BUP for 3 patients ii. HN flag for COC, BUP, and OXY for 1 patient d. 11/12/19 - i. SE flag for AMP, BAR, BZO, COC, MTD, OPI, and OXY for 1 patient and BUP for 5 patients e. 11/26/19 - i. RN flag for BAR, MTD, BZO, and COC for 1 patient, BUP for 2 patients, and OXY for 3 patients ii. HN flag for BUP and OPI for 1 patient and BZO for 2 patients f. 12/5/19 - i. HN flag OPI and AMP for 1 patient, BZO, BAR, and OXY for 2 patients, MTD for 3 patients, and BUP for 4 patients ii. RN flag for AMP for 1 patient, BZO, OXY, and BUP for 2 patients, COC for 3 patients, and OPI for 4 patients g. 12/12/19 - SE flag for AMP for 1 patient h. 12/17/19 - SE flag for OPI for 14 patients i. 12/30/19 - HA flag for BUP for 1 patient 4. On 2/18/2020 at approximately 11:30 am when queried, Testing Personnel #1 (TP1) stated that no patient testing was not repeated for instrument generated flags. 5. On 2/18/2020 at approximately 2:30 pm when queried, TC was not able to provide the surveyor documentation to show the troubleshooting mechanisms indicated for the instrument generated flags. 6. During the interview on 2 /18/2020 at approximately 2:30 pm, the TC confirmed no written procedure was established for the interpretation of patient results when instrument generated flags were present. 3. Further investigation of patient results
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 record review and interview with the Technical Consultant (TC), the laboratory failed to 1) monitor and document the room temperature and humidity of the laboratory each day of patient testing for 3 (October 2019 to December 2019) of 3 months and 2) monitor and document the room temperature and humidity of the laboratory for 2 (January 18 and 30) of 10 days of operation. Findings include: 1. Record review of the "Temp Log" revealed a lack of documentation for room temperature and humidity for the chemistry Medica EasyRa analyzer for 3 (October 2019 through December 2019) of 3 months of operation. 2. Record review of the "Temp Log" revealed from 1/13/20 to 2/18/2020 a lack of documentation for the room temperature and humidity reading for 2 days of testing as follows: a. January 18, 2020 b. January 30, 2020 3. During the interview on 2/18/2020 at 10:32 am, the TC confirmed the laboratory failed to perform and document the room temperature and humidity readings each day of patient testing.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform quality control as required for the toxicology testing for 8 (October 17; November 12 and 13; December 10, 12, 16, 17, and 19 in 2019) of 36 days of testing reviewed. Findings include: 1. Record review for the "Quality Control (QC) Results Detail" report revealed there was no documentation of QC run on days that patient testing was run and reported as follows: a. 10/17/19 - no controls documented b. 11/12/19 - no controls documented c. 11/13/19 - no controls documented d. 12/10/19 - no controls documented for H-Trol 2 for BAR, BZO and COC e. 12/12/19 - no controls documented for H-Trol 1 and 2 for BUP and MTD f. 12/16/19 - no controls documented g. 12/17/19 - no controls documented for BUP and OPI h. 12/19/19 - no controls documented for H-Trol 1 and 2 for BUP, COC, OP, and OXY and Barbiturates (BAR) for H-Trol 1 2. During the interview on 2/18/2020 at approximately 1:30 pm, the TC confirmed that all QC results were not present on the "QC Results Detail" report.
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 record review and interview, the laboratory failed to establish a procedure to include the patient's scanned final report into the electronic medical records (EMR) for 5 (October 2019 to February 2020) of 5 months of operation. Findings include: 1. Record review revealed no procedure was established to maintain the patient's test report in the EMR system. 2. Record review for 11 (#1 - #11) of 11 patient charts audited, the final toxicology report was not scanned into the patients EMR file. 3. On 2/18/2020 at 12:00 pm when queried, the Technical Consultant (TC) stated that no patient reports had been scanned into the EMR system to date. 4. During the interview on 2/18/2020 at 12:00 pm, the TC confirmed a procedure had not been established and that no patient final toxicology reports had been scanned into the EMR system for five months of testing.