Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2047419	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Raise The Bottom	9196 W Barnes St, Boise, ID	

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 a record review and an interview with the laboratory technical supervisor, the laboratory failed to establish and assess the competency of one out of one testing person, the general supervisor, and the technical supervisor in toxicology since the last survey on December 20, 2017. Findings: 1. A review of competency documents for one out of one testing person revealed the laboratory technical supervisor failed to assess the competency for drug confirmation testing on the Sciex 4500 Mass Spectrophotometer since the last survey. 2. A review of competency documents and the procedure manual revealed the laboratory failed to establish a written procedure or policy to assess the competency for the position responsibilities of the technical supervisor and the general supervisor since the last survey. 3. An interview on September 4, 2019 at 11:35 AM, with the laboratory technical supervisor, confirmed the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel.
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 a review of the procedure manual and an interview with the technical supervisor, the laboratory failed to include corrective actions to take when control or calibration material fails to meet the laboratory's specified requirements and limitations in the testing methodology since the last survey on December 20, 2017. Findings: 1. A review of the mass spectrophotometer procedure, revealed the procedure failed to include documentation for corrective actions to take when control or calibration material fails to meet the laboratory's specified requirements and limitations in the testing methodology. 2. An interview on September 4, 2019 at 12:05 PM, with the laboratory technical supervisor, confirmed the laboratory's procedure manual failed to include these corrective actions and limitations to testing.
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 an observation of quality control materials, a record review, and an interview with the laboratory technical supervisor, the laboratory failed to label or indicate the expiration dates for the quality control materials used on the Sciex Mass Spectrophotometer toxicology instrument since the last survey on December 20, 2017. Findings: 1. An observation on September 4, 2019 at 11:45 AM, of the refrigerator used to store toxicology quality control materials, revealed the laboratory failed to label the quality control materials with the expiration dates. 2. A review of laboratory documents revealed the laboratory failed to write the expiration dates of the toxicology quality control materials on the laboratory worksheets. 3. An interview on September 4, 2019 at 11:45 AM, with the laboratory technical supervisor, confirmed the bottles of toxicology quality control materials were not labeled with expiration dates.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a procedure review and laboratory documents, the laboratory failed to verify or establish the criteria for acceptability for the laboratory developed and unassayed UTAK Laboratory's quality control material for use on the Sciex 4500 Mass Spectrophotometer toxicology analytes since the last survey on December 20, 2017. Findings: 1. A review of quality control documents revealed the laboratory failed to establish the quality control acceptability criteria for 59 out of 59 drug analytes performed on the Sciex 4500 Mass Spectrophotometer. 2. An interview on September 4, 2019 at 10:15 AM, with the laboratory technical supervisor, confirmed the laboratory failed to establish the acceptability criteria for the toxicology analytes.