Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0673165	07/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Blackfoot Medical Center	1441 Parkway Dr, Blackfoot, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the previous technical supervisor, the laboratory director failed to sign the American Proficiency Institute (API) attestation statements for the specialties of chemistry and hematology since the last survey on October 11, 2017. Findings: 1. A record review of the API attestation statements revealed the laboratory director failed to sign the attestation statements for the specialties of chemistry and hematology since the last survey. 2. An interview on July 17, 2019 at 8:50 AM, with the previous technical supervisor, confirmed the laboratory director failed to sign the API attestation statements forms.
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: The laboratory failed to monitor and evaluate the overall quality and acceptability of testing performance for the Immtox toxicology analyzer since December 2018. Refer to D5403, D5423, D5437, D5439, D5469, and D5783.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with previous technical supervisor, the laboratory failed to write a procedure for the Dimension EXL 200 chemistry analyzer received in November 2018. Findings: 1. A record review of the laboratory's procedure manual revealed the laboratory failed to write a procedure for the Dimension EXL 200 chemistry analyzer received in November 2018. 2. The laboratory performed approximately 162,000 chemistry, endocrinology, and cardiac tests since July 2018. 3. An interview with the previous technical supervisor on July 17, 2019 at 12:20 PM, confirmed the laboratory failed to write a procedure for the analytes performed on the Dimension EXL 200 and that the testing personnel would look up operating instructions on the internet.
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 record review and an interview with the previous technical supervisor, the laboratory failed to have a written procedure for quality control performance and

	acceptability of control results for the 13-panel drug screen tests, which included: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates, oxycodone, amphetamines, cannabinoids, fentanyl, tramadol, cocaine, as well as, oxidant, pH, specific gravity, and creatinine on the Immtox analyzer since December 2018. This is a repeat deficiency from the last survey on October 11, 2017. Findings: 1. A record review of the laboratory's procedure manual revealed the laboratory failed to include the criteria to determine acceptable quality control results and the established controls limits determined by the laboratory or the manufacturer for the Immtox toxicology analyzer. 2. The laboratory performed approximately 2500 drug screens on the Immtox analyzer since December 2018. 3. An interview with the previous technical supervisor on July 17, 2019, at 4:55 PM, confirmed the laboratory failed to include quality control acceptability and limits.
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 a record review and an interview with the previous technical supervisor and toxicology testing person, the laboratory failed to establish the performance specifications for the following toxicology analytes: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates, oxycodone, amphetamines, cannabinoids, and cocaine, as well as, oxidant, pH, specific gravity, and creatinine performed on the Immtox toxicology analyzer before patient testing in December 2018. Findings: 1. A record review revealed the laboratory failed to establish the performance characteristics for the toxicology analytes, which included verifying the accuracy, precision, sensitivity, specificity, and reportable cut-off limits prior to reporting patient toxicology test results. 2. The laboratory performed approximately 2500 tests on the Immtox analyzer since December 2018. 3. An interview with the previous technical supervisor on July 17, 2019, at 5:15 PM, confirmed the laboratory failed to verify the performance specifications prior to reporting patient test results. 4. An interview with the toxicology testing person on July 17, 2019, at 5:15 PM, confirmed the laboratory failed to verify the performance specifications prior to reporting patient test results.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the toxicology testing person, the laboratory failed to establish the acceptability limits of the calibrators used for the Immtox drug analytes: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates, oxycodone, amphetamines, cannabinoids, fentanyl, tramadol, cocaine, oxidant, pH, specific gravity, and creatinine since the last survey on December 2018. Findings: 1. A record review of the Immtox calibration procedure revealed the laboratory failed to establish the acceptability limits for each drug analyte calibrator. 2. The laboratory performed approximately 2500 toxicology screens since December 2018. 3. An interview with the toxicology testing person on July 17, 2019, at 4:35 PM, confirmed the acceptability limits for the calibration material were not established.
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 a record review and an interview with the previous technical supervisor, the laboratory failed to perform and document calibration verification procedures for the 13-panel toxicology screen which included: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates, oxycodone, amphetamines, cannabinoids, fentanyl, tramadol, cocaine, oxidant, pH, specific gravity, and creatinine at least once every 6

	months or as required by the Immtox toxicology analyzer and as written in the laboratory procedures since December 2018. Findings: 1. A record review of calibration reports for the Immtox 13-panel drug screen and oxidant, pH, specific gravity, and creatinine, revealed the laboratory failed to perform calibration verification procedures since the analyzer began testing patients in December 2018. 2. The laboratory performed approximately 2500 toxicology screens since December 2018. 3. An interview with the previous technical supervisor on July 17, 2019, at 4:50 PM, confirmed the laboratory failed to perform calibration verification procedures on the analytes.
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 a record review and an interview with the previous technical supervisor, the laboratory failed to perform quality control each day of patient testing or establish an Individualized Quality Control Plan (IQCP) for the Alere HIV Antigen/Antibody Combo test kit since the last survey on survey on October 11, 2017. Findings: 1. A record review of the procedure manual revealed the laboratory failed to perform quality control tests each day of patient testing or establish an IQCP for the Alere HIV test kit. 2. The laboratory performed approximately 191 HIV tests since July 2018. 3. An interview with the previous technical supervisor on July 17, 2019, at 1:50 PM, confirmed the laboratory failed to establish an IQCP or perform quality control each day of patient testing.
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 record review and an interview with the toxicology testing person, and the previous technical supervisor, the laboratory failed to establish or verify the acceptability criteria of control materials for the 13-panel toxicology analytes which included: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates, oxycodone, amphetamines, cannabinoids, fentanyl, tramadol, cocaine, as well as, oxidant, pH, specific gravity, and creatinine since the last survey on survey on October 11, 2017. Findings: 1. A record review of the Immtox Quality Control policy for the 13-drug panel, as well as, oxidant, pH, specific gravity, and creatinine revealed the laboratory failed to establish or verify the acceptability criteria for 12 out of 12 unassayed quality control materials. 2. An interview with the toxicology testing person on July 17, 2019, at 4:15 PM, stated the acceptability of the quality control materials were not established. 3. An interview with the previous technical supervisor on July 17, 2019, at 4:25 PM, confirmed the laboratory failed to verify or establish the acceptability criteria for 12 quality control testing materials.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the previous technical supervisor, the laboratory failed to evaluate and take corrective actions for patient toxicology test results when 1 out of 2 quality control levels for creatinine failed to meet the manufacturer's stated reference range for 6 out of 8 days; 1 out of 2 quality control levels failed for benzodiazepine for 2 out of 8 days of patient testing; 1 out of 2 quality control levels failed for buprenorphine for 2 out of 8 days of patient testing; and 2 out of 2 quality control levels failed for cannabinoids failed for 1 out of 8 days of patient testing between April 17, 2019 and May 1, 2019. Findings: 1. A record review of quality control results and corrective action logs revealed the laboratory failed to evaluate and take corrective actions for patient toxicology test results when quality control levels failed to meet the manufacturer's reference value. 2. The laboratory performed approximately 300 toxicology tests in April 2019. 3. An interview with the previous technical supervisor on July 17, 2019, at 5:25 PM, confirmed the laboratory failed to evaluate and take corrective actions for patient toxicology results when quality control failed to meet the manufacturer's reference value.
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 record reviews and an interview with the laboratory director, the laboratory director failed to provide general supervision for the laboratory, as well as, provide overall management and quality assessment of the toxicology laboratory operations. Refer to D6079, D6086, D6093, D6094, and D6100.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory director failed to manage and direct the laboratory personnel and performance of toxicology tests since the last survey on October 11, 2017. Findings: 1. A record review revealed the laboratory failed to establish the performance specifications of the Immtox toxicology analyzer and establish acceptable quality control limits for the Immtox toxicology analyzer for the before patient testing in December 2018. Refer to D5423 and D5469. 2. A record review revealed the laboratory failed to ensure that an on-site general supervisor was available to provide the day-to-day supervision of the high-complexity testing laboratory. Refer to D6142. 3. An interview with the laboratory director on July 17, 2019, at 5:15 PM, confirmed that the Immtox toxicology analyzer failed to have the specification performance verified prior to patient testing, as well as, ensuring the laboratory was operating with General Supervisor.
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 a record review and an interview with the laboratory director, the laboratory director failed to ensure verification activities were performed on the Immtox toxicology analyzer prior to reporting patient results in December 2018. Findings: 1. A record review of the verification procedures for the Immtox revealed the laboratory failed to establish the accuracy, precision, and other performance specifications for the following toxicology analytes: 6-acetylmorphine, barbiturates, benzoylecgonine, buprenorphine, benzodiazepine, ethyl glucuronide, EDDP, methamphetamine, opiates,

	oxycodone, amphetamines, cannabinoids, and cocaine, as well as, oxidant, pH, specific gravity, and creatinine performed on the Immtox toxicology analyzer before patient testing in December 2018. Refer to D5423. 2. An interview with the laboratory director on July 17, 2019, at 5:00 PM, confirmed the laboratory failed to verify the accuracy, precision, and linearity of the toxicology analytes prior to reporting patient results.
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 a review of quality control records in the laboratory, the laboratory director failed to ensure the laboratory quality control procedures for the Immtox toxicology analyzer and the Alere HIV Antigen/Antibody test systems met all CLIA regulations since the last survey on October 11, 2017. Findings: 1. A record review of the quality control documents for the Immtox toxicology analyzer and the Alere HIV Antigen /Antibody test kit revealed quality control acceptability criteria and an Individualized Quality Control Plan was not established for each test system. 2. An interview with the laboratory director on July 17, 2019, at 5:05 PM, confirmed the laboratory director failed to ensure the quality control programs for the toxicology analytes and HIV test kit were established.
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 a record review and an interview with the laboratory director, the laboratory director failed to ensure that quality assessment activities were establish for the Immtox toxicology analyzer since the last survey on October 11, 2017. Findings: 1. A record review of the laboratory's procedure manual revealed the laboratory failed to establish and ensure a quality assessment program was established to ensure accurate and reliable patient test results since the last survey. 2. An interview with the laboratory director on July 17, 2019, at 5:00 PM, confirmed the laboratory director failed to ensure quality assessment activities were performed for the toxicology analytes.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory director failed to ensure a general supervisor provided on-site supervision for testing personnel under 493.1489 (b)(4) since March 2019. Findings: 1. A record review of the CMS-209 Personnel Report form received on July 17, 2019, indicated the laboratory failed to identify a general supervisor for 1 out of 4 testing personnel qualified under 493.1489 (b)(4) since March 2019. 2. An interview with the laboratory director on July 17, 2019, at 5:00 PM, confirmed the laboratory director failed to ensure a general supervisor provided supervision for the laboratory.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on laboratory documents and an interview with the laboratory manager, the laboratory failed to provide an on-site general supervisor to provide day-to-day supervision for high-complexity testing. Refer to D6142.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the previous technical supervisor, the laboratory failed to ensure that an on-site general supervisor was available to provide the day-to-day supervision of the high-complexity testing laboratory since March 2019. Findings: 1. A record review of the CMS-209 Personnel Report form received on July 17, 2019, indicated the laboratory failed to identify a General Supervisor. 2. An interview with the previous technical supervisor on July 17, 2019, at 9:05 AM, confirmed the laboratory failed to have a General Supervisor as of March 2019.