Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D0889073	**(X3) Date Survey Completed** 07/09/2018
Name of Provider or Supplier Boston Mountain Rural Health Center,Inc-Huntsville	**Street Address, City, State** 934 North Gaskill Street, Huntsville, AR	
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**
D0000	On the initial survey performed on July 9, 2018 Boston Mountain Rural Health Center Laboratory was found not to be in compliance with the applicable Standards and Conditions of 42 CFR Part 493, Laboratory Requirements. The following conditions were cited: CFR 493.1409 : Technical Consultant - The responsibilities of the Technical Consultant were not fullfilled.
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: Through observation, review of manfacturer's package insert and interview it was determined that the laboratory failed to amend the expiration date of three of three vials of Cell Dyn 18 Plus hematology control material after opening and and placing the vials in use. Findings follow: 1. Review of the Cell Dyn 18 Plus hematology control material package insert revealed that the vials had "8 consecutive day open tube stability". 2. On a tour of the laboratory on July 9, 2018 at approximately 04:30 PM, three vials of Cell Dyn 18 Plus hematology control vials lot numbers 8155H, 8155N, and 8155L with red colored stains on the exterior of the vials indicating the vials had been opened were observed in a plastic cup in the laboratory refrigerator with no date of opening or amended expiration date on the vials or the container the vials were in. 3. When asked at the time, the testing personnel identified as number 1 on the CMS 209 form stated that the vials were currently the hematology controls in use and the date of opening or amended expiration date was not on the vials or the container the vials were in.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through interview, review of the " Quality Control of Patient Testing" in the policy and procedure manual, lack of documentation and interview it was determined that the laboratory did not monitor quality control for significant changes over time. Findings follow: A.The " Quality Control of Patient Testing " in the laboratory policy and procedure manual defined a shift as "when the control has at least 5 data points consistently above or below the mean" and defined a trend as "when a control changes to at least 5 points increase or decrease" . B. Upon request, the laboratory could produce no documentation (levy-Jennings chart or other method) that monitored possible shifts or trends in quality control performance over time for three of three months requested, February through April of 2018. C. During an interview conducted on July 9, 2018 at approximately 03:15 PM, the Laboratory Coordinator identified as number 2 on the separate personnel identification list said that the laboratory did not employ any method to monitor quality control results for shifts or trends over time from February through April of 2018.
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: Through review of the laboratory's quality control report for March 2018, the package insert for Cell Dyn 18 Plus hematology controls, and interview it was determined that the laboratory failed to establish a target mean value for red blood cell counts for two of three levels of hematology controls in accordance with manufacturer's instruction.

	Findings follow: 1. Review of the package insert for Cell Dyn 18 Plus hematology controls reveals a requirement that the laboratory establish its own target mean within a range of means supplied by the manufacturer. 2. Review of the package insert for Cell Dyn 18 Plus hematology control lot number 8071H reveals a range of means for red blood cell counts of 4.91 to 5.51 and review of the package insert for Cell Dyn 18 Plus hematology control lot number 8071N reveals a range of means for red blood cell counts of 3.85 to 4.35. 3. Review of the laboratory's quality control records for March 2018 reveal that the mean target for red blood cell counts for Cell Dyn 18 Plus hematology control lot number 8071H was 5.53 which is ouside the range of means provided by the manufacturer. 4. Review of the laboratory's quality control records for March 2018 reveal that the mean target for red blood cell counts for Cell Dyn 18 Plus hematology control lot number 8071N was 4.39 which is ouside the range of means provided by the manufacturer. 5. In an interview on July 9, 2018 at approximately 04: 00 PM, the laboratory coordinator identified as number 2 on the separate personnel identification list confirmed that the laboratory mean target values identified above were established outside the range of means supplied by the product manufacturer.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Quality Assurance Policy "Quality Control of Patient Testing", review review of quality control documentation for February through June 2018, review of personnel records for the two current laboratory employees, and interview with organizational personnel and laboratory staff, it was determined the facility failed to meet the Condition of Technical Consultant in that: D6041 - the Technical Consultant failed to ensure that the laboratory was enrolled in a required proficiency testing program for complete blood cell analysis prior to beginning patient testing. D6042 - the Technical Consultant failed to ensure that mean target values were set appropriately for red blood cell counts and that a system for monitoring quality control for shifts and trends over time was established for February through April of 2018. D6046 - the Technical Consultant failed to evaluate and document competency of personnel who performed moderate complexity testing or to utilize the six required criteria for establishing personnel competency.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Through review of the CMS 116 Application Form, Casper 96D report, proficiency testing records, lack of documentation and interview it was determined that the laboratory did not enroll in an approved proficiency testing program for complete blood cell counts during the first six months of operations performing complete blood

	cell counts under a certificate of compliance. Findings follow: 1. Review of the CMS 116 applications for the laboratory revealed that the laboratory requested a status change from a certificate of compliance to a certificate of waiver on 6/9/17 and requested a status change back to a certificate of compliance on 12/11/17. 2. Review of the Casper 96D report revealed that no results were reported by the API proficiency testing agency for complete blood cell counts for the first event of 2018 which was shipped in March of 2018. 3. Upon request, the laboratory could not produce documentation of a subscription to an approved proficiency testing agency prior to the laboratory beginning complete blood cell testing in February 2018. 4. In an interview on 7/9/18 at approximately 02:30 PM, the laboratory coordinator identified as number 2 on the separate personnel identification list stated that complete blood cell count testing was begun on February of 2018 but the laboratory did not subscribe to proficiency testing service for complete blood cell counting until the second event of 2018.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Through review of the laboratory's quality control reports, the laboratory's quality control policy and procedure, Cell Dyn 18 Plus hematology control package insert, lack of documentation, and interview it was determined that the technical supervisor failed to establish a quality control program which allowed the laboratory to monitor the quality control of complete blood cell analysis for changes over time and to ensure that acceptable quality control mean target values were established for red blood cell counts as cited at: D5441 - The technical consultant did not ensure a system of monitoring quality control for complete blood cell analysis for changes over time. D5469 - The technical consultant did not ensure that mean target values for red blood cell counts were established according to manufacturer's instructions.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Through review of the laboratory's personnel records, the CMS 209 form, lack of documentation and interview it was determined that testing personnel competency evaluations for two of two testing personnel were not performed by the technical consultant or personnel identified on the CMS 209 form with the qualifications of a technical consultant or conducted utilizing the required six competency assessment criteria. Findings follows: A. The competency evaluations were not performed by the technical consultant. 1. A. The CMS-209 form completed for the survey lists

	employee #3 as the laboratory's director and technical consultant. 2. Review of one competency evaluation dated July of 2017 for the testing personnel identified as number 1 on the CMS 209 form and two competency evaluations dated December 2016 and December 2017 for the testing personnel identified as number 2 on the CMS 209 form revealed that the competency forms were signed by the person with the title of "supervisor" on the competency form and identified as number 1 on a separate personnel identification sheet. 3. Review of the CMS 209 form revealed that the personnel signing the competency evaluations was not identified as the technical consultant or listed on the CMS 209 form. 4. In an inteview on July 9, 2018 at approximately 02:10 PM, the Laboratory Coordinator identified as number 2 on the separate personnel identification sheet confirmed that the person identified as number 1 on the separate personnel list evaluated the competencies and signed the competency evaluations for the testing personnel identified as numbers 1 and 2 on the CMS 209 form. B. The competency evaluations were not conducted utilizing the six required criteria for determining personnel competency. 1. Review of one competency evaluation dated July of 2017 for the testing personnel identified as number 1 on the CMS 209 form and two competency evaluations dated December 2016 and December 2017 for the testing personnel identified as number 2 on the CMS 209 form revealed that the competency forms were documented by check marks only in the applicable one of three columns with the headers of "competent", "incompetent" and "not applicable". 2. Upon request, the laboratory was unable to provide documentation that indicated which of the criteria were used to determine competency and document that the six required criteria were utilized. 3. In an inteview on July 9, 2018 at approximately 02:10, the Laboratory Coordinator identified as number 2 on the separate personnel identification sheet confirmed that documentation of which of the criteria utilized to evaluate competency and/or document that the six required criteria were utilized were not available.