Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2095592	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Big Sky Laboratory	2509 7th Ave South Suite C1, Great Falls, MT	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records from the American Proficiency Institute (API), biannual verification records, the test volume report and interview with laboratory director (LD) #1, the laboratory failed to perform one out of two biannual verifications for Mycology (KOH Preps) for year 2022. (Repeat Deficiency) Findings: 1. A review of Test Volume Report revealed one KOH Preps was performed from June 14, 2022 to June 14, 2023 (12 months). 2. A review of API records revealed no records of KOH and review of biannual verification records revealed the laboratory failed to perform one of two verifications of KOH in 2022. 3. Interview on June 14, 2023, at 9:00 AM with the LD #1 confirmed the laboratory failed perform one of two biannual verification of Mycology (KOH Preps) or participate in a proficiency testing program for the year 2022.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review of patient results reports, procedure, and interview with the laboratory director (LD) #1, the laboratory failed to establish and verify the reference ranges (normal values) for the laboratory's patient population for the Dimension Xpand Plus chemistry analyzer from June 14, 2021, to June 14, 2023. Findings: 1. A review patient results reports (#23050290, #23020153, #23010145, #23030169 and #22070094) for chemistry, special chemistry and lipid studies listed reference ranges in the report. 2. Expected values listed in the Flex reagent cartridge insert sheets did not match the patient results report's normal reference ranges and no other chemistry procedure with normal reference ranges were available for review. 3. No patient population verification studies for the Dimension Xpand Plus chemistry analyzer were available for review to support the references ranges (normal ranges) listed in the laboratory's patient results reports. 4. An interview with the LD #1 on June 14, 2023, at 11:30 AM, stated the reference ranges (normal values) were established by a different laboratory from June 14, 2021, to June 14, 2023.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, procedure manual and interview with laboratory director (LD) #1, the laboratory failed to establish and follow procedures to certify one of one microscope and one of two centrifuges for accuracy from January 1, 2021 to June 14, 2023. Findings: 1. Observed two centrifuges and one microscope in the laboratory. No certification stickers or records were available for review for one of one microscope and one of two centrifuges (Hettich EBA 200 S). 2. A review of Test Volume Report revealed one KOH prep, and 251 microscopic uranalysis were performed using the microscope from June 14, 2022 to June 14, 2023 (12 months). 3. A review of laboratory procedures revealed the laboratory failed to establish a procedure that defines the function checks on each piece of equipment or instrument it uses, including those that are peripherally involved in patient testing. 4. An interview with LD #1 on June 14, 2023, at 9:40 AM confirmed the laboratory failed to certify the accuracy of one of two centrifuges and for one of one microscope from January 1, 2021 to June 14, 2023.
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 review of chemistry quality control (QC) records, procedures, and interview with the laboratory director (LD) #1, the laboratory failed to establish acceptable criteria (mean and standard deviation) for new lots of Thermo Scientific MAS chemTRAK H liquid assayed general chemistryl controls performed on the Dimension Xpand Plus chemistry analyzer from June 14, 2021, to June 14, 2023. Findings: 1. No correlations studies for new lots of MAS chemTRAK H quality control materials to establish statistical limits for the Dimension Xpand Plus chemistry analyzer were available for review. 2. No chemistry procedure for the evaluation of new lots of quality control and acceptable control limits were available for review. 3. A review of the test volume sheet revealed 36,400 chemistry results were reported from June 14, 2022, to June 14, 2023 (12 months). 4. An interview with LD #1 on June 14, 2023, at 11:15 AM, confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Dimension Xpand Plus chemistry analyzer from June 14, 2021, to June 14, 2023.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review of quality assessment plan, and interview with the laboratory director (LD) #1, the laboratory failed to establish a mechanism to periodically verify the accuracy of its laboratory information system (LIS) for its calculated data and patient specific data from June 14, 2021, to June 14, 2023. Findings: 1. No calculation checks to monitor and verify the data calculated by their laboratory information system for low-density lipoprotein (LDL) cholesterol, very-low-density lipoprotein (VLDL) cholesterol and mean blood glucose were available for review. 2. The laboratory failed to include in their Quality Assessment Plan a mechanism to monitor their LIS system. 3. No quality assessment review of patient test reports for accuracy of patient information, test results and normal ranges to verify that the laboratory is monitoring and evaluating the quality and accuracy of the information supplied to its clients were available for review.(Cross Refer D5421) 4. An interview with the LD #1 on June 14, 2023, at 11:50 AM, confirmed the laboratory failed to perform quality assessment checks of its LIS system's patient specific data and calculation checks from June 14, 2021, to June 14, 2023.