Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2095592	05/07/2025
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD) #1, the laboratory failed to enroll in an HHS-approved proficiency testing program for the isolation and differentiation of Group B Streptococcus (GBS) from May 7, 2023, to May 7, 2025. Findings: 1. A review of the Test Volume Report revealed 52 Strep B Cultures were performed from May 1, 2024, to May 1, 2025. (12 months). 2. A review of 2023 and 2024 American Proficiency Institute (API) testing program records lacked documentation of proficiency testing for the isolation and differentiation of Group B Streptococcus. 3. An interview on May 7, 2023, at 10:30 AM with the LD#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for the isolation and differentiation of Group B Streptococcus from May 7, 2023, to May 7, 2025.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this

	section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with the Testing Personnel (TP) #1, the laboratory failed to follow the manufacturer's instructions for use (IFU) to inoculating vaginal-rectal specimens in a suitable Group B Streptococcus (GBS) enrichment broth before plating and did not perform a Group B Streptococci antigen test on isolated colonies from May 7, 2023, to May 7, 2025. Findings: 1. A review of Hardy Diagnostics GBS Detect instructions for use revealed the laboratory failed to perform 2 of the 5 procedure steps: "1. Using a vaginal-rectal specimen, inoculate a suitable GBS enrichment broth ..." and "5. Using isolated colonies from the GBS Detect plate described in step 4, perform the latex particle agglutination test ... or other tests recommended for the detection of group B streptococci antigen...." 2. A review of "Microbiology Media Check Off Sheet" lacked records of GBS enrichment broths from May 7, 2023, to May 7, 2025. 3. A review of microbiology records lacked documentation of latex particle agglutination testing or other recommended GBS antigen testing from May 7, 2023, to May 7, 2025. 4. An interview on May 7, 2023, at 10:45 AM with TP #1 confirmed the laboratory failed to follow the manufacturer's IFU regarding the inoculation of vaginal-rectal specimens in a suitable GBS enrichment broth before plating and performing a GBS antigen test on isolated colonies from May 7, 2023, to May 7, 2025. 5. A review of the Test Volume Report revealed 52 Strep B Cultures were performed from May 1, 2024, to May 1, 2025. (12 months).
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instruction, procedures, and interview with the Testing Personnel (TP) #1, the laboratory failed to establish the reactivity of each organism used for microbiology quality control (QC) and define its acceptable criteria from May 7, 2023, to May 7, 2025. Findings: 1. A review of the manufacturer's instructions for use for HardyDisk Bacitracin Differentiation Disks, Hardy Diagnostics Group B Streptococcus (GBS) Detect, Hardy Diagnostics MacConkey Agar (MAC) and Hardy Diagnostics Blood Agar (BAP) revealed the following American Type Culture Collection (ATCC) control organisms that where recommended for QC: Streptococcus pyogenes ATCC 19615 Streptococcus agalactiae group B ATCC 13813 Streptococcus agalactiae clinical Strain Enterococcus faecalis ATCC 29212 Escherichia coli ATCC 8739 Pseudomonas paraeruginosa ATCC 9027 Salmonella enterica ATCC 14028 Staphylococcus aureus ATCC 6538 Proteus

	mirabilis ATCC 12453 Escherichia coli ATCC 25922 Streptococcus pneumoniae ATCC 6305 Streptococcus pyogenes ATCC 19615 Staphylococcus aureus ATCC 25923 2. A review of microbiology records lacked documentation of studies to establish the reactivity of each quality control organism it used from May 7, 2023, to May 7, 2025. 3. A review of the laboratory's "General Culturing Guidelines", "Throat Culture" and "Urine Cultures" procedures failed to define the quality control criteria of acceptability of each organism used as QC. 4. A review of the "Microbiology Media Check Off Sheet" and the patient workup log failed to document the identity of quality control organism used, lot numbers, date in use, expiration dates, and the actual reactions observed for the Bacitracin Differentiation Disks, GBS, MAC and BAP media being tested. 5. An interview on May 7, 2023, at 10:55 AM with TP #1 confirmed that the laboratory failed to establish the reactivity of each organism used for microbiology quality control (QC) and define its acceptable criteria from May 7, 2023, to May 7, 2025.