Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2102074	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Big Sky Medical Center	334 Town Center Ave, Big Sky, 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
D0000	An announced CLIA recertification survey was conducted at Big Sky Medical Center on November 4, 2025, by the Montana CLIA Program. The laboratory was surveyed under 42 CFR Part 493 CLIA regulations and was found to be in compliance with condition-level requirements. However, the following standard-level deficiencies were identified during the survey.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #2, the laboratory failed to perform and document corrective action for five of five unacceptable sample scores across two of six chemistry proficiency testing (PT) events from January 1, 2024, to November 4, 2025. Findings: 1. A review of PT records lacked evidence of corrective action for the following unacceptable sample scores: API 2025 Chemistry Core 2nd Event for analytes (sample): Creatinine (CH-07) Magnesium (CH-08) Total Protein (CH-08) Vancomycin (CH-10) API 2025 Chemistry Core 3rd Event for analyte (sample): Uric Acid (CH-15) 2. An interview with TP #2 on November 4, 2025, at 2:15 PM confirmed that the laboratory failed to perform and document corrective action for the five unacceptable samples identified in the two chemistry PT events listed above from January 1, 2024, to November 4, 2025.

D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #2, the laboratory failed to perform and document corrective action for two of two unacceptable sample scores across two of five hematology proficiency testing (PT) events from January 1, 2024, to November 4, 2025. Findings: 1. A review of proficiency testing records lacked evidence of corrective action for the unacceptable sample scores for the following PT events: API 2024 Hematology/Coagulation 1st Event - Urinalysis & Human Chorionic Gonadotropin (HCG) Nitrate (UA-02) API 2025 Hematology/Coagulation 2nd Event - Blood Cell Identification (BCI-07) 2. An interview with TP #2 on November 4, 2025, at 2:20 PM confirmed that the laboratory failed to perform and document corrective action for the two unacceptable sample scores reported in the two hematology PT events listed above from January 1, 2024, to November 4, 2025.
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) (a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on a record review and interview with Technical Supervisor (TS) #1, the laboratory lacked an approved agreement for transfusion services between three of three facilities to define which services are provided directly by the facility and which are provided by the agreement, and failed to ensure the agreement was being met from November 4, 2023, to November 4, 2025. Findings: 1. A review of the laboratory's policies and procedures lacked the following: An approved transfusion service agreement between three facilities: one facility providing blood products (vendor), one facility performing blood typing, and one facility storing and transfusing the blood products. A written step-by-step process to determine which services are provided by each facility. 2. An interview with TS #1 on November 4, 2025, at 5:20 PM confirmed that the laboratory failed to have an approved written transfusion service agreement and step-by-step procedure to outline which services are provided by each facility from November 4, 2023, to November 4, 2025.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) (a)(3)(ii) Immunohematology records, blood and blood product records, and

	transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on a review of immunohematology records and interviews with Testing Personnel (TP) #1 and #2, the laboratory failed to retain documentation of staff performing visual inspection of blood and blood products immediately before distribution of five of five Red Blood Cell (RBC) units and three of three liquid plasma units from April 30, 2024, to March 1, 2025. Findings: 1. A review of emergency release logs lacked documentation that visual checks of blood and blood products were performed immediately before distribution on the following dates: April 30, 2024 - one liquid plasma unit February 7, 2025 - two RBC units February 13, 2025 - two RBC units and two liquid plasma units March 1, 2025 - one RBC unit 2. A review of the laboratory's Emergency Blood Release Procedure failed to include record retention requirements for immunohematology. 3. Interviews with TP #1 and TP #2 on November 4, 2025, at 12:00 PM confirmed that the laboratory was missing the original documentation of visual checks performed immediately before distribution of five RBC units and three liquid plasma units between April 30, 2024, and March 1, 2025.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #1 and #2, the laboratory failed to evaluate the accuracy of their "Not Graded" sample scores for eight of eight proficiency testing (PT) events from January 1, 2024, to November 4, 2025. Findings 1. A review of proficiency testing records lacked documentation that the laboratory evaluated the accuracy of the "Not Graded" sample scores for the following PT events, analyte, and sample identification: API 2024 Chemistry Core 1st Event Bilirubin, Total: CH-02, CH-03, CH-05 Pilot Cardiac Marker: PSC-01, PSC-02 API 2024 Chemistry Core 2nd Event Total Iron: CH-08 API 2024 Hematology /Coagulation 1st Event Advanced Blood Cell Identification: ABI-01, ABI-02, ABI-03, ABI-04, ABI-05, ABI-06, ABI-07 Educational Blood Cell Identification: DIF-01, ECI-01, ECI-02, ECI-03, ECI-04, ECI-05 API 2024 Hematology/Coagulation 2nd Event Advanced Blood Cell Identification: ABI-08, ABI-09, ABI-10, ABI-11, ABI-12, ABI-13, ABI-14 Educational Blood Cell Identification: DIF-02, ECI-06, ECI-07, ECI-08, ECI-09, ECI-10 API 2025 Chemistry Core 2nd Event Bilirubin, Total: CH-07, CH-09, CH-10 API 2025 Chemistry Core 3rd Event Bilirubin, Total: CH-12, CH-15 API 2025 Hematology/Coagulation 1st Event Advanced Blood Cell Identification: ABI-01, ABI-02, ABI-03, ABI-04, ABI-05, ABI-06, ABI-07 Educational Blood Cell Identification: DIF-01, ECI-01, ECI-02, ECI-03, ECI-04, ECI-05 API 2025 Hematology/Coagulation 2nd Event Educational Blood Cell Identification: DIF-02, ECI-06, ECI-07, ECI-08, ECI-09, ECI-10 2. Interviews with TP #1 and TP #2 on November 4, 2025, at 2:30

	PM confirmed the laboratory failed to evaluate the accuracy of their "Not Graded" sample scores for the eight of eight PT events listed above from January 1, 2024, to November 4, 2025.