Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410260	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Phillips County Hospital	311 8th Ave East, Malta, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview with the general supervisor (GS) #1, the laboratory director failed to review, sign and date the Proficiency Testing Attestation Statement forms for nine out of 31 events from January 1, 2022, to June 18, 2024 Findings: 1. Review of API's Proficiency Testing Attestation Statements lacked Laboratory Director's signature, and date for the following proficiencies: 2022 Chemistry Core - 3rd Event 2022 Immunology /Immunohematology 3rd Event 2022 Chemistry - Miscellaneous-2nd Event 2022 Hematology/Coagulation 3rd Event 2023 Immunology/Immunohematology 3rd Event 2024 Hematology/Coagulation 1st Event 2024 Microbiology 1st Event 2024 Immunology/Immunohematology 1st Event 2. Review of API's Attestation Statement for 2023 Microbiology 2nd Event lacked the Laboratory Director's and Testing Personnel's signatures and dates. 3. Interview with GS #1 on June 18, 2024, at 10:00 AM confirmed the laboratory director failed to review, sign and date nine out of 31 Proficiency Testing Attestation Statement forms from January 1, 2022, to June 18, 2024.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7),

	that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) records, CMS-209 Personnel Report Form, personnel files, and policy and procedures, the laboratory failed to perform annual competencies for their testing personnel, general supervisor, and technical supervisor (D5209), failed to review and evaluate ungraded proficiency results obtained from the proficiency testing company and document the review process (D5211), and failed to follow their procedure to complete a corrective action for unsuccessful or discrepant proficiency testing results (D5221).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on a record review and an interview with the general supervisor (GS) #1, the laboratory failed to establish and perform competency assessments for the technical supervisor and general supervisor listed on the CMS-209 Personnel Report form and failed to follow their procedure to perform annual competency assessments on four out of four testing personnel for years 2022 and 2023. Findings: 1. A record review of the CMS-209 Personnel Report Form revealed one personnel listed as general supervisor and one personnel listed as technical supervisor and failed to have a competency assessment performed for years 2022 and 2023. 2. Testing personnel files lacked documentation of competency reviews for years 2022 and 2023. 3. A review of the Competency Testing policy and procedure failed to list the six required procedures as part of their annual competency for testing personnel and failed to assess the technical supervisor and general supervisor position. 4. An interview with GS #1 on June 18, 2024, at 9:15 AM confirmed the laboratory failed to perform annual competencies for their testing personnel, general supervisor, and technical supervisor for the years 2022 and 2023.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) records and an interview with the general supervisor (GS) #1, the laboratory director or designee failed to review and evaluate ungraded proficiency results obtained from the proficiency testing company and document the review process from January 1, 2022, to June 18, 2024. Findings: 1. A review of proficiency testing (PT) records lacked API's Performance Review and Corrective Action forms with the Laboratory Director's or

	Designee's signature, and the date the PT results were evaluated and reviewed from January 1, 2022, to June 18, 2024. 2. A review of PT records revealed the laboratory failed to evaluate the not graded PT results from January 1, 2022, to June 18, 2024 3. An interview with GS #1 on June 18, 2024, at 10:10 AM confirmed the laboratory failed to evaluate the "not graded" proficiency results and document the review process from January 1, 2022, to June 18, 2024.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) records and an interview with general supervisor (GS) #1, the laboratory director or designee failed to follow their procedure to complete a corrective action for unsuccessful or discrepant proficiency testing results for 15 out of 32 events from January 1, 2022, to June 18, 2024. Findings: 1.The laboratory failed to follow their Proficiency Testing policy and procedure to complete a "Corrective Action Checklist" for each unsuccessful result for the following: 2022 Chemistry Core 2nd Event (pH) and 3rd Event (Bilirubin, Direct); 2022 Hematology/Coagulations 1st Event (Blood Cell Identification) and 2nd Event (Blood Cell Identification and Ketones); 2023 Chemistry Core 1st Event (pCO_2); and 2023 Chemistry Miscellaneous 2nd Event (Urine Chemistry); 2023 Hematology/Coagulation 1st Event and 2nd Event (Blood Cell Identification); and 2024 Hematology/Coagulation 1st Event (Microscopy/Urine Sediment). 2. The laboratory failed to perform corrective action for discrepant educational results for the 2022 Hematology/Coagulations 2nd and 3rd Events (Blood Cell Identification), the 2022 Microbiology 1st and 3rd Events (MIC Microscan), and the 2023 Microbiology 1st and 3rd Events (MIC Microscan). 3. An interview with GS #1 on June 18, 2024, at 10:20 AM confirmed the laboratory director or designee failed to follow their procedure to perform a corrective action for unsuccessful or discrepant proficiency testing results for 15 out of 32 events from January 1, 2022, to June 18, 2024.
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 review of the blood bank's policy and procedure and an interview with the general supervisor (GS) #1, the laboratory failed to have a step-by-step procedure for the review of historical blood bank patient data to determine previously identified antibodies and any other serological anomalies from June 18, 2022, to June 18, 2024. Findings: 1. No policy and procedure for checking historical blood bank patient data historical blood bank patient data to determine previously identified antibodies and any other serological anomalies was available for review at the time of the survey. 2.

	An interview with GS #1 on June 18, 2024, at 2:25 PM confirmed the laboratory failed to have a step-by-step procedure for the review of historical blood bank testing results from June 18, 2022, to June 18, 2024.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on observation, record review of blood bank alarm check, and an interview with the general supervisor (GS) #1, the laboratory failed to follow their policy and procedure to perform and document quarterly alarm checks for one out of one blood bank refrigerator and freezer from June 18, 2022 to June 18, 2024. Findings: 1. Observed in the laboratory on June 18, 2024, at 2:10 PM, one blood bank refrigerator containing four group O Rh(D)-negative red blood cells (RBC), four O Rh(D)-positive RBC, one A Rh(D)-negative RBC, and one A Rh(D)-positive RBC, and one blood bank freezer containing two AB fresh frozen plasma (FFP). 2. The laboratory failed to perform quarterly alarm checks for five out of ten quarters (December 2022, March, June, December 2023, and March 2024) to ensure proper storage temperature of their RBC and FFP inventory per their Refrigerator and Freezer "Alarm System Testing" policy and procedure. 3. A review of the laboratory's Procedure Activity Report revealed four blood product transfusions were performed from July 1, 2023, to June 13, 2024 (12 months). 4. An interview with TS #1 on March 26, 2023, at 2:20 PM confirmed the laboratory failed to perform and document quarterly alarm checks at the frequency required by their policies and procedures from June 18, 2022, to June 18, 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on a record review, laboratory policy and procedure, statement of deficiencies, plan of correction for CMS 2567 form dated September 12, 2022, and interview with the general supervisor (GS) #1, the laboratory failed to establish a quality assessment program to monitor and prevent repeat deficiencies from June 18, 2022, to June 18, 2024. Findings: 1. The "QA/QI Guidelines" policy and procedure failed to address monitoring of the quality assessment program. 2. Review of Blood Bank Maintenance Checklist and Scheduled Centrifuge Maintenance checklist lack review for quality assessment. 3. Review of Blood Bank Monthly Temperatures lacked documentation for "Reviewed by" and "Date". 4. The

	laboratory lacked documentation of performing the "QA checklist" to monitor their quality assurance, as stated in the CMS-2567 plan of correction dated September 12, 2022, to prevent repeat deficiencies. (Cross refers to D5555 and D5209). 5. Interview with GS #1 on June 18, 2024, at 4:40 PM stated laboratory staff never implemented the QA checklist and confirmed the laboratory failed to identify and correct problems and prevent their recurrence for the findings listed above.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) testing records, delegation statement, and policy and procedure, the laboratory director failed to ensure proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. 1. A review of the "Delegation Statement" signed by the laboratory director on January 5, 2023 revealed the designees failed to perform their duties assigned "to review and signature of current and/or pending proficiency testing results, documentation/implementation of corrective action for any unsatisfactory or unsuccessful proficiency testing," and/or "quarterly review of external proficiency testing, excluding the blood bank.". 2. A review of proficiency testing attestation statements revealed the laboratory director or designee failed to ensure nine out of 31 attestation statements were signed and dated between January 1, 2022, to June 18, 2024. (Refer to D2009) 3. The laboratory director or designee failed to document their evaluation of all proficiency testing results or use API's Performance Review and Corrective Action forms and failed to review and evaluate 12 out of 12 proficiency testing events' not graded results from January 1, 2022, to June 18, 2024. (Refer to D5211) 4. The laboratory director or designee failed to ensure corrective action was performed for unsuccessful or discrepant proficiency testing results for 15 out of 32 PT events and failed to review and approve eight out of eight Corrective Action Checklist forms from January 1, 2022, to June 18, 2024. (Refer to D5221)
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, policies and procedures, and the statement of deficiencies plan of correction for CMS 2567 form dated September 12, 2022, the laboratory director failed to ensure laboratory staff established and maintained the quality assurance program to prevent repeat deficiencies from June 18, 2022, to June 18, 2024. 1. The laboratory director failed to have the supervisors perform a monthly review of the blood bank monthly temperature logs and blood bank maintenance checklists per the delegation statement to prevent repeat deficiencies from June 18,

	2022, to June 18, 2024 2. The "QA/QI Guidelines" policy and procedure lacked a quality assurance plan for the prevention of repeat deficiencies from June 18, 2022, to June 18, 2024. 3. No QA checklist, as stated in the CMS-2567 plan of correction dated September 12, 2022, was available for review from June 18, 2022, to June 18, 2024. (Refer D5791)
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on a review of the laboratory's delegation statement, personnel files, and statement of deficiencies plan of correction (CMS 2567 form) dated April 8, 2021, the general supervisor failed to perform the duties delegated by the laboratory director and maintain their plan of correction to evaluate the competency of laboratory staff annually for years 2022 and 2023. Findings: 1. A review of the "Delegation Statement" revealed the general supervisor failed to perform the following duties delegated: Annual or semi-annual competency assessment of testing personnel. (Refer D5209) 2 A review of the laboratory's CMS 2567 plan of correction dated April 8, 2021, revealed the general supervisor failed to maintain their plan of correction and evaluate the competency of laboratory staff annually for years 2022 and 2023.