Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410260	08/24/2022
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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on review of Immunohematology records, policy and procedure, and interview with General Supervisor (GS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and returned blood and blood products not used for transfusion from March 23, 2021, to August 24, 2022 Findings: 1. Review of Immunohematology records lacked documentation of temperatures for blood and blood products upon receipt of new shipments and for unused blood or blood products returned to the laboratory. 2. Review of Criteria for Returning and Reissuing of Blood Products policy revealed, "Unit must be returned to Blood Bank Refrigerator within 30 minutes of the documented time of check out and the temperature of the unit must be less than 10C. The temperature will be checked by wrapping the unit around a thermometer and taking the temperature 3 minutes later." and "must be documented in the Blood Bank Worksheet book." 3. Interview with GS #1 on August 23, 2022 at 11:00 AM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and returned blood or blood products not used for transfusion.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of chemistry, serology, immunology, and blood bank records and procedures, the laboratory failed to perform external quality controls as dictated by their IQCP procedure (Refer to D5401); failed to have the laboratory director approve the method performance specifications for the new blood gas analyzer and procedure prior to reporting patient test results. (Refer to D5421); failed to perform function checks for pipettes and centrifuges (Refer to D5435); and failed to consistently document the required information, including visual inspection for blood or blood products issued or returned for reissue. (See D5553); failed to record daily temperatures and perform quarterly alarm checks (See D5555); and failed to develop a quality assessment plan to identify, correct, and prevent problems from recurring (See D5791).
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 record review, policy and procedures, and interview, the laboratory failed to follow written procedures for performing quality control at the frequency dictated by their Individualized Quality Control Plans (IQCP) for the DCA Vantage analyzing microalbumin and creatinine, Consult Diagnostics Mononucleosis Cassette, Serum hCG (Combo Cassette) and H. pylori cassette from June 2021 to August 2022. Findings: 1. Review of IQCPs for DCA-Vantage Microalbumin/Creatinine Urine, Consult Diagnostics Mononucleosis Cassette, Serum hCG (Combo Cassette) and H. pylori cassette revealed, 2 levels of QC is to be performed for "new lot/new shipment and monthly thereafter". 2. Review of microalbumin/creatinine (M/C) quality control (QC) Log lacked QC records for September and October of 2021 and January, February, March, May and June of 2022. 3. Review of Serology and Immunology External QC Log lacked QC records for the following months: a. Serum and Urine QC for February, March and April of 2022 b. Mononucleosis QC for September, October of 2021, January, February, March, April, June, July and August of 2022 c. H. pylori QC for July, September, October, November of 2021 and January, February, March, April, May, June and August of 2022 4. Interview with GS #1 on August 24, 2022, at 2:20 PM confirmed the laboratory failed to perform QC as dictated by their IQCP for microalbumin, creatinine, mononucleosis, Serum hCG and H. pylori.
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 observation, review of manufacturer operator's manual, and interview with the General Supervisor (GS) #1, the laboratory failed to have the laboratory director evaluate and approve the performance specifications of the OPPTI CCA TS2 blood gas analyzer and procedure prior to reporting patient test results. Findings: 1. Observed OPTI CCA-TS2 Analyzer available to test analytes: pH, carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), sodium (Na+), potassium (K+), ionized calcium (Ca++), chloride (Cl-), glucose (Glu), blood urea nitrogen (BUN), lactate (Lac), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO2) in the laboratory. 2. Review of operator's manual states, "OPTI Medical recommends the following as a minimum testing frequency of QC materials; SRC levels 1 and 3 at least 1x per day in operation and OPTI Check or OPTI Check Plus Liquid Controls 1-month intervals and with each new shipment of cassettes". 3. No Individualized Quality Control Plan (IQCP) study or procedure was available for review to allow for less than the required testing of one control every eight hours. 4. The verification evaluation and instrument manual used as the procedure for the OPPTI CCA TS2 blood gas analyzer lacked review and approval by laboratory director prior to patient testing. 5. Interview with the (GS) #1 on August 24, 2022, at 4: 30 PM, confirmed these findings.
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, policy and procedures, and interview with General Supervisor (GS) #1 the laboratory failed to establish and follow procedures to perform function checks to verify the accuracy of five pipettes and seven centrifuges from January 1, 2021, to August 24, 2022. Findings: 1. Observation of the centrifuges available for use lacked calibration labels to include revolutions per minute (RPM) and timer function checks. 2. Review of Blood Bank Maintenance Checklist and Scheduled Centrifuge Maintenance Checklist lacked documentation of biannual timer and tachometer checks for seven centrifuges. 3. Review of Inter-Mountain Biomedical Services pipet verification documents lacked verification records for year 2021 and 2022. 4. Review of Quality Control policy

	revealed QC-QA frequency intervals for centrifuges are semi-annually and lacks a description for the frequency of verification for pipettes. 5. An interview with the GS#1 on August 24, 2022, at 3:40 PM, confirmed these findings.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of policy and procedures, records and interview with General Supervisor (GS) #1, the laboratory failed to consistently document the required information including visual inspection checks for 24 out of 36 units of blood or blood products released for transfusion or returned for reissue from January 11, 2021, to August 24, 2022. Findings: 1. Review of "Issuing of Blood for Transfusion" policy revealed visual inspections are performed when "Units are received by the laboratory; RN checks out a unit of blood to be transfused; Preparing to return to ARC; and Preparing to transfer to another medical facility." 2. Review of "Criteria for Returning and Reissuing of Blood Products" policy states "Unit must have been checked out from our Blood Bank refrigerator and documented properly in the Blood Bank Worksheet book" and "The unit's return to the Blood Bank Refrigerator must be documented in the Blood Bank Worksheet book, with a note on the next line stating that it was returned + why.". 3. Review of "Transfusion Service Testing Record" log lacked one or more of the required information for either units released (component, issued by, visual inspection, issued to, date/time of units) or returned (date/time, technologist, disposition, reason why) on the following dates: 01/18/2021, 2/15/2021, 3/2/2021, 3/5/2021, 6/24/2021, 10/0720/21, 10/8/2021, 10/18/2021, 12/01/2021, 1/17 /2022, 3/7/2022, 3/23/2022, 07/29/2022, 4. Interview with GS #1 on August 24, 2022, at 11:30 AM, confirmed these findings.
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: Based on review of the blood bank's policy and procedures, records of blood bank's refrigerator and freezer alarm checks for 2021, daily temperature logs for November 2021 and March 2022, and an interview with the General Supervisor (GS) #1, the laboratory failed to record daily temperature and perform and document quarterly alarm inspection checks for 1 of 1 blood bank refrigerator and freezer.. Findings: 1. Review of "Quality Control" policy for "QC-QA Frequency Intervals" revealed, the

	frequency of blood bank refrigerator's alarm activation for visual and audible is quarterly. 2. Review of the "Blood Bank Maintenance Checklist and Scheduled Centrifuge Maintenance Checklist" records revealed, alarm checks for the blood bank refrigerator and freezer are scheduled "Quarterly (Due March, June, Sept, Dec)" and lacked documentation of alarm checks for year 2021. 3. Review of Blood Bank Refrigerator-Temperature policy revealed, "Daily, 2 temperatures must be checked, recorded and initialed on the Blood Bank Monthly Temperature Log.", 4. Review of Blood Bank Monthly Temperature Log for JULY 2022 lack entry for days 7/10, 7/23,7 /24 and 7/25 and for November 2021 lack entry for 11/9, 11/25, 11/26, 11/27 and 11 /28. 5. An interview with GS #1 on August 24, 2022, at 11:50 a.m. confirmed these findings.
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: Based on record review, policy and procedures, and interview with General Supervisor (GS) #1, the laboratory failed to establish a quality assessment plan that identifies and corrects problems and prevent their recurrence related to their Individual Quality Control Plan (IQCP) required frequency to perform quality control for microalbumin, creatinine, mononucleosis, urine and serum human chorionic gonadotropin (HCG), and H. pylori, daily temperature logs for the storage of blood and blood products, inspection and documentation requirements for the issue and reissue of blood and blood products for transfusion, functions checks of pipettes and centrifuges from January 1, 2021 to August 24, 2022. Findings: 1. Review of Blood Bank Maintenance Checklist and Scheduled Centrifuge Maintenance checklist lack review for quality assessment. 2. Review of Blood Bank Monthly Temperatures for November 2021 and March 2022 lacked documentation for "Reviewed by" and "Date". 3. Review of IQCPs for DCA-Vantage Microalbumin/Creatinine Urine, Consult Diagnostics Mononucleosis Cassette, Serum hCG (Combo Cassette) and H. pylori cassette revealed, "The Quality Assessment is an ongoing review of the QC process." 4. Review of M/C QC Log DCA Vantage lacks review for quality assessment. 5. Review of Serology and Immunology External QC Log revealed "External QC: Perform with each new kit lot number and each new shipment date" and does not address requirements for monthly QC for HCG, Mononucleosis and H. pylori and lacks review for quality assessment. 6. No corrective action or remedial training records were available for review regarding the lack of monthly QC, blood bank documentation, function checks and temperature records. Cross refer D5401, D5435, D5555, D5553, 7. Review of "Blood Bank Refrigerator - Temperature" revealed, "When the pathologist comes for a site visit, pull these charts for review. Temperature chart must be kept for 5 years." 8. Jewett Temperature Charts lacked review by laboratory director (LD #1). 9. Interview with GS #1 on August 24, 2022, at 4:40 PM, confirmed the laboratory failed to identify and correct problems and prevent their recurrence for the findings listed above.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of written laboratory policies and procedures, review of laboratory records, and interviews, it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory's analytical system, including assuring compliance with the applicable regulations for immunohematology, quality assurance, and quality control plan procedures and programs. Cross refer to D5401, D5421, D5435, D5553, D5555 and D5791