Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410260	03/27/2018
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
D0000	Based on an on-site recertification survey conducted on 3/26/18-3/27/18, deficiencies were cited for Phillips County Hospital in Malta, MT.
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 observation, record review, and interview, the laboratory failed to follow the laboratory policy and procedure for microalbumin/creatinine from 3/22/16 to 3/26/18. The findings include: 1. On 3/26/18 at 1:15 p.m., a DCA Vantage was observed in the laboratory. 2. On 3/26/18 at 1:15 p.m., staff member A stated microalbumin/creatinine was performed on the DCA Vantage. 3. A review on 3/27/18 at 8:35 a.m. of the Phillips County Hospital microalbumin/creatinine (M/C) quality control (QC) Log for the DCA Vantage documented controls run on 12/30/16, 2/14/17, 4/24/17, 6/3/17, 8/9/17, 10/13/17, 10/26/17, and 1/2/18. 4. A review on 3/27/18 at 8:35 a.m. of the Phillips County Hospital Individual Quality Control Plan (IQCP) for DCA-Vantage Microalbumin/Creatinine Urine Policy and Procedure stated in the Quality Control Plan to run test panels "at new lot/new shipment and monthly there after." 5. On 3/27/18 at 8:35 a.m., staff member D stated the controls were not run monthly.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on record review and interview, the current laboratory director failed to approve, sign, and date two of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/27/18 at 1:35 p.m. of the Phillips County Hospital IQCP for DCA-Vantage Microalbumin/Creatinine Urine and IQCP for Antimicrobial Susceptibility Testing and Organism Identification Microscan System were not signed as approved by the current laboratory director. 2. On 3/27/18 at 1:35 p.m., staff member A stated the previous laboratory director had signed approval.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow manufacturer directions for establishing a new patient mean for one of two lots of recombiplastin reagent reviewed. The findings include: 1. On 3/26/18 at 1:15 p.m., an Instrumentation Laboratory (IL) ACL Elite analyzer was observed in the laboratory. 2. On 3/26/18 at 1:15 p.m., staff member A stated prothrombin times (PT) were performed on the IL ACL Elite analyzer. 3. A review on 3/26/18 at 5:00 p.m. of the calculations for the patient mean normal value was not documented for the previous lot of recombiplastin (lot number N0160676) used from approximately 1/2017 through 3/2018. 4. On 3/26/18 at 5:00 p.m., staff member A stated the new lots are ordered and shipped at the end of the calendar year and started in use at the beginning of the year. 5. A review on 3/27/18 at 7:40 a.m. of the IL ACL Elite analyzer manufacturer instructions included instructions that the mean normal range "needs to be verified on each lot change of PT reagent as per your laboratory regulating agency." 6. A review on 3/27/18 at 7:40 a.m. of the Phillips County Hospital ACL Elite Calibration Policy and Procedure included instructions to calculate the mean of the patient PT values once a year and when instructed to calibrate from IL. It also stated to "retain worksheet and file with the calibration paperwork in the Coulter IL ACL Instruments Validation Documentation, Maintenance, Service, and Calibration binder."
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include the number of controls in two of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/27/18 at 1:35 p.m. of the Phillips County Hospital IQCP for DCA-Vantage Microalbumin/Creatinine Urine Quality Control Plan lacked the number of controls performed. 2. On 3/27/18 at 1:35 p.m., staff member A stated the number was not in the IQCP.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include testing personnel potential failures and sources of error due to testing personnel in three of three Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 3/27/18 at 1:35 p.m. of the Phillips County Hospital IQCP for DCA-Vantage Microalbumin/Creatinine Urine, IQCP for Alere Triage-D-Dimer, and IQCP for Antimicrobial Susceptibility Testing and Organism Identification Microscan System all lacked testing personnel potential failures and sources of error due to testing personnel. 2. On 3/27/18 at 1:35 p.m., staff member A stated the IQCPs did not address the personnel.
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 observation, record review, and interview, the laboratory failed to maintain an audible alarm system for blood storage and perform regular inspections of the alarm system from 3/22/16 to 3/26/18. The findings include: 1. A review on 3/27/18 at 11:10 a.m. of the Phillips County Hospital Laboratory Blood Bank Maintenance Checklist quarterly refrigerator alarm checks for 2017 documented missing alarm

checks, incomplete alarm checks, alarms going off at inappropriate temperatures without corrective action, inappropriate acceptable temperatures, and signatures of review without corrective action. a. March 2017 alarm check performed on 3/8/17. 1. Too cold temp: blank. Response time: Blank. Responder initials: blank. Ok temp: blank. 2. Too hot temp: 7.0. Response time: 20 sec. Responder initials: completed. Ok temp: 4.2. 3. Reviewed on 3/22/17. 4. Corrective action was not documented. b. June 2017 alarm check performed on 6/15/17. 1. Too cold (cold scratched out and handwritten "hot") temp: 11.0. Response time: 3 min. Responder initials: completed. Ok temp: 4.0. 2. Too hot temp: blank. Response time: blank. Responder initials: blank. Ok temp: blank. 3. Reviewed on 9/20/17. 4. Corrective action was not documented. c. September 2017 alarm check performed on 9/28/18. 1. Too cold temp: 11.0. Response time: 15 sec. Responder initials: completed. Ok temp: 4.0. 2. Too hot temp: blank. Response time: blank. Responder initials: blank. Ok temp: blank. 3. Not signed as reviewed. 4. Corrective action was not documented. d. December 2017 alarm check was not performed but included an undated signature of review. 2. A review on 3/27/18 at 11:10 a.m. of the Phillips County Hospital Refrigerator-Alarm System Testing Policy and Procedure included the "blood bank alarm system should be checked quarterly to prove correct function of the alarm at temperatures above and below normal range." It included instructions on how to perform the alarm check at above and below the normal range. The acceptable temperature range in the Policy states the "low activation temperature is 1.5 degrees C. High activation temperature is 5.5 degrees C. If activation temperatures are too high or too low, begin corrective action. Retest the temperatures and record the data in the corrective action portion of the log sheet. If the temperatures are incorrect again, the supervisor should be notified immediately so that further corrective actions may begin." 3. A review on 3/27/18 at 11:15 a.m. of the Phillips County Hospital Laboratory Blood Bank Maintenance Checklist quarterly refrigerator alarm checks for 2016 documented missing alarm checks, incomplete alarm checks, alarms going off at inappropriate temperatures without corrective action, incomplete documentation, inappropriate acceptable temperatures, and signatures of review without corrective action. a. March 2016 alarm check performed on 3/23/16. 1. Too cold temp: 1.8. Response time: 30 sec. Responder initials: completed. Ok temp: 2.7. 2. Too hot temp: 2.4. Response time: 30 sec. Responder initials: completed. Ok temp: 2.7. 3. Reviewed on 6/22/16. 4. Corrective action was not documented. b. June 2016 alarm check performed on 6/1/16. 1. Too cold temp: 2.0. Response time: 3 min. Responder initials: completed. Ok temp: 3.0. 2. Too hot temp: 5.7. Response time: 3 min. Responder initials: completed. Ok temp: 3.0. 3. Reviewed on 6/22/16. 4. Corrective action was not documented. c. September 2016 alarm check performed on 9/30/16. 1. Too cold temp: blank. Response time: blank. Responder initials: completed. Ok temp: 1.2. 2. Too hot temp: blank. Response time: blank. Responder initials: completed. Ok temp: 5.3. 3. Reviewed on 11/15/16. 4. Corrective action was not documented. d. December 2016 alarm check performed on 12/29/16. 1. Too cold temp: 2.4. Response time: 20 sec. Responder initials: completed. Ok temp: 3.2. 2. Too hot temp: 5.5. Response time: blank. Responder initials: completed. Ok temp: 3.6. 3. No signature of review. 4. Corrective action was not documented. 4. On 3/27/18 at 11:15 a.m., staff member A stated the alarm documentation did not make sense. The alarm on the refrigerator shorted out and the new alarm sounded on the temperature probe reader in the blood bank room, sends a text message to staff member A immediately, and sends an email to staff member A immediately. The new temperature probe reader was programmed to alarm at 1.9 degrees C and 8.1 degrees C. 5. On 3/27/18 at 11:25 a.m., the alarm was observed at sounding at a too hot temperature of 11.0 degrees C. The alarm on the temperature probe reader sounded only in the blood bank room. The text message and email to staff member A to notify the laboratory of the alarm sounding were not received by

	staff member A. 6. On 3/27/18 at 11:48 a.m., the alarm was observed at sounding at a too cold temperature of 1.89 degrees C. The alarm on the temperature probe reader sounded only in the blood bank room. The text message and email to staff member A to notify the laboratory of the alarm sounding were not received by staff member A.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform annual competency evaluations on 3 of 4 employees. The findings include: 1. A review on 3 /26/18 at 2:50 p.m. of the Phillips County Hospital Lab Competency evaluations were lacking annual evaluations for the following employees. a. 2016 missing for staff members A, B, and C. b. 2017 missing for staff member A. c. 2017 was missing five of six required sections (direct observation of test performance, monitoring results, reviewing records, direct observation of maintenance, and blind sample testing) for staff members B and C. 2. On 3/26/18 at 2:50 p.m., staff member A stated the competency evaluations were not in the files. 3. A review on 3/26/18 at 3:00 p.m. of the Phillips County Hospital Competency Testing Policy and Procedure included "all employees must prove annual competency with a passing score of 85%."