

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410425	<b>(X3) Date Survey Completed</b>  05/14/2024
<b>Name of Provider or Supplier</b>  Billings Clinic Broadwater	<b>Street Address, City, State</b>  110 North Oak Street, Townsend, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a record review, and interview with the Technical Supervisor (TS) #1, the laboratory failed to follow their policy and procedure and retain two years of quality control (QC) records for the ABL80 FLEX CO-OX blood gas analyzer from May 15, 2022, to July 23, 2023. Findings: 1. A review of the "Record Retention" policy and procedure and request for quality control records revealed the laboratory failed to follow their procedure to retain two years of ABL80 FLEX CO-OX quality control records from May 15, 2022, to July 23, 2023. 2. Based off the test volume sheet, 24 blood gas patient tests were performed from April 30, 2023, to April 30, 2024 (12 months). 3. An interview with TS #1 on May 15, 2024, at 3:35 PM confirmed that the laboratory did not retain two years of blood gas QC records from May 15, 2022, to July 23, 2023.</p>
<b>D3035</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii)</p> <p>In addition, the laboratory must retain 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).</p> <p>This STANDARD is not met as evidenced by: Based on a record review and interview with Technical Supervisor (TS) #1, the</p>

laboratory failed to follow their procedures and retain ten years of blood bank temperature records and visual checks of blood bank inventory from January 1, 2023, to March 31, 2023. Findings: 1. A review of the policy and procedure for "Record Retention" and "Blood Bank Quality Assurance" revealed the laboratory failed to follow their procedures to retain ten years of their "Daily Checklist/Temperature Log" containing blood bank-related temperature logs and visual checks of blood bank inventory from January 1, 2023, to March 31, 2023. 2. An interview with TS #1 on May 15, 2024, at 12:34 PM confirmed two units of O-negative were maintained in inventory. 3. An interview with TS #1 on May 15, 2024, at 12:35 PM confirmed that the laboratory was missing Daily Checklist/Temperature Logs for the months of January, February, and March of 2023.

**D5026**

**IMMUNOHEMATOLOGY**  
CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:  
Based on a record review of immunohematology and the laboratory's policy and procedure, the laboratory failed to have a step-by-step procedure for the review of historical blood bank patient data (refer to D5401); failed to complete their blood bank quality control (QC) records in their entirety for three out of four records (refer D5551); and failed to perform and document quarterly alarm checks for two of the four quarters in 2023, as well as record high and low temperature alarm activation in 2022 (refer to D5555).

**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 record review of chemistry and hematology, and the laboratory's policy and procedure, the laboratory failed to include in their policy and procedure the reference intervals (normal values) for complete blood counts (refer to D5403); failed to follow the manufacturer's instructions to update the coagulation instrument with the new lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value and the new calculated mean normal prothrombin time (refer to D5411); and failed to verify lipase and C-reactive protein (CRP) normal reference ranges (refer to D5421).

**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 blood bank logs, the laboratory's policy and procedure, and an interview with the technical supervisor (TS) #1, the laboratory failed to have a step-by-step procedure for the review of historical blood bank patient data from May 15, 2022, to May 15, 2024. Findings: 1. No policy and procedure for checking historical blood bank patient data was available for review at the time of the survey. 2. An interview with TS #1 on May 15, 2024, at 1:05 PM confirmed the laboratory failed to have a step-by-step procedure for the review of historical blood bank testing results from May 15, 2022, to May 15, 2024.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on a review of hematology procedures, and an interview with the technical supervisor (TS) #1, the laboratory failed to include in their policy and procedures the reference intervals (normal values) for complete blood counts from May 15, 2022, to May 15, 2024. Findings: 1. No reference intervals (normal values) were available in the hematology procedure manual for complete blood counts performed on the Sysmex XS-1000i hematology analyzer from May 15, 2022, to May 15, 2024. 2. An interview with TS #1 on May 15, 2024, at 5:10 PM confirmed the laboratory failed to include the normal values for complete blood counts in their procedures and that the normal values were verified at a laboratory located in Billings, MT from May 15, 2022, to May 15, 2024.

**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 a record review, observation, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the manufacturer's instructions and update the Sysmex CA-620 coagulation instrument with the new lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value and the new calculated mean normal prothrombin time from February 26, 2024, to May 15, 2024. Findings: 1. A record review of the new prothrombin reagents started on February 26, 2024, revealed that the new lot (#564652A) of Dade Innovin reagent's product insert had an ISI value of 1.06, and a review of the laboratory's calculated mean normal prothrombin time (MNPT) for the laboratory's patient population had a value of 10.9 seconds. 2. An observation of one Sysmex CA-620 coagulation instrument in the laboratory on May 15, 2024, at 3:00 PM revealed the laboratory failed to update the instrument's ISI value of 1.02 and MNPT of 10.6 seconds for the new lot of prothrombin reagents put into use on February 26, 2024. 3. An email request to TS #1 on May 28, 2024, at 1:20 PM revealed 134 prothrombin time patient tests were performed from February 26, 2024, to May 15, 2024. 4. An interview with TS #1 on May 15, 2024, at 3:05 PM confirmed the ISI value and MNPT were not the current values for the PT reagents used from February 26, 2024, to May 15, 2024, and corrected the values at the time of the interview.

**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 a review of the chemistry verification records, laboratory procedures, and an interview with the technical supervisor (TS) #1, the laboratory failed to verify lipase and C-reactive protein (CRP) normal reference ranges were appropriate for the laboratory's patient population prior to the laboratory director's approval and patient testing from July 14, 2023, to May 15, 2024. Findings: 1. The laboratory failed to provide verification studies to verify the Siemens Dimension's normal reference ranges for analytes lipase and CRP are appropriate for the laboratory's patient population prior to the laboratory director's approval and patient testing from July 14, 2023, to May 15, 2024. 2. The laboratory failed to provide a procedure to address how the laboratory verifies the performance of new assays, instruments, or methods. 3. An interview with TS #1 on May 15, 2024, at 4:39 PM confirmed the lack of verification studies of normal ranges for analytes lipase and CRP performed on the Siemens Dimension EXL chemistry analyzer prior to the laboratory director's approval and patient testing from July 14, 2023, to May 15, 2024.

**D5551**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 a review of blood bank logs, policy and procedures and an interview with the technical supervisor (TS) #1, the laboratory failed to complete their blood bank quality control (QC) records in their entirety for three out of four records. Findings: 1. A review of blood bank QC logs for 4/4/2022, 4/26/2022, and 2/25/2024 lacked documentation of either lot numbers, expiration dates, refrigerator temperature, incubator temperature, and/or reviewed by and date. 2. A review of the "Blood Bank Quality Assurance" policy and procedure failed to include a review of quality control records. 3. An interview with TS #1 on May 15, 2024, at 1:00 PM confirmed the laboratory failed to complete, in their entirety, three out of four blood bank QC records.

**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 a review of policy and procedure, blood bank alarm check records, and an interview with the technical supervisor (TS) #1, the laboratory failed to perform and document quarterly alarm checks for two of the four quarters in 2023, as well as record high and low temperature alarm activation in 2022 for one blood bank refrigerator. Findings: 1. The laboratory failed to perform and record two of four quarterly alarm checks on the blood bank refrigerator in 2023, as required by their "Blood Bank Quality Assurance" procedure to ensure proper storage temperature for two group O Rh(D)-negative Red Blood Cells (RBCs) units maintained in inventory. 2. The laboratory quarterly blood bank alarm check logs for 2022 lacked documentation of the high and low temperature alarm activation required by their Blood Bank Temperature Monitoring and Alarm Testing procedure. 3. An interview with TS #1 on March 26, 2023, at 2:20 PM confirmed the findings listed above.

**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 chemistry, hematology, and immunohematology record review, policy and procedures, and an interview with the technical supervisor (TS) #1, the laboratory director (LD) #1 failed to ensure that the quality assessment program was maintained and effectively monitored by laboratory staff from May 15, 2022, to May 15, 2024. Findings: 1. The laboratory director failed to ensure staff retained the blood gas analyzer's quality control (QC) records for two years (refer to D3031) and the blood bank-related temperature logs and visual checks of blood bank inventory for ten years (refer to D3035). 2. The laboratory director failed to ensure lab staff followed the manufacturer's instructions to update the coagulation instrument with the new lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value and the new calculated mean normal prothrombin time (refer to D5411). 3. The laboratory director failed to ensure staff completed in their entirety the blood bank quality control worksheets and blood bank alarm check worksheets (refer to D5551 and D5555). 4. An interview with TS #1 on May 15, 2024, at 4:39 PM confirmed the laboratory director failed to ensure laboratory staff maintained the quality assurance program of the above-listed items from May 15, 2022, to May 15, 2024.