

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D0410733	<b>(X3) Date Survey Completed</b> 12/10/2025
<b>Name of Provider or Supplier</b> Barrett Hospital & Healthcare Laboratory	<b>Street Address, City, State</b> 600 Mt Highway 91 South, Dillon, 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>D0000</b>	The Montana CLIA Program conducted an announced CLIA recertification survey, completed on December 10, 2025. The laboratory was found out of compliance with the following conditions: 42 CFR 493.1217 Condition: Immunohematology.
<b>D5026</b>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1217</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Immunohematology procedures, laboratory records, manufacturer's instructions, and interview with the Technical Supervisor (TS) #1, the laboratory failed to ensure the requirements for the specialty of Immunohematology. Findings: 1. The laboratory failed to establish two of two procedures. (Refer to D5401) 2. The laboratory failed to have written procedures for Immunohematology ORTHO Vision Swift quality control. (Refer to D5403) 3. The laboratory failed to document the quality control's antibody and antigen reactivity performed on the ORTHO Vision Swift analyzer. (Refer to D5551) 4. The laboratory failed to perform visual inspection of stored red blood cells. (Refer to D5553)</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedures and an interview with Technical Supervisor (TS) #1, the laboratory failed to establish two of two procedures to detect ABO discrepancies and weak D testing. Findings: 1. On 12/10/25 at 1:15 PM, TS #1 confirmed the laboratory performed ABO and weak D testing using the ORTHO Vision Swift analyzer. 2. A review of the laboratory's written procedure revealed no procedures for the following: a. To detect and resolve ABO discrepancies b. When to perform weak D testing. 3. An interview with TS #1 on December 10, 2025, at 1:20 PM confirmed the laboratory did not have a procedure to detect and resolve ABO discrepancies or weak D testing. 4. A review of the laboratory's test volume sheet revealed 423 ABO group, and Rh tests were performed on patient specimens from December 9, 2024 to December 9, 2025 (12 months).

**D5403**

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

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of procedures, manufacturer's instructions for use, and an interview with Technical Supervisor (TS) #1, the laboratory failed to have complete quality control (QC) procedures for two of two procedures for microbiology manual cultures and immunohematology testing performed on the ORTHO Vision Swift analyzer. Findings: 1. A review of the microbiology quality control KWIK-STIK™ Plus instructions for use state microorganisms are 2 passages from the reference culture. The laboratory's written procedure lacked a step-by-step process for maintaining microbiology QC stock and working cultures. 2. The written procedure for microbiology manual culture testing did not include a QC procedure. 3. The written procedure for immunohematology testing on the ORTHO Vision Swift analyzer did not include a QC procedure. 4. An interview with TS #1 on December 10, 2025, at 3:30 PM confirmed the above findings. 5. Review of the test volume sheet revealed the laboratory performed 1,883 microbiology cultures and 856 immunohematology tests on patient specimens from December 9, 2024 to December 9, 2025 (12 months).

**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.

This STANDARD is not met as evidenced by:

Based on review of immunohematology records, manufacturer's instructions, and an interview with Technical Supervisor (TS) #1, the laboratory failed to follow the manufacturer's instructions for documenting the reactivity of each antibody and antigen testing performed on the ORTHO Vision Swift analyzer from December 9, 2024 to December 10, 2025. Findings: 1. On December 10, 2025, at 1:23 PM, TS #1 confirmed the laboratory performed antibody and antigen testing using the MTS Buffered Gel Card and the AlbaQ-Chek Simulated Whole Blood Controls on the ORTHO Vision Swift analyzer. 2. The Ortho Vision MTS Buffered Gel Card instructions, under "Quality Control" state that reactivity must be present with the positive sample only and provide a reaction grading scale: 0 (Negative), 1+, 2+, 3+, 4+, or mixed field. 3. The AlbaQ-Chek Simulated Whole Blood Controls instructions, under "Interpretation of Results" state expected test results: (0) negative reaction and (+) positive reaction. 4. A review of ORTHO Vision Swift analyzer quality control records showed no documentation of antibody and antigen reactivity. 5. An interview with TS #1 on December 10, 2025, at 1:25 PM confirmed the above findings. 6. A review of the test volume sheet revealed the laboratory performed 856 immunohematology tests on patient specimens from December 9, 2024 to December 9, 2025 (12 months).

**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).

This STANDARD is not met as evidenced by:

Based on observation, record review, and an interview with Technical Supervisor (TS) #1, the laboratory failed to document visual inspection checks for fourteen of fourteen red blood cell (RBCs) units stored from December 9, 2023 to December 10, 2025. Findings: 1. Observed on December 10, 2025, at 1:00 PM in the laboratory, one blood bank refrigerator with an inventory of fourteen RBC units (six units of Type O, Rhesus (Rh) factor-positive; two units of Type O, Rh-negative; and six units of Type A, Rh-positive). 2. A review of the laboratory's storage records from December 9, 2023 to December 10, 2025, revealed no evidence the laboratory documented the visual inspection of the RBS units during storage. 3. An interview with TS #1 on December 10, 2025, at 1:05 PM, confirmed the laboratory did not perform and document visual inspection of stored RBCs units from December 9, 2023 to

December 10, 2025. 4. A review of the laboratory's test volume sheet revealed 423 ABO group and Rh tests were performed on patient specimens from December 9, 2024 to December 9, 2025 (12 months).

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:  
Based on review of procedures, instrument manuals, records, and interviews, the laboratory director failed to approve three of three instrument manuals, failed to ensure manufacturer's instructions and procedures were accessible to three of eight testing personnel (TP), and failed to establish quality control (QC) procedures for immunohematology and microbiology during the period from December 9, 2023 to December 10, 2025. Findings: 1. The laboratory director failed to approve the manufacturer's instrument manuals for the ORTHO Vision Swift analyzer, Vitros 7600 chemistry analyzer, and Vitros 5600 chemistry analyzer. 2. On December 10, 2025, at 1:45 PM, the state surveyor requested quality control data from the ORTHO Vision Swift analyzer. TP #3 and TP #4 failed to provide QC data and did not provide a procedure or manufacturer's manual. 3. On December 10, 2025, at 2:30 PM, the state surveyor requested microbiology procedures for quality control. TP #1 and TP #4 failed to provide any of the written microbiology procedures. 4. The laboratory director failed to establish quality control procedures for immunohematology and microbiology. (Cross refer D5403, and D5551). 5. An interview with the technical supervisor on December 10, 2025 at 3:40 PM, confirmed the laboratory director had not approved the manufacturer's instrument manuals, failed to ensure accessibility of manufacturer's instructions and procedures to all staff, and failed to establish quality control procedures for immunohematology and microbiology during the period from December 9, 2023 to December 10, 2025.

**D6139**

**CLINICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1457(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:  
Based on record review and an interview with Technical Supervisor (TS) #1, the clinical consultant failed to ensure two of two patient-specific interpretive elements were included in the patients' result reports: the test methodology used to test prostate-specific antigen (PSA) and the source of the estimated glomerular filtration rate (eGFR) calculation from December 9, 2023 to December 10, 2025. Findings: 1. A review of the patient's result report (ID#253380023CB) for PSA lacked the test methodology used. 2. A review of the patient's result report (ID#253380023CB) for eGFR lacked the source of the eGFR calculation. 3. An interview with TS #1 on December 10, 2025, at 10:30 AM confirmed the clinical consultant failed to ensure the patient's result report included the methodology used for PSA and the source of the eGFR calculation during the period from December 9, 2023 to December 10, 2025.