Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1051277	06/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Animas Surgical Hospital	575 Rivergate Lane, Durango, CO	

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 initial certification survey conducted on June 05, 2025, deficiencies were cited for Animas Surgical Hospital in Durango, Colorado.
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 a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to establish a written policy or procedure to ensure the storage conditions of stored blood products are appropriate to prevent deterioration of the products during a failure of the laboratory's monitored refrigerator. The laboratory performs approximately 225 immunohematology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a written policy or procedure to document and monitor the temperature of stored blood products to prevent the deterioration of the blood products in case of a failure of their monitored refrigerator since testing began on October 1, 2024. 2. An interview with the GS on June 5, 2025, at approximately 12:15 PM, confirmed that the laboratory failed to establish a written policy or procedure to document and monitor the temperature of stored blood products to prevent the deterioration of the blood products in case of a failure of their monitored refrigerator.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c)

	(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with the technical supervisor (TS), the laboratory failed to include specific policies and procedures on how to enter results into the patient record, and what action (s) to take when the test system is out of service for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system since the laboratory began testing on October 1, 2024. The laboratory performs approximately 12,799 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory was using manufacturer's operators manuals for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system. 2. A review of the manufacturer's operators manuals, and the laboratory's policies and procedures manual for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system revealed that the laboratory failed to include separate policies for how to enter results into the patient record, and what action(s) to take when the test system is out of service. 3. An interview with the laboratory's TS on June 5, 2025, at approximately 11:00 AM, confirmed that the laboratory failed to include specific policies and procedures on how to enter results into the patient record, and what action (s) to take when the test system is out of service for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system since the laboratory began testing on October 1, 2024.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 a review of the laboratory's policies and procedures manual, and an interview with the technical supervisor (TS), the laboratory failed to have the policies and procedures for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system, approved and signed by the current laboratory director (LD) before their use in the laboratory since testing began on October 1, 2024. The laboratory performs approximately 12,799 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory was using the manufacturer's operating manuals for their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system, but had no evidence the manuals were approved or signed by the LD prior to their use in the laboratory. 2. An interview with the laboratory's TS on June 5, 2025, at approximately 11:00 AM, confirmed the laboratory failed to have their manufacturer's operating manuals for

	their Sysmex CA-600 coagulation instrument, Sysmex XP-300 hematology instrument, Vitros 5600 chemistry instrument, and Ortho Workstation blood banking system approved and signed by the current LD prior to their use in the laboratory.
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 a review of the laboratory's policies and procedures manual, a review of the laboratory's blood bank daily checklist, and an interview with the general supervisor (GS), the laboratory failed to have policies and procedures in place to visually inspect and document the inspection of red blood cells during storage and immediately prior to issue, and failed to document the visual inspection of red blood cells during storage and immediately prior to issue. The laboratory conducts approximately 225 immunohematology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed there was no policy or procedure in place to visually inspect and document the inspection of red blood cells during storage and immediately prior to issue. 2. A review of the laboratory's blood bank daily checklist revealed the laboratory did not document the visual inspection of red blood cells during storage or immediately prior to issue. 3. An interview with the laboratory's GS on June 5, 2025, at approximately 12:45 PM, confirmed that the laboratory failed to have policies and procedures in place to visually inspect and document the inspection of red blood cells during storage and immediately prior to issue, and failed to document the visual inspection of red blood cells during storage and immediately prior to issue.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, blood bank records, and an interview with the general supervisor (GS), the laboratory failed to document their quarterly alarm check, and who notified the laboratory of the alarm, for their temperature monitoring system attached to their blood product storage refrigerator since the laboratory began patient testing on October 1, 2024. The laboratory conducts approximately 225 immunohematology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory failed to follow their policy and procedure for documenting quarterly alarm checks for their temperature monitoring system attached to their blood product storage refrigerator. 2. A review of blood bank records revealed the laboratory failed to document the quarterly alarm checks and failed to document who notified the

	laboratory of an alarm from their temperature monitoring system attached to their blood product storage refrigerator. 3. Based on an interview with the laboratory's GS on June 5, 2025, at approximately 12:20 PM, confirmed that the laboratory had failed to document their quarterly alarm check, and who notified the laboratory of the alarm, for their temperature monitoring system attached to their blood product storage refrigerator since the laboratory began patient testing on October 1, 2024.