Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2324893	08/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Monument Health Box Elder Clinic	375 Berky Drive, Box Elder, SD	

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	An on-site validation survey was conducted on August 12, 2026 with the following standard level deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, instruction sheet provided to patients for Urinalysis (UA) collection at home, laboratory test volumes, and interview with the Technical Consultant (TC) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to follow their own written policies and procedures for specimen transportation condition (temperature) for 8 of 8 months (Random review August 2025 to April 2026) Findings Included: 1) Review of the laboratory's policy titled 'Monument Health Urine Sample Collection Requirements, Policy Stat ID: 18693990, stated the following on page 3 of 8: "E. Delay in Transport: 1. If there is a delay in transport to the lab, refrigerate specimen" In addition, the policy stated the following on page 4 of 8: "A. Infants (U-Bag Collection) ...6. If transport delay greater than 30 minutes, refrigerate sample". 2) Review of the laboratory's instruction sheet provided to patients for UA collection at home titled 'Clean Catch UA Instructions' did not contain direction on specimen transportation or storage (temperature) requirements, as shown in the laboratory's policy. 3) Review of the laboratory's test volumes revealed 914 UA specimens processed and performed between August 2025 and April 2026. 4) In an

	interview on August 12, 2026 at 11:44 AM, TC#1 confirmed the laboratory failed to follow the policies and procedures in ensuring patients knew specimen transportation and storage requirements for at home UA collection.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, review of the laboratory's policy, temperature logs, and interview with Technical Consultant (TC) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define conditions for acceptable temperature ranges for room temperature and humidity for 8 of 8 months reviewed (August 2025 to April 2026). Findings Included: 1) During a laboratory tour on August 12, 2026 at 11:40 AM, the following laboratory supplies were observed available for use in the Nurse Station room with no temperatures defined, monitored or documented: a. 1 box of Becton Dickinson (BD) Universal Viral Transport for Virus, Chlamydiae, Mycoplasmas and Ureaplasmas, Lot Number N50253101, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. b. 10 Copan eSwabs, Lot Number 480C, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. c. 1 Cepheid GeneXpert Swab Specimen Collection Kit, Lot Number 191H09, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. The following instruments were observed in use within the laboratory with no temperature ranges defined: a. 1 Sysmex XN-430, Serial Number 2802520, Manufacturer operating temperature requirements 15 to 35 degrees Celsius; Humidity requirements 20 to 85% non condensing. b. 1 Cepheid GeneXpert, Serial Number 120001418, Manufacturer operating temperature requirements 15 to 30 degrees Celsius; Humidity requirements 10 to 95% non condensing. 2) Review of the laboratory's policy titled 'Monument Health Laboratory Temperature and Humidity Monitoring, Policy Stat ID: 21030629' stated the following on page 5 of 8: "Ambient (Room) Temperature and Humidity: A. Acceptable ranges vary by manufacturer and will be kept at each individual laboratory location..." 3) Review of the laboratory's Securitas Healthcare temperature and humidity monitoring system revealed daily monitoring of temperatures of the laboratory only and not the Nurse Station room, with no acceptable ranges defined for temperatures and humidity to alert if out of range. 4) In an interview on August 12, 2026 at 11:44 AM, TC #1 confirmed the findings since August 2025 through April 2026, the laboratory did not define, monitor and/or document temperatures and humidity in accordance with manufacturer instructions and per policy.