

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2162449	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Craig Hospital	Street Address, City, State 3425 S Clarkson St, Englewood, 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	A validation survey was conducted on 09/02/2026 and standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, policies, and an interview with the Technical Consultant (TC), the laboratory failed to have a policy and documented competency for 1 of 1 TC. Findings Include: a. The laboratory was asked to provide a policy for competency assessment of the TC based on duties delegated by the laboratory director. No policy was provided. b. The laboratory was asked to provide documentation of the competency assessment for the TC. No documentation was provided. c. During an interview on 09/02/2026 at 10:10 AM, the TC, as listed on the CMS-209, confirmed that the laboratory does not have a policy, and a competency assessment was not performed.
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 a review of the laboratory's records, direct observation, and interview with the Technical Consultant (TC), the laboratory failed to ensure supplies and equipment were stored according to the manufacturer's instructions for 2 of 2 months reviewed.

Findings Include: a. A review of the laboratory's room temperature records for May and June of 2026 revealed the defined room temperature range was 39F -77F (degrees Fahrenheit), which converts to 3.9-25C (degrees Celsius). b. During a laboratory tour on 09/02/2026 at 12:10 PM, the following items were observed: i. 1 i-STAT Chem8+ cartridge, lot number H26110; manufacturer's room temperature storage requirement: 18-30C/64-86F. ii. 2 i-STAT CG4+ cartridges, lot number M26147; manufacturer's room temperature storage requirement: 18-30C/64-86F. iii. 6 anaerobic blood culture bottles, lot number 0001064386; manufacturer's storage requirement: 15-30C. iv. 4 aerobic blood culture bottles, lot number 004103828; manufacturer's storage requirement: 15-30C. v. 2 aerobic blood culture bottles, lot number 000410407; manufacturer's storage requirement: 15-30C. c. During an interview on 09/02/2026 at 12:10 PM, the TC, as listed on the CMS-209, confirmed the laboratory's defined room temperature range was too wide.