

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0516894	(X3) Date Survey Completed 12/16/2025
Name of Provider or Supplier Wray Community District Hospital	Street Address, City, State 1017 W 7th St, Wray, 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 recertification survey conducted on December 16, 2025, deficiencies were cited for Wray Community District Hospital in Wray, Colorado.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the surveyor review of 2024 and 2025 Proficiency Testing (PT) documents and an interview with the technical consultant 1 (labeled as TC1 on the CMS 209), the laboratory failed to enroll in a PT program for both HCG (serum-quantitative) and HCG (serum-qualitative). Findings include: 1. A review of the laboratory PT documents revealed that the laboratory performed HCG (serum- quantitative) in 2024 Event 1, HCG (serum-qualitative) in 2024 Event 2, HCG (serum- qualitative) in 2024 Event 3, HCG (serum-quantitative) in 2025 Event 1, HCG (serum-quantitative) in 2025 Event 2, and HCG (serum-qualitative) in 2025 Event 3. 2. An interview with technical consultant 1 (labeled as TC1 on the CMS 209), on December 16, 2025, at 2: 41 PM confirmed that the laboratory performed either HCG (serum-qualitative) or HCG (serum-quantitative) in PT events reviewed, despite offering both.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p>

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on the surveyor review of the laboratory quality control documents and an interview with the general supervisor, the laboratory failed to perform Quality Control (QC) at least once each day patient specimens are tested with Cepheid GeneXpert Xpert Xpress MVP test. The laboratory has performed 219 Cepheid GeneXpert Xpert Xpress MVP tests since the start of the test in 2024. Findings include: 1. A review of the QC documents for Cepheid GeneXpert Xpert Xpress MVP test revealed that the laboratory performs QC once monthly. 2. An interview with the general supervisor on December 16, 2025, at 4:35 PM revealed that the laboratory performs QC once monthly for Cepheid GeneXpert Xpert Xpress MVP test.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on the surveyor review of the laboratory competency documents and an interview with the technical consultant 1 (labeled TC1 on the CMS 209) and technical consultant 2 (labeled TC2 on the CMS 209), the laboratory failed to maintain documentation on five out of five testing personnel competencies in 2024. Findings include: 1. A review of the laboratory competency documents revealed that the laboratory did not have documentation for competencies in 2024. 2. An interview with technical consultant 1 (labeled TC1 on the CMS 209) and technical consultant 2 (labeled TC2 on the CMS 209) on December 16, 2025, at 02:54 PM confirmed that the laboratory did not have documentation for five out of five testing personnel competencies in 2024.