

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0055684	(X3) Date Survey Completed 09/03/2026
Name of Provider or Supplier Denver Health Ancillary Clinic Services	Street Address, City, State 1100 Federal Blvd, Denver, 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 09/03/2026 and standard level deficiencies were cited.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) (a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on direct observation, the CASPER-155D report, proficiency testing (PT) records, and an interview with staff, the laboratory failed to report proficiency testing results to CMS for 8 of 8 testing events reviewed. Findings Include: a. On 09/03/2026 at 9:13 AM, 3 boxes of GeneXpert StrepA (Group A Streptococcus) cartridges were observed in the laboratory. b. A review of the CASPER-155D report revealed no reported results for Bacteriology. c. A review of the laboratory PT records revealed the laboratory incorrectly reported method code "1390" indicating the test was waived for the following 8 events reviewed: 1. College of American Pathologists (CAP) 2024-1, 2024-2, 2024-3, 2025-1, 2025-2, 2025-3, 2026-1, 2026-2. d. During an interview on 09/03/2026 at 11:31 AM, the Technical Consultant (TC), as listed on the CMS-209, and the Outpatient Operations Manager confirmed, using the CAP website, that the laboratory was reporting the test as waived. In an email sent 09/03/2026 at 3:41 PM, the Outpatient Operations Manager confirmed that the laboratory's GeneXpert instrument is a moderate complexity instrument.
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 09/03/2026, at 12:25 PM, the TC, as listed on the CMS-209, and the Outpatient Operations Manager confirmed that the laboratory did 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 direct observation and an 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 that the defined room temperature range was 18-30C [degrees Celsius]. b. On 09/03/2026, at 10:16 AM, the following items were observed in the laboratory: 1. 6 boxes of GeneXpert CoV-2/Flu/RSV plus (severe acute respiratory syndrome coronavirus 2 /influenza, respiratory syncytial virus); manufacturer's room temperature storage requirements: 2-28C. 2. 3 boxes of GeneXpert CoV2 plus; manufacturer's room temperature storage requirements: 2-28C. 3. 3 boxes of GeneXpert Strep A (Group A Streptococcus); manufacturer's room temperature storage requirements: 2-28C. 4. 6 cases of Lithium Heparin blood draw tubes; manufacturer's room temperature storage requirements: 4-25C. d. During an interview on 09/03/2026, at 10:16 AM, the TC, as listed on the CMS-209, confirmed that the laboratory's defined room temperature range was too wide.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observations and an interview with staff, the laboratory failed to remove expired reagents from use for 1 of 3 reagents. Findings Include: a. On 09/03/2026, at 10:33 AM, 1 viral transport media (VTM) vial, with expiration date 08/26/2026, was observed in the laboratory refrigerator. b. During an interview on 09/03/2026 at 10:35 AM, the Technical Consultant, as listed on the CMS-209, and the Outpatient Operations Manager confirmed that the VTM is used as quality control for the CoV-2/Flu/RSV (severe acute respiratory syndrome coronavirus 2/influenza, respiratory syncytial virus) assay and was last used on 05/09/2026.