

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0644326	(X3) Date Survey Completed 02/19/2026
Name of Provider or Supplier Colorado Dept Of Public Health & Environment	Street Address, City, State 8100 Lowry 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Revisit 2/18/2026 - 2/19/2026 New Findings. Based on review of the laboratory procedure and direct observation, the laboratory failed to follow their own written policy (ENV 1126) for labeling 1 of 1 working culture. Findings included: 1. Review of "ENV 1126: Microbiology QC Reference Strain Maintenance Version 2.1" stated, "Transfer of Frozen Stock Culture Inoculum to Fresh Media...5. All working cultures should be labeled with the official name and strain ID of the reference organism, supplier lot/batch (if available) the subsequent Passage # from the original supplied seed stock, the date and analyst initials." 2. During a tour of the microbiology department on 2/19/2026 at 8:50 am, a media plate was observed labeled, "MALDI QC 3B, 4B, 2/17." The media plate did not include the official name and strain ID of the reference organism, and analyst initials.</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Revisit 2/18/2026 - 2/19/2026 New Findings. Based on review of a non-compliance report, interview with the serology supervisor, and test reports, the laboratory failed to ensure effectiveness of corrective actions for 2 of 4 reports reviewed. Findings included: 1. Review of a "Non Compliance" report (#1064) completed on 2/10/2026 included an issue with reporting patient QuantiFERON TB gold testing results (17 in total from 2024 and 2025). The non compliance report stated, "An epidemiologist reached out regarding quantiferon TB gold testing results where the result stated 'indeterminate' but had a reportable comment on the report that the sample was not tested." 2. Review of a QFT patient report included "0.00 IU/mL" results for the Nil, TB1, TB2, and Mitogen with 'indeterminate.' Since the identified issue, the laboratory implemented a "Testing Not Performed" option in the LIS for out of temperature and beyond stability specimens (unsatisfactory - unsats). 3. Review of a corrected QFT patient report from 12/19/2025 (sample 2512170008) included "0.00 IU/mL" results for the Nil, TB1, TB2, and Mitogen and "Testing Not Performed" by "Quantiferon TB Gold", "Result Interpretation," and "Unsat." In addition, the report included "Unsat sample. Specimen cannot be tested, plasma would not separate from blood after multiple centrifuge cycles. Please recollect a new sample and resubmit for testing." The report continued to include "0.00 IU/mL" values for the test components of Quantiferon TB Gold test. 4. Review of a patient report for serology testing (sample 2602020089) from 2/2/2026 included, "Serology Lab, Unsat, Test not performed, Sample received out of temperature. Please submit a new sample for analysis." The report did not include which test was not performed. During an interview with the serology supervisor on 2/19/2026 at 11:57 pm stated the test was for rapid plasma reagin (RPR) and acknowledged the report did not communicate that to the submitter. 5. The laboratory's corrective actions failed to effectively communicate recollection requirements to submitters. The laboratory did not specify the test type (RPR) requiring recollection and included contradictory numerical values (0.00 IU/mL) for QFT test components alongside "test not performed" comments, creating confusion about whether testing occurred.