

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0512004	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Littleton Pediatric Medical Center	Street Address, City, State 206 W County Line Rd, Suite 110, Highlands Ranch, 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 May 7, 2026, deficiencies were cited for Littleton Pediatric Medical Center in Highlands Ranch, Colorado.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of College of American Pathologists (CAP) laboratory proficiency testing (PT) records and an interview with the technical consultant (TC), the laboratory failed to ensure that Hematology Auto Differentials PT samples (Event 1, 2026) were tested in the same manner as patient specimens for 5 of 5 samples. The findings include: 1. Surveyor review of the laboratory PT records for Hematology Auto Differentials FH16 Event 1 revealed that testing personnel 1 (TP1) performed testing on samples 01-05 on January 26, 2026, and testing personnel 2 (TP2) performed testing on the same five samples on January 30, 2026. 2. During an interview on May 7, 2026, at 11:00 AM, the TC confirmed that the laboratory's regular procedure for patient specimens is to have only one staff member perform and report a hematology auto differential. 3. The TC further confirmed that by having both</p>

TP1 and TP2 test the same set of PT samples prior to submitting the results, the laboratory failed to treat the PT samples in the same manner as they would have handled routine patient specimens

D2010

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(2)

(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:
Based on surveyor review of College of American Pathologists (CAP) laboratory proficiency testing (PT) records and an interview with the technical consultant (TC), the laboratory failed to ensure that Hematology Auto Differentials PT samples (Event 1, 2026) were tested the same number of times as routine patient specimens for 5 of 5 samples. The laboratory staff tested the PT samples three times (triplicate), while the routine laboratory procedure required patient specimens to be tested only two times (duplicate). The findings include: 1. Surveyor review of the laboratory PT records for the Hematology Auto Differentials Event 1 (2026) revealed that testing personnel 1 (TP1) and testing personnel 2 (TP2) performed testing on samples 01-05 three times each. 2. During an interview on May 7, 2026, at 11:30 AM, the TC confirmed that the laboratory's routine standard operating procedure for patient samples is to perform testing two times. The TC further confirmed that for the 2026 Hematology Auto Differentials Event 1 PT samples, TP1 and TP2 performed the testing three times, which did not follow the routine practice used for patient specimens.