

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2035630	(X3) Date Survey Completed 08/10/2026
Name of Provider or Supplier Middle Park Medical Center - Granby	Street Address, City, State 1000 Granby Park Dr South, Granby, 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 August 10, 2026, deficiencies were cited for Middle Park Medical Center - Granby in Granby, Colorado.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (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 a review of the blood bank log, a review of the blood bank quality control (QC) documents, and an interview with the technical supervisors (TS 1 and TS 2), the laboratory failed to perform daily QC for the antibody typing and screening. Findings include: 1. A review of the blood bank patient log revealed that there were 1 patient sample tested on 5/7/2026, 2 patient samples tested on 5/8/2026, 5 units of blood received on 5/8/2026, and 1 patient sample tested on 5/9/2026. 2. A review of the blood bank quality control log revealed that QC was performed on 5/7/2026 at 8 AM and then on 5/10/2026 at 1 PM. 3. An interview with the technical supervisors (TS 1 and TS 2) on 8/10/2026 at 3:05 PM confirmed that there were no quality control performed on 5/8/2026 and 5/9/2026.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory test menu, a review of the laboratory documents, and an interview with the technical supervisors (TS 1 and TS 2), the laboratory failed to evaluate and define the relationship between test results using the different methodologies, specifically automated cell identification and manual cell identification. Findings include: 1. A review of the laboratory test menu revealed that this laboratory offers both automated cell identification with Siemens Dimension and manual cell identification. 2. A review of the laboratory documents revealed that there is no documentation of comparison between the two methodologies of automated and manual identification. 3. An interview with the technical supervisors (TS 1 and TS 2) on 8/10/2026 at 3:25 confirmed that there were no documentation of comparison between automated and manual cell identification.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:
Based on a review of the testing personnel competency documents and an interview with the technical supervisors (TS 1 and TS 2), the laboratory failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing (PT) samples to evaluate the competency of the staff. Findings include: 1. A review of the testing personnel competency documents revealed that the competency for all testing personnel since 2024 have been performed through direct observation of the analytic process. There were no documented blind samples or PT samples included as a part of the competency assessment. 2. An interview with TS 1 and TS 2 on 8/10/2026 at 2:10 PM confirmed that the technical supervisors directly observed competency assessment for all testing personnel and there were no documented blind samples or PT samples included as a part of the competency assessment.