

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1064719	(X3) Date Survey Completed 09/01/2026
Name of Provider or Supplier Miramont Family Medicine - Parker	Street Address, City, State 9251 20 Mile Rd, Parker, 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 09/01/2026 and standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the laboratory director or designee failed to attest to the routine integration of PT samples into the patient workload for 7 of 8 events. Findings Include: a. A review of the laboratory PT records revealed the attestation statement form lacked the laboratory director or designee's signature for American Proficiency Institute (API) Chemistry Core events 2025-1, 2025-2, 2025-3, 2026-1, and Hematology/Coagulation 2025-1, 2025-2, 2026-1. b. During an interview on 09/01/2026 at 10:32 AM, TP #1, as listed on the CMS-209, confirmed the attestations were unsigned.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the

	proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the CMS-155D report, the laboratory's proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the laboratory failed to perform and document remedial action for Thyroid Stimulating Hormone (TSH) for 1 of 5 events (2025-2026) reviewed. Findings Include: a. A review of the CMS-155D report revealed that for the 2025-2 event, the laboratory received an unsatisfactory score of 60% for TSH. b. A review of the laboratory's PT records, American Proficiency Institute (API) Chemistry Core, confirmed the unsatisfactory score. c. The laboratory was asked to provide documentation of remedial action. No documentation was provided. d. During an interview on 09/01/2026 at 10:32 AM, TP #1, as listed on the CMS-209, confirmed the laboratory did not perform remedial action for the unsatisfactory score.
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, a review of the manufacturer's package insert, and an interview with Testing Personnel (TP) #1 the laboratory failed to ensure 5 of 5 boxes of quality control material were stored according to the manufacturer's instructions. Findings Include: a. On 09/01/2026, at 12:01 PM, the following items were observed in the freezer (serial number RZ776655) located in the laboratory: i. 3 boxes of Triage Total 5 control 1 ii. 2 boxes of Triage Total % control 2 b. A review of the "Quidel Triage Total 5 Control" package insert revealed "Store frozen at -20C [degrees Celsius] or colder in a non- defrosting freezer". c. The laboratory was asked to provide evidence that the freezer was non-defrosting. No documentation was provided. d. During an interview on 09/01/2026 at 12:10 PM, TP #1, as listed on the CMS-209, confirmed these findings. The laboratory performs 6,774 hematology and 14,591 chemistry tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on direct observations, a review of the manufacturer's package insert, and an interview with Testing Personnel (TP) #1, the laboratory failed to label 2 of 2 liquid assayed immunoassay controls with expiration dates. Findings Include: a. On 09/01/2026 at 12:05 PM, two open "Liquid Assay Immunoassay Controls" (level 1 and level 2) were observed in the laboratory refrigerator. The bottles had no expiration dates. b. A review of the manufacturer's package insert "FREND Immunoassay Control Kits" revealed, "Upon opening containers, product is stable for 30 days when stored at 2-8C [degrees Celsius] in tightly closed containers." c. During an interview on 09/01/2026 at 12:03 PM, TP #1, as listed on the CMS-209, confirmed that staff had not labeled the bottles with a new expiration date.

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 laboratory's procedures, quality control (QC) records, and an interview with Testing Personnel (TP) #1, the laboratory failed to perform quality control for 7 of 15 months reviewed. Findings Include: a. A review of the procedures "Free T4 [FT4] Testing Procedure", PSA [prostate specific antigen] Testing Procedure", "TSH [thyroid stimulating hormone] Testing Procedure", and "Vitamin D [VitD] Testing Procedure" revealed "External QC Testing ...It is recommended at a minimum that two levels of controls be run once per month, or with each new lot, or new shipment (even if from the same lot previously in use)." b. A review of the laboratory's individualized quality control plan (IQCP) for FT4, PSA, TSH, and VitD revealed "Two levels of external QC are to be performed at least once per month or for the following parameters: 1. Each new lot ...2. Each new shipment (regardless if the lot does not change)". c. A review of the laboratory's QC records revealed that QC was not performed in the following months: Test: Month/Year (Patients reported) 1. FT4: 01/2025 (9), 02/2025 (12), 08/2025 (3), 9/2025 (5) 2. PSA: 01/2025 (24), 02/2025 (23), 09/2025 (13), 12/2025 (14) 3. TSH: 02/2025 (47), 07/2025 (38), 09/2025 (47), 03/2026 (56) 4. VitD: 01/2025 (12), 02/2025 (7), 08/2025 (10), 09/2025 (11) d. During an interview on 09/01/2026 at 11:09 AM, TP #1, as listed on the CMS-209, confirmed the findings.