Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0877112	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Middle Park Health - Walden	350 Mckinley St, Walden, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) scores and staff confirmation, the laboratory failed to achieve successful PT performance of 80% in 2 of 3 consecutive testing events for pO2 of blood gases in the subspecialty of Routine Chemistry in 2019 (Ref D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) scores and staff confirmation, the laboratory failed to achieve successful performance for the analyte of pO2 of Blood Gases in the subspecialty of Routine Chemistry in 2 out of 3 consecutive PT events using API (American Proficiency Institute). Findings include: Scores for pO2 of Blood Gases: 3rd Event of 2018: 60% 1st Event of 2019: 0%
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of the operator's manual, maintenance records, and laboratory director interview, the laboratory failed in 2018 and 2019 to ensure the humidity in the laboratory met the manufacturer's required operating conditions for the Quidel TriageMeter analyzer and approximately 100 patient specimens are tested annually. Findings include: a. The laboratory performs non-waived troponin and D-dimer testing on patient specimens using the TriageMeter analyzer. b. The operator's manual for the TriageMeter analyzer stated the relative humidity in the laboratory must be between 10 and 85%. c. Maintenance records showed the room humidity had not been monitored in the lab in 2018 or 2019. d. On 5-16-19 at approximately 3:30 p.m., the laboratory director stated the laboratory had no hygrometer with which to monitor the room humidity. e. On 5-16-19 at approximately 3:30 p.m., the laboratory director confirmed the laboratory had not ensured a testing environment of at least 10% relative humidity each day of patient testing as required by the operator's manual for the TriageMeter analyzer.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the quality assessment (QA) plan, competency assessment records, and laboratory director confirmation, the technical consultant failed in 2018 to assess the competency of 4 of 4 established testing personnel who performed moderate complexity testing and 550 patient specimens were tested and reported in 2018. Findings include: a. The laboratory uses the Quidel Triage MeterPro to test

	patient specimens for troponin, BNP, and D-dimer levels. b. The laboratory uses the Epocal Epoc System to test patient specimens for blood gases (pH, pCO2, pO2), hematocrit, sodium, potassium, chloride, total CO2, and lactate levels. c. The QA plan states that for established testing personnel, department specific competency assessments will be completed annually. d. Competency assessment records for 2018 could not be found in the laboratory. e. On 5-16-19 at about 3 p.m., the laboratory director stated that there had been a change of laboratory managers and competency records for 2018 could not be found. The laboratory director further stated that she was hired as the director in 2019, so she didn't know whether competency assessment had been performed in 2018. f. On 5-16-19 at about 3:15 p.m., the laboratory director confirmed that the laboratory had no evidence that competency assessment of the testing personnel had been performed by the technical consultant in 2018 as required by their QA plan and the federal CLIA regulations.