Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0933088	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Umpqua Medical Pc	1813 W Harvard Ave Suite 436, Roseburg, OR	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on interview with the Office Manager, the Laboratory Director (LD) and review of written laboratory records made available for my review during survey 10 /24/2023, the laboratory failed to enroll in a CMS approved Proficiency Testing (PT) program for moderate complexity hematology testing performed at this laboratory in 2022 and 2023 to date. Findings include: 1. Upon review of the laboratory documents supplied for review during survey, no written or digital documentation of performance or evidence of enrollment in a CMS approved PT program could be produced. 2. Interview with the Office Manager and LD at 1:30 pm confirmed that there was no documentation of PT enrollment or performance for 2022 and 2023 to date to her knowledge. 3. The laboratory reports performing 2400 Hematology Complete Blood Counts (CBC's) on their patients annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of written laboratory documents made available for review during survey 10/24/2023 and interview with the Office Manager, the laboratory failed to ensure a written procedure for the ongoing mechanism to monitor and correct issues identified as quality indicators in a practice wide quality assessment (QA) plan / program was in place and being followed. Findings include: 1. Review of written laboratory documents made available for review during survey revealed the laboratory failed to ensure any QA program / plan was in place and being followed during 2022 and 2023 to date. 2. The Office Manager confirmed during interview at 1:30 pm that no written procedure for a QA plan / program was in place and had been approved by the LD for 2022 and 2023 to date. 3.The Office Manager confirmed during interview at 1:30 pm that the practice did not have an active and Laboratory Director (LD) approved QA plan or active QA monitors in place for this laboratory for 2022 and 2023 to date.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of written laboratory documents made available for review during survey 10/24/2023 and interview with the Office Manager, the laboratory failed to ensure Quality Assessment (QA) monitors were composed and reviewed with corrective action when appropriate, at least twice a year. Findings include: 1. Review of the written laboratory documents made available for review during survey, the laboratory failed to provide evidence of QA monitoring events in place or their review during 2022 and 2023 to date. 2. CLIA regulations require at least two (2) QA monitoring events be conducted and documented each year. 3. The Office Manager confirmed during survey that no QA monitors had been in place or monitored for 2022 or 2023 to date.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the written laboratory documents provided for review during

	survey 10/24/2023 and interview with the Office Manager, the Laboratory Director (LD) failed to fulfill the duties of the LD. Findings include: Please see D6015, D6021, D6041
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on interviews with the Office Manager, the Laboratory Director (LD) and review of written laboratory records made available for review during survey 10/24 /2023, the LD failed to enroll this laboratory in a CMS approved Proficiency Testing (PT) program for moderate complexity hematology testing performed during 2022 and 2023 to date. Findings include: 1. Upon review of written laboratory documents supplied for review during survey, no documentation of PT performance or evidence of PT enrollment in a CMS approved PT program could be produced for 2022 or 2023 to date.. 2. Interview with the Office Manager and LD at 1:30 pm confirmed that there was no written or digital documentation of PT enrollment or performance for any PT event in 2022 and 2023 to date. 3. The laboratory reports performing 2400 Hematology Complete Blood Counts (CBC's) on their patients annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of written laboratory records provided for review during survey 10/24 /2023 and interview with the Office Manager, the Laboratory Director (LD) failed to ensure a written Quality Assessment (QA) program / plan with QA monitors being in place and followed for 2022 and 2023 to date. Findings include: 1. Upon review of written documents supplied for review during survey, no QA plan signed and dated by the LD for 2022 and 2023 to date could be produced. 2. Upon request for evidence of QA monitoring events for 2022 and 2023 to date, none could be produced. 3. CLIA regulations require at least two (2) monitoring events and corrective action (CA) if indicated through QA monitoring and assessment of outcomes of these events. 4. Interview with the Office Manager at 1:45 pm confirmed these findings. 5. The laboratory reports performing 2400 Hematology Complete Blood Counts (CBC's) annually.