Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2132505	(X3) Date Survey Completed 01/22/2025
Name of Provider or Supplier Pain Care Specialists Of Oregon	**Street Address, City, State** 2211 Nw Professional Dr Suite 100, Corvallis, 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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the educational documentation for the person listed on the CMS 209 form as the Technical Supervisor (TS) and also General Supervisor (GS) for Toxicology, submitted during survey 1/22/2025, interview with the testing personnel (TP#1) and review of past experience records in the specialty of Chemistry, sub-specialty Toxicology, the Laboratory Director (LD) failed to ensure that the laboratory had a qualified TS or GS for Toxicology assays performed in this lab. Findings incude: 1. See D6079
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on review of educational documents of the testing personnel (TP #1) listed on the CMS form 209, also listed as the Technical Supervisor (TS) and the person listed as the General Supervisor (GS), the Labortory Director (LD) failed to ensure the two (2) persons assuming the role of TS and GS since last survey, were qualified to do so. Findings include: Technical Supervisor (TS): 1. Upon review of educational records for the person listed on the CMS 209 form during survey 1 22 2025, as the TS and as the sole testing personnel (TP #1), it was revealed that TP#1 did not meet the 42 CFR 493 regulations for Technical Supervisor and the qualifications required to be a TS in a high complexity toxicology laboratory. 2. When requested by emails, dated 1 29 2025 - 2 5 2025, TP #1 could not provide evidence of 4 years or more of experience in Clinical Chemistry or Toxicology, in a clinical laboratory setting, to qualify as a TS. 3. TP #1 listed as the TS was hired by this lab in 6 2023, after the last CLIA survey. The laboratory failed to notify CLIA Compliance OHA of the change in TS and submit the requisite change of Technical Supervisor with required documentation, as required by 42 CFR 493.51. 4. In an email sent 1 29 2025 to TP #1 and the LD regarding the need for further verification of 4 years of experience, The LD did not respond. 5. The laboratory reports performing 6200 individual toxicology analytes annually. General Supervisor (GS): 1. Upon review of records for the person listed on the CMS 209 form during survey 1 22 2025, as the GS, it was revealed that there was inadequate documentation of clinical experience to qualify as a GS in a high complexity Toxicology laboratory. 2. When further documentation of clinical experience was requested of the LD 2 5 2025 by email , the LD did not respond. When asked again by email, 2 6 2025, the LD did not respond again and thus could not provide evidence of 4 years or more of experience in Clinical Chemistry or Toxicology, in a clinical laboratory setting, for the person designated on the CMS 209 form as the GS. 3. The laboratory reports performing 6200 individual toxicology analytes annually.