

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D1075583	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Pacific Pathology Associates Inc	Street Address, City, State West Valley Hospital, Dallas, 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	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the previous CMS form 116 and current CMS form 116 submitted during survey August 13, 2024, and interview with the newly proposed Laboratory Director (LD), the laboratory failed to ensure a qualified Laboratory Director (LD) was in place since February 25, 2023. Findings include: 1. See D6079</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the previous CMS form 116 and current CMS form 116 submitted</p>

during on site survey August 13, 2024, and interview with the newly proposed Laboratory Director (LD) as of August 13, 2024, the laboratory failed to ensure a qualified Laboratory Director (LD) was in place. Findings include: 1. Attempts to schedule this on site survey did not occur with the LD of record due to no response or confirmation of receipt of the scheduled survey by email or phone. A phone call July 29, 2024, to the laboratory phone number of record connected me to the LD for the main hospital laboratory at West Valley Hospital, also a Pathologist for Pacific Pathology, where this CLIA is also located, outside the main lab. 2. Phone interview with the LD for the main hospital laboratory July 29, 2024 revealed that the LD of record for this lab had left employment with Pacific Pathology February 24, 2023. He stated a second Pacific Pathology pathologist had assumed responsibility for this location February 25, 2023 but she had also left this position June 28, 2024. When asked for the current LD for this site, he could not tell me who was responsible for this lab at this time. 3. Regulation CFR 493.51 states that the laboratory must inform the State Agency (SA) within 30 days when there is a change in LD. No change of LD CMS form 116 or LD qualification form had been submitted / received by the Oregon Health Authority - CLIA Compliance section as of August 5, 2024. 4. The number of days that passed from the previous survey until current survey are as follows: A. Date of last survey May 16, 2022 to February 24, 2023 when LD of record left equals 284 days. B. February 25, 2023 to June 28, 2024 when second pathologist was assuming responsibility equals 489 days. C. June 29, 2024 to August 13, 2024 when there was no qualified pathologist assuming duties as LD for this site equals 45 days. D. Number of days since the LD of record left Pacific Pathology February 25, 2023 until August 13, 2024 equals 534 days. 5. The laboratory reports performing one (1) frozen section procedure since the last survey May 16, 2022.