

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0625543	(X3) Date Survey Completed 11/12/2024
Name of Provider or Supplier Pacific Pathology Associates, Hospital	Street Address, City, State 665 Winter Street, Salem, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from the College of American Pathologists (CAP) for 2023 and 2024, and interview with the Laboratory Director (LD), the laboratory failed to ensure that the LD and testing personnel (TP) performing histological interpretation of immunohistochemical (IHC) stains on human tissue attested to their integration of bi-annual CAP survey slides into the patient workload. Findings include: 1. Upon review of PT records submitted for review during survey, it was revealed that the following had no attestation from either TP or the LD. 2023 Test for HER2-B marker for breast cancer, event #2 2023 Test for ER/PGR marker for breast cancer, event #2 2024 Test for HER2-B marker for breast cancer, event #1 2024 Test for HER2-B marker for breast cancer, event #2 2024 Test for ER/PGR marker for breast cancer, event #1 2. Interview with the LD at 2:15 pm 11 /12/2024 confirmed that the laboratory had failed to ensure the attestation for all TP and the LD had been signed and dated for the dates listed above. 3. The laboratory reports performing four hundred and twenty one (421) breast hormone marker panels annually. Each panel includes the ER, PGR and Her2 hormone markers.</p>