

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628303	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier Central Oregon Pathology Consultants	Street Address, City, State 1348 Ne Cushing Dr Suite 200, Bend, 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
D5625	<p>CYTOLOGY CFR(s): 493.1274(c)(3)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and microscopic review of gynecologic specimen slides it was determined that the laboratory failed to follow written policies and procedures to identify prior gynecologic cases as having a more significant lesion. The laboratory failed to identify one of twenty-one prior negative gynecologic cases as having a more significant lesion than originally reported from December 2020 and January 2021. Findings include: 1. The laboratory failed to follow the procedure QUALITY IMPROVEMENT PROGRAM, 3. ENSURING ACCURACY, RELIABILITY AND PROMPTNESS OF TESTING AND REPORTING which stated, "5 year review of all pap smears if new diagnosis of HSIL." 2. The Survey Team reviewed records titled FIVE YEAR RETROSPECTIVE REVIEW OF NEGATIVE PAPS: PATIENTS WITH A CURRENT DIAGNOSIS OF HSIL or MALIGNANCY from December 2020 and January 2021. 3. The Survey Team reviewed twenty-one previous negative gynecologic cases from sixteen current cases of HSIL and determined that the laboratory failed to identify one of twenty-one prior negative gynecologic cases as</p>

	<p>having a more significant lesion than was originally reported. Prior negative case includes: - P17-05437 4. During an interview on June 3, 2021 at 10:00 AM the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, final test reports and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. The laboratory failed to identify the basis for the correction on two of two cytology final test reports from April 1 through April 8, 2021. Findings include: 1. The laboratory failed to follow the written procedure titled CORRECTED REPORT POLICY which stated, "Enter a case note explaining the reason for the correction." 2. The laboratory failed to indicate the reason for the correction on two of two corrected cytology reports from April 1 through April 8, 2021. Corrected reports include: - P19-01635 - P21-03782 3. During an interview on June 2, 2021 at 10:00 AM the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on the microscopic review of 360 random negative gynecologic cases/360 slides and the corresponding final test reports from April 2021 and confirmation by Laboratory Director/Technical Supervisor A on June 2, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. P21-03703 04/01/2021 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR /TECHNICAL SUPERVISOR A DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. P21-03709 04/01/2021 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>