

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2146088	(X3) Date Survey Completed 06/12/2024
Name of Provider or Supplier Yosemite Pathology Medical Group Inc	Street Address, City, State 2303 Camino Ramon Ste 104, San Ramon, CA	
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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of cytology proficiency testing (PT) enrollment records and interviews the laboratory failed to enroll in an approved PT program for gynecologic examination. Refer to D2001.</p>
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> <p>This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that the laboratory failed to enroll in a CMS-approved cytology PT program for</p>

gynecologic examination for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2022 and 2023. 2. During an interview on June 11, 2024 at 2:00 PM, when asked if the laboratory had enrolled in an approved cytology PT program for 2022 and 2023, the Compliance Manager replied "no." 3. During a telephone interview on June 11, 2024 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of cytology PT enrollment records and interviews the laboratory failed to establish and follow written policies and procedures to detail the process for PT enrollment and individual participation in a CMS approved PT program for gynecologic cytology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for laboratory enrollment and individual participation in an annual gynecologic cytology PT testing event. 2. During an interview on June 11, 2024 at 2:00 PM, the Compliance Manager stated there was not a policy or procedure for enrollment in an approved gynecologic cytology PT program. 3. During a telephone interview on June 11, 2024 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

A. Based on review of manufacturer's instructions, lack of morphology certification records and interviews the laboratory failed to follow manufacturer's instructions for Technical Supervisors to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (TPPT) in 2022, 2023 and January 1, 2024 to the date of the survey. Findings include: 1. The HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 5000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification records for one Technical Supervisor. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During an interview on June 11, 2024 at 2:00 PM, when asked if the laboratory had found the morphology certificates for the Hologic ThinPrep Pap test training, the Compliance Manager replied "no." 4. During a telephone interview on June 11, 2024 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor. B. Based on review of manufacturer's instructions, lack of morphology certification records and interviews the laboratory failed to follow manufacturer's instructions for Technical Supervisors to evaluate gynecologic cytology specimens using the Becton Dickinson (BD) SurePath Pap Test in 2022, 2023 and January 1, 2024 to the date of the survey. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification records for the one Technical Supervisor who performed diagnostic interpretations of BD SurePath Pap Tests in 2022, 2023 and January 1, 2024 to the date of the survey. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on June 11, 2024 at 2:00 PM, when asked if the laboratory had found the morphology certificates for the BD SurePath Pap test training, the Compliance Manager replied "no." 4. During a telephone interview on June 11, 2024 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, gynecologic cytology slide preparations and corresponding final test reports the laboratory failed to follow written policies and procedures to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify thirteen of fifty-one gynecologic cytology slide preparations as being unsatisfactory in January through December 2023 and January 1, 2024 to the date of the survey. Findings include: 1. The laboratory failed to follow the policy UNSATISFACTORY SPECIMENS which stated: "Cytology Specimens will be reported as unsatisfactory due to the following criteria: 1. Scant or acellular 2. Obscuring blood 3. Obscuring inflammation 4. Obscuring bacteria 5. Obscuring lubricant 6. Degenerative or lack of specimen preservation 7. Excessive cytolysis /autolysis." 2. The laboratory failed to identify and report thirteen of fifty-one

	<p>gynecologic cytology slide preparations as unsatisfactory for evaluation in January through December 2023 and January 1, 2024 to the date of the survey. Cytology slide preparations include: -23R-40832 -23R-40972 -23R-42334 -23R-45866 -23R-45993 -24R-01525 -24R-03128 -24R-08846 -24R-11757 -24R-12701 -24R-14128 -24R-14364 -24R-16033 3. The Laboratory Director/Technical Supervisor confirmed these findings on June 12, 2024 at 1:30 PM.</p>
<p>D6076</p>	<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 laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program (refer to D6088) and failed to ensure the one Technical Supervisor had the required morphology training to evaluate and report Hologic ThinPrep Pap Tests and Becton Dickinson SurePath Pap Tests (refer to D5411).</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interview the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2022 and 2023. Findings include: 1. The Laboratory Director failed to ensure the laboratory was enrolled in an HHS-approved PT program for 2022 and 2023. Refer to D2001.</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 microscopic review of 346 gynecologic cytology cases/364 slides from October 2023 through December 2023 and January 1, 2024 to the date of the survey and confirmation by the Laboratory Director/Technical Supervisor on June 12, 2024 the Technical Supervisor failed to verify the accuracy of nineteen gynecologic cytology tests. 1. 23R-41748 10/31/2023 Imaged ThinPrep Pap Test (I-TPPT)</p>

LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy, reactive changes SURVEY TEAM DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 2. 23R-41758 11/02/2023 I-TPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 3. 23R-42247 11/05/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 4. 23R-42224 11/05/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 5. 23R-40832 10/26/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 6. 23R-40972 10/26/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 7. 23R-42334 11/05 /2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 8. 23R-45866 12/05/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 9. 23R-45993 12/05 /2023 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 10. 24R-06507 02/16/2024 I-TPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: High Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 11. 24R-06502 02/16 /2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Reactive cellular changes associated with Trichomonas SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Herpes (HSV) LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Herpes (HSV) 12. 24R-01525 01/19/24 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells, obscuring lubricant and inflammation LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 13. 24R-03128 01/26 /2024 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells, obscuring lubricant LABORATORY DIRECTOR/TECHNICAL

SUPERVISOR DIAGNOSIS: Unsatisfactory 14. 24R-08846 03/16/24 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 15. 24R-11757 03/25/24 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 16. 24R-12701 03/29 /2024 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 17. 24R-14128 04/09/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 18. 24R-14364 04/09/24 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells, obscuring lubricant and inflammation LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 19. 24R-16033 04/23/24 I-TPPT LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to too few epithelial cells, obscuring lubricant LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory

D9999

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