

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0610978	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Yosemite Pathology Medical Group Inc	Street Address, City, State 782 Delnero Dr, Sonora, 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 annual gynecologic cytology proficiency testing (PT) enrollment records and interview with the Director of Laboratory Services, the laboratory failed to enroll in an annual CMS-approved PT program for gynecologic cytology examination for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide annual gynecologic cytology PT enrollment records for 2020 and 2021. 2. The Director of Laboratory Services confirmed on May 23, 2022 at 3:50 PM, that the laboratory performed gynecologic cytology testing for 2020 and 2021 and did not enroll in an annual CMS-approved gynecologic cytology PT program for 2020 and 2021.</p>
D5623	<p>CYTOLOGY CFR(s): 493.1274(c)(2)</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) (2) Laboratory comparison of clinical information, when available, with cytology</p>

reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL) or malignant neoplasms with available histopathology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology to determine the causes of any discrepancies. 2. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

D5625

CYTOLOGY
CFR(s): 493.1274(c)(3)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. 2. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

D5629

CYTOLOGY
CFR(s): 493.1274(c)(5)

(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) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient

cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:

A. Based on review of laboratory policies and procedures, lack of statistical records and interview, the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six gynecologic statistics. The laboratory failed to document six of six required annual gynecologic statistics for 2020 and 2021.

Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of six of six gynecologic statistics. 2. The Survey Team requested and the laboratory failed to provide six of six required annual gynecologic statistics for 2020 and 2021. 3. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

B. Based on review of laboratory policies and procedures, lack of statistical records and interview, the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics. The laboratory failed to document three of three required annual nongynecologic statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics.

Statistics include: -Number of cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records of the three required annual nongynecologic statistics for 2020 and 2021. 3. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

D5633

CYTOLOGY

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor for each Technical Supervisor who performed primary examinations of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that individual maximum workload limits were established by the Laboratory Director/Technical Supervisor, for each Technical Supervisor that performed primary examinations on nongynecologic cytology specimens. 2. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

<p>D5637</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for each Technical Supervisor who performed primary examinations on nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary when performing primary examinations on nongynecologic cytology specimens. 2. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.</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 the lack of Laboratory Directors review of manufactures instructions and interview, 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 CMS-approved gynecologic cytology PT program for 2020 and 2021 (refer to D6088); and failed to ensure that four of four Technical Supervisors had received the appropriate morphology training prior to reporting gynecologic patient specimens (refer to D6102).</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 annual gynecologic cytology PT enrollment records and interview, the Laboratory Director failed to ensure that the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2020 and 2021. Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an annual CMS-approved PT program for gynecologic cytology examination for 2020 and 2021. 2. The Survey Team requested and the laboratory failed to provide records of enrollment in an annual CMS-approved cytology PT program for gynecologic</p>

Cytology examination for 2020 and 2021. 3. During an interview on May 23, 2022 at 3:50 PM, when asked if the Laboratory Director had enrolled the laboratory in an annual CMS-approved PT program for gynecologic cytology examination for 2020 and 2021, the Director of Laboratory Services replied "no, not for this facility."

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

A. Based on interview, the Laboratory Director failed to follow manufacturer's instructions and failed to ensure that four of four Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2021 and to the date of the survey in 2022. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 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 for four of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 3. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services. B. Based on interview, the Laboratory Director failed to follow manufacturer's instructions and failed to ensure that four of four Technical Supervisors who performed BECTON DICKINSON SUREPATH (BD SurePath) Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2021 and to the date of the survey in 2022. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "BD SurePath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for four of four Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests in 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 3. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(2)(3)

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview, the Technical Supervisor failed to establish individual workload limits for two of two Technical Supervisors who performed primary examinations on nongynecologic cytology specimens in January-May 2022. Cross refer to D5633. Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors who performed primary examinations on nongynecologic cytology specimens in January-May 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor C 2. During an interview on May 25, 2022 at 9:45 AM, these findings were confirmed with the Director of Laboratory Services.

D9999

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