

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0617581	(X3) Date Survey Completed 03/23/2022
Name of Provider or Supplier Oroville Hospital Dept Of Pathology	Street Address, City, State 2767 Olive Hwy, Oroville, 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
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation of three of three annual statistics and failed to document one of three statistics (refer to D5629); failed to follow written policies and procedures for the establishment of individual workload limits (refer to D5633); failed to follow written policies and procedures to reassess workload limits at least every six months (refer to D5637); and failed to follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of Technical Supervisors and Cytotechnologists.</p>

The laboratory failed to assess the competency of three of three Technical Supervisors and one of one Cytotechnologist in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Technical Supervisors and Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for three of three Technical Supervisors and one of one Cytotechnologists in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 -Technical Supervisor #3 Cytotechnologists include: - Cytotechnologist 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

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:
Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required cytology statistics. The laboratory failed to document one of three required annual statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required cytology statistics. Statistics include: - The number of cytology cases examined; - The number of specimens processed by specimen type; - The number of patient cases reported by diagnosis (including the number reported as unsatisfactory). 2. The Survey Team requested and the laboratory failed to provide of one of three required annual statistic for 2020 and 2021. Statistic includes: - The number of patient cases reported by diagnosis (including the number reported as unsatisfactory). 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

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, lack of laboratory records and interview it was determined that the laboratory failed to follow laboratory policies and procedures to ensure individual maximum workload limits were established for individuals performing primary screening. The laboratory failed to ensure workload limits were established for three of three Technical Supervisors and one of one Cytotechnologists for 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The laboratory failed to follow the written procedure CYTOLOGY WORK LOAD POLICY FOR CYTOTECHNOLOGIST AND PATHOLOGIST which stated: "at least every six months the medical director further establishes each cytotechnologist's maximum slide screening workload limit..." "If a pathologist is a primary screened, then pathologist will follow all the workload policies just like cytotechnologist." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for three of three Technical Supervisors and one of one Cytotechnologists for 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 Cytotechnologist includes: - Cytotechnologist 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D5637

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

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to follow the procedure for reassessment of workload limits for three of three Technical Supervisors and one of one Cytotechnologists every six months in 2020 and 2021. Findings include: 1. The laboratory failed to follow the written procedure CYTOLOGY WORK LOAD POLICY FOR CYTOTECHNOLOGIST AND PATHOLOGIST which stated: "Given the legal maximum, at least every six months the medical director further establishes each cytotechnologist's maximum slide screening workload limit. If a pathologist is a primary screener, then pathologist will follow all the workload policies just like cytotechnologist". 2. The Survey Team requested and the laboratory failed to provide documentation of reassessment of workload limits for three of three Technical Supervisors and one of one Cytotechnologists in 2020 and 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 Cytotechnologist includes: - Cytotechnologist 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D5645

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

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of

the site or laboratory.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure records would be maintained of the total number of slides examined and the total number of hours spent examining slides. The laboratory failed to maintain records of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period during 2020, 2021 and to the date of the survey in 2022 for three of three Technical Supervisors. Cross refer to D6133 Findings include: 1. The laboratory failed to follow the written procedure CYTOLOGY WORK LOAD POLICY FOR CYTOTECHNOLOGISTS AND PATHOLOGISTS which stated: "The cytology laboratory maintains records of the number of slides examined and the number of hours devoted to screening and the number of hours devoted to other duties in 24-hour period. The record is documented in (Daily Cytology Slides Workload Log)". 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined and the total number of hours three of three Technical Supervisor spent examining cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Laboratory Director failed to ensure written policies and procedures were established for a quality assessment program for all phases of cytology testing. 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality assessment program and failed to identify and document failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of three of three Technical Supervisors and one of one Cytotechnologists performing cytology test procedures in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5209 Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established to assess the competency of the Technical Supervisors and the Cytotechnologist. 2. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director /Technical Supervisor #1.

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 the lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish individual workload limits and failed to reassess workload limits at least every six months for three of three Technical Supervisors and one of one Cytotechnologists in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established individual maximum workload limits for three of three Technical Supervisors and one of one Cytotechnologists in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director /Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 Cytotechnologist includes: - Cytotechnologist 2. The Survey Team requested and the Technical Supervisor failed to provide documentation of reassessment of workload limits for three of three Technical Supervisors and one of one Cytotechnologists in 2020 and 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 Cytotechnologist includes: - Cytotechnologist 3. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D6133

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(6)

In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

This STANDARD is not met as evidenced by:
Based on lack of laboratory records and interview it was determined that three of three Technical Supervisors performing primary screening of cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Technical Supervisors failed to provide records of the total number of slides screened and the total number of hours three of three Technical Supervisor devoted to screening cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. During an interview on March 22, 2022 at 10:20 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor #1.

D9999

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