

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2125074	(X3) Date Survey Completed 03/24/2021
Name of Provider or Supplier Pathology Consultants Of New Mexico	Street Address, City, State 1160 Commerce Dr, Ste A, Las Cruces, NM	
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, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to compare gynecologic cytology with a diagnosis of HSIL or malignancy with available histopathology reports (refer to D5623); failed to establish written policies and procedures to review all prior negative gynecologic specimens received within the previous five years for each patient with a current High Grade Squamous Intraepithelial Lesion (HSIL) or malignancy (refer to D5625); failed to establish written policies and procedures for an annual evaluation and comparison of six of six laboratory statistics (refer to D5629); failed to establish written policies and procedures to establish reassess and document a workload limit for five of five Technical Supervisors (refer to D5633, D5637 and D6547); failed to establish written policies and procedures to prorate the workload limit for five of five Technical Supervisors when examining slides in less than an eight hour day (refer to D5641); failed to document the total number of slides and the total number of hours spent examining slides in each 24-hour period for five of five Technical Supervisors (refer to D5645); failed to establish written policies and procedures to document the workload limit for five of five Technical Supervisors (refer to D5647); failed to establish written policies and procedures to ensure that unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish written policies and procedures to specify on a corrected report the</p>

basis for correction (refer to D5659). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

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 five of five Technical Supervisors in 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the diagnostic competency of five of five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for five of five Technical Supervisors who performed microscopic evaluations in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 3. During an interview with the Survey Team on March 22, 2021 at 2:38 PM, Laboratory Director/Technical Supervisor A confirmed these findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

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 a quality assessment procedure and document quality assessment activities for 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for general laboratory quality assessment. 2. The Survey Team requested and the laboratory failed to provide documentation of quality assessment activities for 2020 and to the date of the survey in 2021. 3. During an interview with the Survey Team on March 22, 2021 at 5:00 PM, the Director of Cytology confirmed these findings.

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 two laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for entering and reporting of cytology test results in the laboratory information system (LIS). 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology proficiency testing (PT) enrollment and participation of personnel that perform gynecologic cytology testing. 3. During an interview with the Survey Team on March 22, 2021 at 5:00 PM, the Director of Cytology confirmed these finding.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of laboratory records and interview it was determined that the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for one of one stain processes, each day of use in 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide Diff-Quik stain assessment records. 2. During an interview with the Survey Team on March 22, 2021 at 5:00 PM, the Director of Cytology confirmed these findings.

D5623

CYTOLOGY

CFR(s): 493.1274(c)(2)

(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 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 it was determined that the laboratory failed to establish written policies and procedures to compare clinical information with the cytology reports and to compare gynecologic cytology with a diagnosis of HSIL or malignancy, with available histopathology reports. 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 HSIL or malignant gynecologic cytology cases with available histopathology reports. a. The laboratory failed to establish written procedures to describe what constituted a discrepancy between a cytology diagnosis and the correlating histology report and how the causes of discrepancies would be determined and documented. 2. During an interview with the Survey Team on March 22, 2021 at 2:38 PM, Laboratory Director/Technical Supervisor A confirmed these findings.

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 it was determined that 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. 2. During an interview with the Survey Team on March 22, 2021 at 2:38 PM, Laboratory Director/Technical Supervisor A confirmed these findings.

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 and interview it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the annual statistical evaluation of six of six required laboratory statistics. 2. During an interview with the Survey Team on March 22, 2021 at 2:10 PM, the Director of Cytology confirmed these finding.

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 establish written policies and procedures to ensure that individual maximum workload limits were established for five of five Technical Supervisors during the years 2020 and to the date of the survey in 2021. 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 for five of five Technical Supervisors.. 2. The Survey Team requested and the laboratory failed to provide documentation of an individual workload limit for five of five Technical Supervisors for 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 3. During an interview with the Survey Team on March 22, 2021 at 9:20 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

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 establish written policies and procedures to ensure that the workload limit for five of five Technical Supervisors was reassessed and adjusted when necessary at least every six months during 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment and adjustment when necessary of workload limits at least every six months for five of five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for five of five Technical Supervisors during 2020. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 3. During an interview with the Survey Team on March 22, 2021 at 9:20 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

D5641

CYTOLOGY
 CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
 Cross refer to D5645 Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for five of five Technical Supervisors would be prorated when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for five of five Technical Supervisors when examining slides in less than an 8-hour day. 2. During an interview with the Survey Team on March 22, 2021 at 9:20 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

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 ensure that the laboratory maintained records for five of five Technical Supervisors of the total number of slides

and the total number of hours spent evaluating slides per 24-hour period from July 2020 to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides and total number of hours spent evaluating slides in 2020 and to the date of the survey in 2021. 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides and total number of hours five of five Technical Supervisors spent evaluating slides during each 24-hour period in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 3. During an interview with the Survey Team on March 22, 2021 at 9:20 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

D5647

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

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

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 ensure that records were available to document the workload limit for five of five Technical Supervisors for 2020 and to the date of the survey in 2021. Cross refer to D5633 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for five of five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records to document the workload for five of five Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 3. During an interview with the Survey Team on March 22, 2021 at 9:20 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic and nongynecologic slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory gynecologic specimens were identified and reported as unsatisfactory. 2. The Survey Team requested and the laboratory failed to provide

	<p>written policies and procedures to ensure that unsatisfactory nongynecologic specimens were identified and reported as unsatisfactory. 3. During an interview with the Survey Team on March 22, 2021 at 3:00 PM the Laboratory Director/Technical Supervisor A confirmed this finding.</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 and interview it was determined that the laboratory failed to establish written policies and procedures for issuing a corrected report to include the basis for the correction. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for issuing a corrected report to include the basis for the correction. 2. During an interview with the Survey Team on March 23, 2021 at 3:18 PM the Laboratory Director/Technical Supervisor A confirmed this finding.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records, and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Cross Refer to D5403, D5473, D5623, D5625, D5629, D5633, D5637, D5641, D5645, D5655 and D5659.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of final test reports and interview it was determined that the</p>

laboratory failed to ensure that 40 of 40 final test reports from February and March 2021 indicated the address of the laboratory location where the test was performed. Findings include: 1. The Survey Team reviewed 40 final test reports reported from February and March 2021. Forty of 40 final test reports did not indicate the correct address of the laboratory where the test was performed. Reports include: - C21-961 - C21-1628 - C21-2439 - C21-2637 - C21-2767 - C21-2939 - C21-3003 - C21-3319 - C21-3342 - C21-3536 - C21-3651 - C21-3685 - C21-3687 - C21-3711 - C21-3756 - C21-3774 - C21-3795 - C21-3808 - C21-3813 - C21-3982 - C21-4174 - C21-4181 - C21-4292 - C21-4297 - C21-4312 - C21-4313 - C21-4433 - C21-4456 - C21-4460 - C21-4474 - C21-4563 - C21-4571 - C21-4572 - C21-4591 - C21-4666 - C21-4693 - C21-4712 - C21-4721 - C21-4767 - C21-4913 2. During an interview with the Survey Team on March 22, 2021 at 10:30 AM the Laboratory Director/Technical Supervisor A confirmed this finding.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

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 ongoing mechanism to monitor, assess, and correct problems in the postanalytic phases of cytology testing. Cross Refer to D5805 and D6094

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established (refer to D6094); and failed to evaluate the competency and training needs of five of five Technical Supervisors (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

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 Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5403, D5473, D5623, D5625, D5629, D5633, D5637, D5641, D5645, D5647, D5655 and D5805.

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 interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5291 and D5791.

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 the review of laboratory policies and procedures and interview it was determined that Laboratory Director/Technical Supervisor A failed to evaluate the competency of five of five Technical Supervisors who performed microscopic evaluations and reporting of gynecologic and nongynecologic cytology results for 2020 and to the date of the survey in 2021 Cross refer to D5209

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 it was determined that the Laboratory Director/Technical Supervisor failed to establish and reassess the workload limits at least every six months and make adjustments when necessary for five of five Technical Supervisors in 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637

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 review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor failed to document the total number of slides and total number of hours devoted to examining slides during each 24-hour period in 2020 and to the date of the survey in 2021. Cross refer to D5645

D9999

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