

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1013919	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier Doctors Hospital At Renaissance Laboratory	Street Address, City, State 5501 South Mccoll Road, Edinburg, TX	
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 interviews the laboratory failed to establish and follow written policies and procedures to assess the competency of Cytotechnologists (refer to D5209); failed to follow manufacturer's instructions for required morphology certification (refer to D5411); failed to follow written policies and procedures to ensure the review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was documented (refer to D5625); failed to establish and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); 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); failed to follow written policies and procedures to ensure that gynecologic cytology slide preparations interpreted to exhibit reactive or reparative changes were confirmed by a Technical Supervisor (refer to D5649); and failed to follow written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation (refer to D5655).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</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.

This STANDARD is not met as evidenced by:

A. Based on review of laboratory policies and procedures and interview with the Pathology Manager the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. 2. During an interview on March 27, 2024 at 8:40 AM these findings were confirmed by Pathology Manager. B. Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Pathology Manager the laboratory failed to establish and follow written policies and procedures to assess the competency of the Cytotechnologists. The laboratory failed to assess the competency of two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on March 27, 2024 at 8:40 AM these findings were confirmed by Pathology Manager.

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 interview with the Pathology Manager the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology slide preparations using the Hologic ThinPrep Pap Test (TPPT) in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL stated: -"Evaluation of microscope slides produced with the ThinPrep 5000 processor 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 one of two Technical Supervisors. Technical Supervisor includes: -Technical Supervisor B a. Diagnostic evaluations of Hologic TPPT's were performed by Technical Supervisor B without the required morphology certification in 2022, 2023 and January 2024 to the date of the survey in 2024. 3. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of five Cytotechnologists who performed diagnostic interpretations of

HologicThinPrep Pap Tests in 2022 and 2023. Cytotechnologist includes: - Cytotechnologist D a. Diagnostic evaluations of Hologic TPPT's were performed by Cytotechnologist D without the required morphology certification in 2022 and 2023. 4. During an interview on March 27, 2022 at 8:40 AM these findings were confirmed by Pathology Manager. B. Based on review of manufacturer's instructions, lack of morphology certification records and interview with the Pathology Manager the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology slide preparations using the Becton Dickinson (BD) SurePath Pap Test in 2022, 2023 and January 2024 to the date of the survey in 2024. 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 for one of two Technical Supervisors. Technical Supervisor includes: -Technical Supervisor B a. Diagnostic evaluations of BD SurePath Pap Tests were performed by Technical Supervisor B without the required morphology certification in 2022, 2023 and January 2024 to the date of the survey in 2024. 3. The Survey Team requested and the laboratory failed to provide the required morphology certification for two of five Cytotechnologists. Cytotechnologists include: -Cytotechnologist C -Cytotechnologist E a. Diagnostic evaluations of BD SurePath Pap Tests were performed by Cytotechnologist C without the required morphology certification in 2022 and 2023 b. Diagnostic evaluations of BD SurePath Pap Tests were performed by Cytotechnologist E without the required morphology certification in 2022. 4. During an interview on March 27, 2024 at 8:40 AM these findings were confirmed by Pathology Manager.

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, laboratory correlation records and gynecologic cytology slide preparations the laboratory failed to follow written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. The laboratory failed to identify one of seven cases from June 2023 through December 2023 as having a more significant lesion. Findings include: 1. The laboratory failed to follow the procedure GYN CYTOLOGY/HISTOLOGY CORRELATION PROCEDURE which stated: -"C. Resulting review of preceding pap smear...3. If the pap smear diagnosis has changed by two or more degrees, this represents a major disagreement." 2. The Survey Team reviewed records titled DIAGNOSTIC CORRELATION REPORT: GYN V. HISTO CORRELATION and the corresponding slides from June 2023 through December 2023. a. The Survey Team reviewed seven cases and

identified one of seven cases as having a more significant lesion than reported by the laboratory. Case includes: -RP-23-37666 b. On March 27, 2024 the Laboratory Director/Technical Supervisor A reviewed the case and 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, retrospective review records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure that the review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy was documented. The laboratory failed to document the review of prior negative gynecologic cases for 18 of 18 HSIL or malignant cases from June 2023 through November 2023. Findings include: 1. The laboratory failed to follow the procedure GYN AND NON-GYN CYTOPATHOLOGY QUALITY ASSURANCE AND QUALITY CONTROL SURVEILLANCE which stated: "All available previously negative slides received within the past five years as well as histological material are reviewed and documented." 2. The Survey Team reviewed records titled 5-YEAR RETROSPECTIVE REVIEW. The laboratory failed to document the review of prior negative gynecologic cases for 18 of 18 HSIL or malignant cases from June 2023 through November 2023. Cases include: -RP-23-16585 -RP-23-18440 -RP-23-18615 -RP-23-18925 -RP-23-19062 -RP-23-19453 -RP-23-19538 -RP-23-19684 -RP-23-20270 -RP-23-21212 -RP-23-22434 -RP-23-22933 -RP-23-25336 -RP-23-30806 -RP-23-31151 -RP-23-32937 -RP-23-36850 -RP-23-37534 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Laboratory Director /Technical Supervisor A who stated "If I agree with them all, I just initial and date the monthly report on the front page."

D5627

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

Records of initial examinations and all rescreening results must be documented.

This STANDARD is not met as evidenced by:
Based on review of retrospective review records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to document the rescreen results for 26 of 26 previous negative gynecologic cytology cases on current cases with a diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy from June 2023 through November 2023 . Findings include: 1. The Survey Team reviewed records titled 5-YEAR RETROSPECTIVE REVIEW. The laboratory failed to

document the rescreen results for 26 of 26 previous negative gynecologic cytology cases on current cases with a diagnosis of HSIL or malignancy from June 2023 through November 2023. Cases include: -RP-18-34714 -RP-19-01185 -RP-19-07206 -RP-19-16712 -RP-19-19087 -RP-19-19379 -RP-19-27540 -RP-19-32547 -RP-19-36827 -RP-20-08300 -RP-20-15473 -RP-20-23028 -RP-21-00837 -RP-21-07011 -RP-21-07946 -RP-21-08298 -RP-21-17332 -RP-21-18305 -RP-21-20099 -RP-21-28149 -RP-21-35921 -RP-22-08814 -RP-22-18232 -RP-22-20623 -RP-22-27593 -RP-23-10048 2. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Laboratory Director/Technical Supervisor A who stated "If I agree with them all, I just initial and date the monthly report on the front page."

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 workload limit records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of nongynecologic cytology slide preparations. Technical Supervisor A failed to establish an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of nongynecologic cytology slide preparations. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director /Technical Supervisor A -Technical Supervisor B 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by the Laboratory Director /Technical Supervisor A who stated "We didn't set thresholds because we don't come close to the federal limit."

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 workload limit reassessment records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of

nongynecologic cytology slide preparations. Technical Supervisor A failed to reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how Technical Supervisor A would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide reassessed maximum workload limits for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director /Technical Supervisor A -Technical Supervisor B 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by the Laboratory Director /Technical Supervisor A who stated "We didn't set thresholds because we don't come close to the federal limit."..

D5639

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

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, workload records and interviews the laboratory failed to follow written policies and procedures to ensure the maximum number of slides examined by an individual in each 24-hour period did not exceed 100 slides. The laboratory failed to ensure that one of five Cytotechnologists did not exceed the maximum daily workload limit of 100 slides in 52 of 72 days from August 7, 2023 through October 31, 2023. Findings include: 1. The laboratory failed to follow the policy CYTOTECNOLOGIST WORKLOAD which stated: "Federal regulations require that cytotechnologists may examine up to 100 slides per 24 hours (average 12.5 slides/hour) and in not less than eight hours. These limits apply to both manual and automated screening. Our cytotechnologist screening limits have been established at the maximum allowable limits." 2. The Survey Team reviewed records titled CYTOLOGY DAILY WORKLOAD. One of five Cytotechnologists exceeded the maximum daily workload limit of 100 slides 52 of 72 days from August 7, 2023 through October 31, 2023. Cytotechnologist includes: -Cytotechnologist A Dates include: -08/07/2023 Slides examined: 102 -08/08/2023 Slides examined: 106 -08/09/2023 Slides examined: 105 -08/10/2023 Slides examined: 108 -08/11/2023 Slides examined: 105 -08/14/2023 Slides examined: 106 -08/15/2023 Slides examined: 102.5 -08/17/2023 Slides examined: 103 -08/18/2023 Slides examined: 103.5 -08/19/2023 Slides examined: 111 -08/20/2023 Slides examined: 104.5 -08/21/2023 Slides examined: 102.5 -08/22/2023 Slides examined: 101 -08/23/2023 Slides examined: 105.5 -08/24/2023 Slides examined: 103.5 -08/25/2023 Slides examined: 104.5 -08/28/2023 Slides examined: 101.5 -08/29/2023 Slides examined: 104.5 -08/30/2023 Slides examined: 103.5 -09/04/2023 Slides examined: 103.5 -09/05/2023 Slides examined: 106.5 -09/06/2023 Slides examined: 102.5 -09/07/2023 Slides examined: 107 -09/08/2023 Slides examined: 102 -09/11/2023 Slides examined: 109.5 -09/13/2023 Slides examined: 104 -09/14/2023 Slides examined: 102.5 -09/15/2023 Slides examined:

103.5 -09/18/2023 Slides examined: 104 -09/19/2023 Slides examined: 102.5 -09/20/2023 Slides examined: 104 -09/21/2023 Slides examined: 102 -09/22/2023 Slides examined: 105.5 -09/26/2023 Slides examined: 110 -09/27/2023 Slides examined: 101 -09/28/2023 Slides examined: 109 -09/29/2023 Slides examined: 100.5 -09/30/2023 Slides examined: 107.5 -10/04/2023 Slides examined: 102.5 -10/05/2023 Slides examined: 108 -10/06/2023 Slides examined: 102 -10/07/2023 Slides examined: 105.5 -10/09/2023 Slides examined: 101 -10/10/2023 Slides examined: 107 -10/13/2023 Slides examined: 104.5 -10/17/2023 Slides examined: 108 -10/18/2023 Slides examined: 108 -10/19/2023 Slides examined: 105 -10/21/2023 Slides examined: 107 -10/23/2023 Slides examined: 103.5 -10/26/2023 Slides examined: 104.5 -10/27/2023 Slides examined: 103 3. During an interview on March 26, 2024 at 4:52 PM Cytotechnologist A confirmed that the records titled CYTOLOGY DAILY WORKLOAD manually completed by the Cytotechnologists included all slides screened by the Cytotechnologists. 4. During an interview on March 27, 2024 at 1:30 PM these findings were discussed with Laboratory Director/Technical Supervisor A.

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:
Based on review of laboratory policies and procedures, lack of workload limit records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for two of two Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.

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:

A. Based on review of laboratory policies and procedures, lack of laboratory workload records and interviews the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours spent examining slides per 24-hour period. The laboratory failed to maintain records of the total number of slides examined per 24-hour period and the number of hours spent examining slides per 24-hour period for two of two Technical Supervisors who performed primary screening of nongynecologic cytology slide preparations in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the policy CYTOPATHOLOGY QUALITY MANAGEMENT PLAN which stated: -"In accordance with CLIA regulations the Cytotechnologist/Pathologist (when applicable) will record the daily workload of slides reviewed including the total screening hours." 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined and the number of hours spent examining slides per 24-hour period for two of two Technical Supervisors who performed primary screening of nongynecologic cytology slide preparations in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, lack of laboratory workload records and interview with the Pathology Manager the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours spent examining slides per 24-hour period. The laboratory failed to maintain records of the number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022, 2023 and January 2024 to the date of the survey in 2024. The laboratory failed to maintain records of the total number of slides examined and the number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022 and 2023. The laboratory failed to maintain records of the total number of slides examined and the number of hours spent examining slides per 24-hour period for one of five Cytotechnologists in 2022. Findings include: 1. The laboratory failed to follow the policy CYTOPATHOLOGY QUALITY MANAGEMENT PLAN which stated: -"In accordance with CLIA regulations the Cytotechnologist/Pathologist (when applicable) will record the daily workload of slides reviewed including the total screening hours." 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022, 2023 and January 2024 to the date of the survey in 2024. Cytotechnologists include: - Cytotechnologist A -Cytotechnologist B 3. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined and the number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022 and 2023. Cytotechnologists include: -Cytotechnologist C - Cytotechnologist D a. During an interview on March 26, 2024 at 3:00 PM these findings were confirmed by Pathology Manager who stated that "Contractors do not record their workload here." 4. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined and the number of hours spent examining slides per 24-hour period for one of five Cytotechnologists in 2022.. Cytotechnologist includes: -Cytotechnologist E a. During an interview on March 26, 2024 at 3:00 PM these findings were confirmed by Pathology Manager who stated that "Contractors do not record their workload here.". 5. During an interview on March 27, 2024 at 1:30 PM these findings were confirmed by Laboratory Director

/Technical Supervisor A.

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 workload limit records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for Technical Supervisors who perform primary screening of cytology specimens. The laboratory failed to maintain records of the workload limit for two of two Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for Technical Supervisors who performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A

D5649

CYTOLOGY

CFR(s): 493.1274(e)(1)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities: (e)(1)(i) Squamous cell. (e)(1)(i)(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H). (e)(1)(i)(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1). (e)(1)(i)(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion. (e)(1)(i)(D) Squamous cell carcinoma. (e)(1)(ii) Glandular Cell (e)(1)(ii)(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular). (e)(1)(ii)(B) Atypical cells favor neoplastic (endocervical or glandular). (e)(1)(ii)(C) Endocervical adenocarcinoma in situ. (e)(1)(ii)(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS. (e)(1)(iii) Other malignant neoplasms.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, cytology final test reports and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure that a Technical Supervisor

confirmed each gynecologic slide preparation interpreted to exhibit reactive or reparative changes. The laboratory failed to ensure that a Technical Supervisor confirmed 48 gynecologic cytology slide preparations interpreted to exhibit reactive or reparative changes from June 2022 through December 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the policy GYN AND NON-GYN CYTOPATHOLOGY QUALITY ASSURANCE AND QUALITY CONTROL SURVEILLANCE which stated: -"All abnormal Gyn cytology findings can only be interpreted by the pathologist including:...e.) Reactive or repair" 2. The Survey Team reviewed gynecologic cytology final test reports from June 2022 through December 2023 and January 1, 2024 to the date of the survey in 2024. The laboratory failed to ensure that a Technical Supervisor confirmed 48 gynecologic slide preparations interpreted to exhibit reactive or reparative changes from June 2022 through December 2023 and January 2024 to the date of the survey in 2024. Slide preparations include: -RP-22-17205 -RP-22-17518 -RP-22-23345 -RP-22-24428 -RP-22-24756 -RP-22-25343 -RP-22-29284 -RP-22-31303 -RP-22-32304 -RP-22-35355 -RP-23-01205 -RP-23-18689 -RP-23-32721 -RP-23-36016 -RP-23-36211 -RP-23-36245 -RP-23-36472 -RP-23-36552 -RP-23-37397 -RP-23-37406 -RP-23-37722 -RP-23-37730 -RP-23-37738 -RP-23-37931 -RP-23-39252 -RP-23-39682 -RP-24-01089 -RP-24-02419 -RP-24-02519 -RP-24-02933 -RP-24-03003 -RP-24-03094 -RP-24-03229 -RP-24-03297 -RP-24-03843 -RP-24-04689 -RP-24-05466 -RP-24-05712 -RP-24-05715 -RP-24-05814 -RP-24-06111 -RP-24-06194 -RP-24-06341 -RP-24-06502 -RP-24-07005 -RP-24-07203 -RP-24-07627 -RP-24-08214 3. During an interview on March 27, 2024 at 1:30 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.

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 and confirmation by the Laboratory Director/Technical Supervisor A 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 one of three gynecologic cytology slide preparations as being unsatisfactory for evaluation in January 2023. Findings include: 1. The laboratory failed to follow the policy GYN AND NON-GYN CYTOPATHOLOGY QUALITY ASSURANCE AND QUALITY CONTROL SURVEILLANCE which stated: -"Criteria for unsatisfactory GYN specimens include: a. Hypo-cellular or a cellular Sure Path slide or Thin Prep." a. The laboratory failed to identify and report one of three gynecologic cytology slide preparations as unsatisfactory for evaluation in January 2023. The Laboratory Director /Technical Supervisor A confirmed these findings on March 27, 2024. Cytology slide preparation includes: -RP-23-01851

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to establish and follow written policies and procedures for a mechanism to monitor, assess and correct problems identified in the analytic cytology systems. 2. The laboratory failed to have a program to monitor, assess and correct problems when Cytotechnologists exceeded maximum daily workload limits. (Refer to D5639) a. The laboratory failed to monitor, assess and correct problems with CYTOLOGY DAILY WORKLOAD records for two of five Cytotechnologists in 2022, 2023 and January 2024 to the date of the survey in 2024. The workload records were not signed to reflect supervisory review. Cytotechnologists include: - Cytotechnologist A -Cytotechnologist B 3. The laboratory failed to have a program to monitor, assess and correct problems when gynecologic cytology slide preparations with interpretations of reactive or reparative changes were not confirmed by a Technical Supervisor. (Refer to D5649) 4. During an interview on March 27, 2024 at 1:30 PM these findings were reviewed with the Laboratory Director/Technical Supervisor A.

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 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 be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); and failed to ensure the competency of two of two Cytotechnologists (refer to D6103).

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, lack of laboratory records and interview the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure the Technical Supervisor established workload limits for Technical Supervisors who performed evaluation and reporting of cytology specimens and that criteria were established to reassess workload limits every 6 months. (Refer to D5633, D5637, D5647, D6130) 2. The Laboratory Director failed to provide direction and oversight to ensure the Cytotechnologists did not exceed the maximum daily workload limit of 100 slides. (Refer to D5639) 3. The Laboratory Director failed to provide direction and oversight to ensure all individuals who performed primary screening of cytology slide preparations documented the number of slides examined and the number of hours spent examining slides during each 24-hour period. (Refer to D5645) 4. The Laboratory Director failed to provide direction and oversight to ensure gynecologic cytology slide preparations interpreted to exhibit reactive or reparative changes were confirmed by a Technical Supervisor. (Refer to D5649)

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:
Based on review of manufacturer's instructions, lack of morphology certification records and interview with the Pathology Manager the Laboratory Director failed to ensure that all testing personnel had the appropriate morphology training prior to testing patient specimens. Cross refer to D5411 Findings include: 1. The Laboratory Director failed to ensure one of two Technical Supervisors had the required morphology certification for Hologic ThinPrep Pap Tests. 2. The Laboratory Director failed to ensure one of two Technical Supervisors had the required morphology certification for BD SurePath Pap Tests. 3. The Laboratory Director failed to ensure one of five Cytotechnologists had the required morphology certification for Hologic ThinPrep Pap Tests. 4. The Laboratory Director failed to ensure two of five Cytotechnologists had the required morphology certification for BD SurePath Pap Tests.

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:

A. Based on review of laboratory policies and procedures and interview with the Pathology Manager the Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors who perform analytic and postanalytic cytology duties. Findings include: 1. The Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors who perform analytic and postanalytic cytology duties. (Refer to D5209) B. Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Pathology Manager the Laboratory Director failed to ensure that written policies and procedures were established and followed to assess, monitor and maintain the competency of Cytotechnologists who perform analytic cytology duties. The Laboratory Director failed to ensure that the competency of two of two Cytotechnologists was assessed in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of Cytotechnologists who perform analytic and postanalytic cytology duties. (Refer to D5209)

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on microscopic review of 248 random negative gynecologic cytology cases/248 slides from January 2023 through December 2023 and January 2024 to the date of the survey in 2024 and confirmation by the Laboratory Director/Technical Supervisor A on March 27, 2024 the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. RP-23-01851 01/21/23 Hologic ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for intraepithelial lesio or malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity and obscuring blood TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory due to scant cellularity

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 workload limit records and interview with the Laboratory Director/Technical Supervisor A the Technical Supervisor failed to establish and reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. Technical Supervisor A failed to provide documentation of an established maximum workload limit for two of two Technical Supervisors who performed primary examination of nongynecologic cytology slide preparations in 2022, 2023 and January 2024 to the date of the survey in 2024. (Refer to D5633) 2. Technical Supervisor A failed to provide documentation of a reassessed workload limit at least every six months for two of two Technical Supervisors who performed primary examination of nongynecologic cytology slide preparations in 2022, 2023 and January 2024 to the date of the survey in 2024. (Refer to D5637) 3. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.

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 the lack of workload records and interview with Technical Supervisor A two of two Technical Supervisors failed to document the number of slides evaluated and the number of hours devoted to screening slides during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. Two of two Technical Supervisors failed to document the total number of slides evaluated during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024.. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B a. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Technical Supervisor A. 2. Two of two Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024.. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B a. During an interview on March 26, 2024 at 2:10 PM these findings were confirmed by Technical Supervisor A.

D6166

CYTOTECHNOLOGIST RESPONSIBILITIES
 CFR(s): 493.1485(b)

The cytotechnologist is responsible for documenting, for each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer.

This STANDARD is not met as evidenced by:
 Based on the lack of laboratory workload records and interview with the Pathology Manager two of five Cytotechnologists failed to document the total number of slides

examined during each 24-hour period in 2022 and 2023. One of five Cytotechnologists failed to document the total number of slides examined during each 24-hour period in 2022. Findings include: 1. The Survey Team requested and the Pathology Manager failed to provide documentation of the total number of slides examined per 24-hour period for two of five Cytotechnologists in 2022 and 2023. Cytotechnologists include: -Cytotechnologist C -Cytotechnologist D 2. The Survey Team requested and the Pathology Manager failed to provide documentation of the total number of slides examined per 24-hour period for one of five Cytotechnologists in 2022. Cytotechnologists include: -Cytotechnologist E 3. During an interview on March 26, 2024 at 3:00 PM these findings were confirmed by Pathology Manager who stated that "Contractors do not record their workload here."

D6167

CYTOTECHNOLOGIST RESPONSIBILITIES
CFR(s): 493.1485(c)

The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period.

This STANDARD is not met as evidenced by:
Based on review of laboratory workload records and interview with the Pathology Manager two of five Cytotechnologists failed to document the total number of hours spent examining slides during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Two of five Cytotechnologists failed to document the total number of hours spent examining slides during each 24-hour period in 2022 and 2023. One of five Cytotechnologists failed to document the total number of hours spent examining slides during each 24-hour period in 2022 Findings include: 1. The Survey Team requested and the Pathology Manager failed to provide documentation of the total number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022, 2023 and January 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. The Survey Team requested and the Pathology Manager failed to provide documentation of the total number of hours spent examining slides per 24-hour period for two of five Cytotechnologists in 2022 and 2023. Cytotechnologists include: -Cytotechnologist C -Cytotechnologist D 3. The Survey Team requested and the Pathology Manager failed to provide documentation of the total number of hours spent examining slides per 24-hour period for one of five Cytotechnologists in 2022. Cytotechnologists include: -Cytotechnologist E 4. During an interview on March 26, 2024 at 3:00 PM these findings were confirmed by Pathology Manager.

D9999

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