

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0325229	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Hazard Arh Regional Medical Center	Street Address, City, State 100 Medical Center Drive, Hazard, KY	
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 policies and procedures for the maintenance and verification of the staining process (refer to D5403); failed to establish written policies and procedures for prevention of cross-contamination (refer to D5619); failed to establish written policies and procedures for the evaluation of three of three annual statistics (refer to D5629); failed to establish written policies and procedures for the establishment of individual workload limits and failed to reassess workload limits at least every six months (refer to D5633 and D5637); failed to establish 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 establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined per 24-hour period and the hours spent examining slides (refer to D5645); failed to establish written policies and procedures to document the workload limit (refer to D5647); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655) and failed to establish written policies and procedures for corrected final reports (refer to D5659).</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of preanalytic quality assessment records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. The laboratory failed to document preanalytic quality assessment activities during 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 for an ongoing program to monitor, assess and correct problems identified in the preanalytic laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director /Technical Supervisor #1 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 five laboratory policies and procedures and interview with Laboratory Director/Technical Supervisor #1, 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 to describe the laboratory's requirements for performing daily stain assessment. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's system for maintenance of the Papanicolaou Stain. 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

D5619

CYTOLOGY

CFR(s): 493.1274(b)(3)

(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of stain maintenance records and interview with the Cytotechnologist, the laboratory failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. The Survey Team requested and the laboratory failed to provide documentation of cases with a high potential for cross-contamination which had been stained separately. The laboratory failed to provide records of the changing of stains and reagents following staining in 2020, 2021 and to the date of survey in 2022. 3. During an interview on November 15, 2022 at 11:00 AM, the Cytotechnologist 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, statistical records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to have written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics. The laboratory failed to document two of three required annual nongynecologic statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics. 2. The Survey Team requested and the laboratory failed to provide two of three required annual nongynecologic statistics for 2020 and 2021. Statistics include: -

	<p>Number of specimens processed by specimen type. - Number of patient cases reported by diagnosis, including the number reported as unsatisfactory. 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.</p>
<p>D5633</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for Cytotechnologists and Technical Supervisors who performed primary examination of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established individual maximum workload limits for Cytotechnologists and Technical Supervisors who performed primary examination of nongynecologic cytology specimens. 2. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.</p>
<p>D5637</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for Cytotechnologists and Technical Supervisors who performed primary examination of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how Cytotechnologist's and Technical Supervisors' workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.</p>
<p>D5641</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(2)(ii)</p> <p>(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</p>

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 #1, the laboratory failed to establish written policies and procedures to ensure that the workload limits for Cytotechnologists and Technical Supervisors would be prorated when examining cytology slides in less than an eight-hour work day. The laboratory failed to prorate the workload limits for one of one Cytotechnologists and two of two Technical Supervisors 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 prorate the workload limits for Cytotechnologists and Technical Supervisors when examining non-gynecologic cytology slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records of prorated workload limits for one of one Cytotechnologists and two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022.

Cytotechnologists include: - The Cytotechnologist Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 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 workload records and interview with the Cytotechnologist, the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides Cytotechnologists and Technical Supervisors examined and the number of hours per 24-hour period. The laboratory failed to provide records for one of one Cytotechnologists and two of two Technical Supervisors of the number of slides and the number of hours spent examining slides per 24-hour period for 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 ensure that the laboratory maintained records of the total number of slides Cytotechnologists and Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the number of slides examined and the number of hours spent examining slides for one of one Cytotechnologists and two of two Technical Supervisors for 2020, 2021 and to the date of the survey in 2022.

Cytotechnologists include: - The Cytotechnologist Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3. During an interview on November 16, 2022 at 10:00 AM, the Cytotechnologist confirmed these findings.

<p>D5647</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(4)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory workload limit records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for Cytotechnologists and Technical Supervisors who performed primary examination of nongynecologic cytology specimens. The laboratory failed to provide records of workload limits for one of one Cytotechnologists and two of two Technical Supervisors during 2020, 2021 and through 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 ensure records were available to document the workload limit for Cytotechnologists and Technical Supervisors who performed primary examination of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Cytotechnologists and two of two Technical Supervisors who performed primary examination of nongynecologic cytology specimens during 2020, 2021 and to the date of the survey in 2022. Cytotechnologists include: - The Cytotechnologist Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3. During an interview on November 16, 2022 at 9:00 AM, the Laboratory Director /Technical Supervisor #1 confirmed these findings.</p>
<p>D5655</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Cytotechnologist, the laboratory failed to establish written policies and procedures to ensure unsatisfactory 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 slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on November 15, 2022 at 11:00 AM, the Cytotechnologist confirmed these findings.</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>

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview with the Cytotechnologist, the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. 2. During an interview on November 15, 2022 at 11:00 AM, the Cytotechnologist confirmed these findings.

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, lack of quality assessment records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish 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 in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5619, D5629, D5645 and D5659 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for the prevention of cross-contamination (See D5619). b. The laboratory failed to document a system for monitoring and evaluating annual statistics (See D5629). c. The laboratory failed to document a system for the recording of the number of slides examined and the amount of time examining slides in each 24-hour period (See D5645). d. The laboratory failed to document a system for monitoring and evaluating the basis for correction on final test reports (See D5659). 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

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, lack of laboratory records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems. The

	<p>laboratory failed to document postanalytic quality assessment activities 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 for an ongoing program to monitor, assess and correct problems identified in the postanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of postanalytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews, the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology duties (refer to D6103).</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of quality assessment records and interview with the Laboratory Director/Technical Supervisor #1, the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services. The Laboratory Director failed to identify and document failures in quality as they occurred during 2020, 2021 and to the date of the survey in 2022. Cross refer to D5391, D5791 and D5891 Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program for all phases of cytology testing (See D5391, D5791 and D5891). 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality for all phases of cytology testing as they occurred during 2020, 2021 and to the date of the survey in 2022 (See D5391, D5791 and D5891). 3. During an interview on November 16, 2022 at 9:10 AM the Laboratory Director/Technical Supervisor #1 confirmed these findings.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p>

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 competency assessment records and interview with the Laboratory Director/Technical Supervisor #1, the Laboratory Director failed to establish written policies and procedures to assess the competency of Cytotechnologists and Technical Supervisors. The laboratory failed to provide documentation of competency of one of one Cytotechnologist and two of two Technical Supervisors 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 provide written policies and procedures to describe the process for assessing the competency of Cytotechnologists and Technical Supervisors.. 2. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Cytotechnologists and two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Cytotechnologists includes: - The Cytotechnologist Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director /Technical Supervisor #1 confirmed these findings..

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 workload limit records and interview with the Laboratory Director/Technical Supervisor #1, the Technical Supervisor failed to establish an individual workload limit and failed to reassess workload limits at least every six months for one of one Cytotechnologists and two of two Technical Supervisors 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 laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Cytotechnologists and two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Cytotechnologists include: - The Cytotechnologist Technical Supervisors include: - Laboratory Director /Technical Supervisor #1 - Technical Supervisor #2 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of one Cytotechnologists and two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Cytotechnologists include: - The Cytotechnologist Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3.

During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director /Technical Supervisor #1 confirmed these findings.

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 workload records and interview with the Laboratory Director/Technical Supervisor #1, two of two Technical Supervisors performing primary examination of cytology specimen slides failed to document the number of slides examined and the number of hours devoted to examining slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5645 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined for two of two Technical Supervisors 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 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours two of two Technical Supervisors spent examining cytology 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 3. During an interview on November 16, 2022 at 9:10 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

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 review of laboratory policies and procedures, lack of laboratory workload records and interview with the Cytotechnologist, one of one Cytotechnologists failed to provide documentation of the total number of slides examined in the laboratory, for each 24 hour period in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5645 Findings include: 1. The Survey Team requested and the Cytotechnologist failed to provide records of the number of slides examined for each 24-hour period of slide examination for 2020, 2021 and to the date of the survey in 2022. 2. During an interview on November 16, 2022 at 10:00 AM, the Cytotechnologist confirmed these findings.

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 policies and procedures, lack of laboratory workload records and interview with the Cytotechnologist, one of one Cytotechnologists failed to provide documentation of the total amount of hours spent examining slides for each 24 hour period in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5645 Findings include: 1. The Survey Team requested and the Cytotechnologist failed to provide records of the number of hours spent examining slides for each 24-hour period in 2020, 2021 and to the date of the survey in 2022. 2. During an interview on November 16, 2022 at 10:00 AM, the Cytotechnologist confirmed these findings.

D9999

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