

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645099	(X3) Date Survey Completed 06/22/2022
Name of Provider or Supplier Bernhardt Laboratories	Street Address, City, State 3728 Philips Hwy Suite 64, Jacksonville, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of annual gynecologic cytology proficiency testing (PT) program instructions, annual gynecologic cytology PT participation records and interviews with the PT Proctor, Acting General Manager and Cytology Supervisor Facility B (CLIA #10D0645099) failed to meet the specified requirements for gynecologic cytology PT examination in 2020, 2021 and 2022. Facility B referred a gynecologic cytology PT set consisting of ten slides to Facility A (CLIA #10D2144349) in 2021 and 2022 (refer to D2013). The laboratory failed to administer the annual gynecologic cytology PT as required by the PT program's instructions in 2020, 2021 and 2022 (refer to D2015). Findings include: 1. Facility B referred a gynecologic cytology PT set consisting of ten slides to Facility A by courier for analysis by Technical Supervisor C in 2021 and 2022 (refer to D2013). a. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor. b. During an interview on June 22, 2022 at 9:14 AM these findings were confirmed by Acting General Manager. 2. The laboratory failed to follow the PT program's instructions in 2020, 2021 and 2022 (refer to D2015). a. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor.</p>

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on review of PT provider instructions, annual gynecologic cytology PT participation records, interviews with the PT Proctor and Acting General Manager and review of PT policies and procedures Facility B referred a gynecologic cytology PT set consisting of 10 slides to Facility A for analysis by Technical Supervisor C in 2021 and 2022. The PT Proctor failed to sign the result form within the timeframe established by the PT program for eight of eleven result forms in 2020 and eleven of twelve result forms in 2021. The PT proctor failed to sign the result form as required by the PT program for one of two Technical Supervisors in 2022. Findings include: 1. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: -"Testing material is not allowed to travel between sites." a. During an interview on June 21, 2022 at 9:50 AM PT Proctor stated: -Facility B referred a PT set consisting of ten slides to Facility A for analysis by Technical Supervisor C in 2021 and 2022. b. During an interview on June 22, 9:14 AM these findings were confirmed by Acting General Manager. 2. The Survey Team reviewed annual gynecologic cytology PT participation records for 2021. Facility B referred a gynecologic cytology PT set consisting of 10 slides to Facility A for analysis by Technical Supervisor C in 2021. a. Technical Supervisor C tested on the 10-slide testing slideset #34459 on February 9, 2021. 3. The Survey Team reviewed annual gynecologic cytology PT participation records for 2022. Facility B referred a gynecologic cytology PT set consisting of 10 slides to Facility A for analysis by Technical Supervisor C in 2022. a. Technical Supervisor C tested on the 10-slide testing slideset #34364 on February 9, 2022. 4. During an interview on June 21, 2022 at 9:50 AM PT Proctor stated: -A 10-slide gynecologic cytology PT set was sent by Facility B to Facility A by courier for analysis by Technical Supervisor C in 2021 and 2022. -Technical Supervisor C reviewed the slides and completed the PT result form at Facility A then returned the slides and result form by courier to Facility B the following day in 2021 and 2022. - There was no proctor present during PT examination at Facility A in 2021 and 2022. - "We treat as a routine patient sample." a. During an interview on June 22, 2022 at 9:14 AM these findings were confirmed by Acting General Manager. 5. The laboratory failed to follow procedure PROFICIENCY TESTING which stated: -"It is prohibited to accept PT from another laboratory or refer PT specimen to another laboratory." a.

During an interview on June 22, 2022 at 9:14 AM, the Acting General Manager confirmed that FACILITY B referred PT specimens to FACILITY A for analysis by Technical Supervisor C at FACILITY A.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of annual gynecologic cytology PT program instructions, annual gynecologic cytology PT participation records and interviews with the PT Proctor, Acting General Manager and Cytology Supervisor the laboratory failed to administer and document the PT examination as required by the PT provider's laboratory proctor instructions in 2020, 2021 and 2022. Findings Include: 1. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: - "Monitor the test environment." a. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor who stated: -There was no proctor at Facility A during gynecologic cytology PT events in 2021 and 2022. 2. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: - "Observe the time and collect all test materials from the examinee after 2 hours, whether or not he or she has completed the test." a. During an interview on June 21, 2022 at 9:50 AM PT Proctor stated: -Technical Supervisor C examined the PT slides and completed the result form at Facility A then returned the materials by courier on the following day in 2021 and 2022. 3. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: -"The testing material can only be opened by a passing proctor; the director needs to notify all staff once the testing material is received by the laboratory, but only a passing proctor is allowed break the security seal and check the contents of the package." a. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor who stated: -Upon receipt into the laboratory PT Proctor opened the package and inspected its contents with Cytology Supervisor. -Cytology Supervisor was not a proctor. b. During an interview on June 21, 2022 at 5:05 PM these findings were confirmed by Cytology Supervisor. 4. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: -"Record the examinees stop time on the result form. Have the examinee sign in the area marked 'Examinee signature'. Sign your name by 'Proctor signature.'" a. The Survey Team reviewed annual gynecologic cytology PT result forms for 2020. PT Proctor failed to sign the result form within the timeframe established by the PT program for eight of eleven result forms in 2020. 2020 CAP

GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULT FORMS include: - Kit #32740356, Slideset #34431 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740357, Slideset #34430 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740358, Slideset #34430 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740359, Slideset #34430 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740360, Slideset #34430 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740361, Slideset #34423 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32740362, Slideset #34423 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 -Kit #32747323, Slideset #34423 Ten slides Examinee signature date: 10/05/2020 PT Proctor signature date: 10/07/2020 b. The Survey Team reviewed annual gynecologic cytology PT result forms for 2021. PT Proctor failed to sign the result form within the timeframe established by the PT program for eleven of twelve result forms in 2021. 2021 CAP GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULT FORMS include: -Kit #33843584, Slideset #34461 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #33843585, Slideset #34461 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #33843586, Slideset #34461 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #33843587, Slideset #34460 Ten slides Examinee signature date: 02/09/2021 PT Proctor signature date: 02/10/2021 -Kit #33843588, Slideset #34460 Ten slides Examinee signature date: 02/09/2021 PT Proctor signature date: 02/10/2021 -Kit #33843589, Slideset #34460 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #33843590, Slideset #34460 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #33843592, Slideset #34459 Ten slides Examinee signature date: 02/09/2021 PT Proctor signature date: 02/10/2021 -Kit #33843593, Slideset #34459 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #34749630, Slideset #34459 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 -Kit #34749631, Slideset #34459 Ten slides Examinee signature date: 02/08/2021 PT Proctor signature date: 02/10/2021 c. The Survey Team reviewed annual gynecologic cytology PT result forms for 2022. PT Proctor failed to sign the result form as required by the PT program for one of two Technical Supervisors in 2022. Technical Supervisor includes: -Technical Supervisor C 2022 CAP GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULT FORM includes: -Kit #35112812, Slideset #34364 Ten slides Examinee signature date: 02/09/2022 PT Proctor signature and date were blank. d. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor who stated: - Result forms were not faxed to the PT program until after PT Proctor signed the result forms. -"I'm not sure who faxed it to CAP", after being shown the result form for Technical Supervisor C for 2022. 5. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: -"Fax the result form immediately after the examinee is done. Do not wait until the end of the test event to fax the result form." a. During an interview on June 21, 2022 at 9:50 AM these findings were confirmed by PT Proctor who stated: -PT Proctor batched and faxed the individual result forms together.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, observation and interview with the Cytoprep Technician the laboratory failed to follow written policies and procedures to ensure positive patient identification during specimen processing and staining. The laboratory failed to label one of one nongynecologic cytology slide with a complete accession number and other unique identifier during specimen processing on June 21, 2022. Findings include: 1. The procedure GENERAL NON-GYN PREPARATION STEPS stated: -"Label with pencil the accession number and other identification on the frosted ends of each slide." 2. During observation of specimen processing and staining on June 21, 2022 at 10:26 AM the Survey Team identified one of one nongynecologic cytology slides without a complete accession number and other unique identifier. Specimen includes: Specimen Identification: Written on Specimen Slide: -C22-000286 (Patient last name), 286 3. During an interview on June 21, 2022 at 10:26 AM these findings were confirmed by Cytoprep Technician who stated that only the patient last name and partial accession number are written on slides for nongynecologic specimens processed on the Hologic ThinPrep 2000 Processor. The label with the full accession number is not placed on the slide until after staining is completed. 4. During an interview on June 21, 2022 at 4:15 PM these findings were reviewed with Laboratory Director/Technical Supervisor A, Acting General Manager and Cytology Supervisor.

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 61 laboratory policies and procedures and interview with the Cytology Supervisor 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 process for gynecologic cytology specimen processing using the Hologic ThinPrep 5000 Processor. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for gynecologic cytology specimen processing using the Hologic ThinPrep Imaging System. 3. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Cytology Supervisor.

D5629

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

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Acting General Manager the laboratory failed to establish written policies and procedures for an annual statistical evaluation of two of three required nongynecologic cytology statistics. The laboratory failed to document two of three required nongynecologic statistics for 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of two of three required nongynecologic cytology statistics. Statistics include: -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide two of three required nongynecologic annual statistics for 2021. Statistics include: -The number of specimens processed by specimen type - The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Acting General Manager. B. Based on review of laboratory policies and procedures, laboratory records and interview with the Acting General Manager and Cytology Supervisor the laboratory failed to follow written policies and procedures for an annual statistical evaluation of six of six required gynecologic cytology statistics. The laboratory failed to document an evaluation of six of six required gynecologic statistics in 2021. Findings include: 1. The procedure ANNUAL STATISTICS stated: -"For cytopathology cases, statistical records are maintained on the number of cases of the following cytopathology results: 1. The total number of cytology cases (Gyn and Non-Gyn) 2. The total number of diagnostic category (NEG, ASCUS, LGSIL, HGSIL) by preparation type 3. The total number of significant cytology/histology discrepancies 4. Cases for which histopathology results are available to compare with malignant or high-grade squamous intraepithelial lesion (HGSIL) cytopathology results 5. Total number of negative cases rescreened before

signout 6. Cases for which the rescreen resulted in reclassification as premalignant or malignant 7. The number of unsatisfactory specimens 8. Each individual cytologist's statistics are compared against the lab's overall statistical values." 2. The Survey Team requested and the laboratory failed to provide six of six required gynecologic cytology statistics in 2021. Statistics include: -Number of cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) -Number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -Number of gynecologic cases where cytology and histology are discrepant -Number of 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 3. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Acting General Manager. Acting General Manager stated that the annual statistics provided by the laboratory for 2021 included cases that were signed out at Facility A and Facility B.

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, cytology slide preparations and corresponding final test reports and interview with 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 and report three of three gynecologic cytology slide preparations from April 4, 2022 to April 19, 2022 as "Unsatisfactory for Evaluation". Findings include: 1. The procedure ANNUAL STATISTICS stated: -"An adequate Liquid Base Specimen has an estimated minimum of approximately 5000 well-preserved well visualize squamous epithelial cells. NOTE: THE ESTIMATE CAN BE MADE BY COUNTING 10 FIELDS WITH 8-10 SQUAMOUS CELLS PER FIELD TO ACHIEVE APPROXIMATE COUNT OF 5000 CELLS." 2. The laboratory failed to identify and report three of three gynecologic cytology slide preparations from April 4, 2022 to April 19, 2022 as "Unsatisfactory for Evaluation" due to insufficient numbers of required squamous cells. Cases include: -P2022-011924 -P2022-011946 -P2022-013996 3. During an interview on June 22, 2022 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.

D5657

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

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

This STANDARD is not met as evidenced by:
Based on the review of laboratory policies and procedures and interview with the Acting General Manager the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Acting General Manager.

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 PT policies and procedures, annual gynecologic cytology PT participation 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 that the laboratory followed the requirements of the annual gynecologic cytology PT program (refer to D6089 and D6090); and failed to follow manufacturer's instructions to ensure testing personnel received appropriate training to perform Hologic gynecologic cytology testing (refer to D6102).

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of annual PT program instructions, annual gynecologic cytology PT participation records and interviews with the PT Proctor, Acting General Manager and Cytology Supervisor the Laboratory Director failed to ensure testing of samples for the gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to administer the PT events as required by the PT program's instructions. Facility B referred a gynecologic cytology PT set consisting of 10 slides to Facility A for analysis by Technical Supervisor C in 2021 and 2022. The PT Proctor failed to sign the result form within the timeframe established by the PT program for eight of eleven result forms in 2020 and eleven of twelve result forms in 2021. The PT proctor failed to sign the result form as required by the PT program for one of two Technical Supervisors in 2022. The laboratory failed to administer the PT examination as required by the PT provider's laboratory proctor instructions in 2020, 2021 and 2022. Cross refer to D2013 and D2015 Findings include: 1. Facility B referred a gynecologic cytology PT set consisting of 10 slides to Facility A for

analysis by Technical Supervisor C in 2021 and 2022 (refer to D2013). 2. The Laboratory Director failed to ensure the laboratory administered the PT events as required by the PT program's instructions in 2020, 2021 and 2022 (refer to D2015).

D6090

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of annual gynecologic cytology PT program instructions, annual gynecologic cytology PT participation records and interviews with the PT Proctor and Acting General Manager the Laboratory Director failed to ensure the results of the annual gynecologic cytology PT were returned within the timeframe established by the gynecologic cytology PT program in 2020, 2021 and 2022. The PT Proctor failed to sign the result form within the timeframe established by the PT program for eight of eleven result forms in 2020 and eleven of twelve result forms in 2021. The PT proctor failed to sign the result form as required by the PT program for one of two Technical Supervisors in 2022. Cross refer to D2015 Findings include: 1. The Laboratory Director failed to ensure the results were returned within the timeframe established by the PT program in 2020, 2021 and 2022 (refer to D2015).

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

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

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

This STANDARD is not met as evidenced by:

A. Based on review of manufacturer's instructions, laboratory records and interview with Laboratory Director/Technical Supervisor A the Laboratory Director failed to ensure that two of two Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020, 2021 and to the date of the survey in 2022. 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 Director failed to provide the required morphology certification for two of two Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Laboratory Director/Technical Supervisor A. B. Based on review of manufacturer's instructions, laboratory records and interview with Cytology Supervisor the Laboratory Director failed to ensure that one of five Cytotechnologists

who evaluated Hologic ThinPrep Pap Tests using the Hologic Review Scope had received the appropriate training prior to reporting patient specimens in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The HOLOGIC THINPREP IMAGING SYSTEM REVIEW SCOPE OPERATOR'S MANUAL stated: -"Only personnel who have been appropriately trained should operate the ThinPrep Imaging System Image Processor or Review Scope." 2. The Survey Team requested and the Laboratory Director failed to provide the required review scope certification for one of five Cytotechnologists who performed diagnostic interpretations of Hologic ThinPrep Pap Tests using the Hologic Review Scope in 2020, 2021 and to the date of the survey in 2022. Cytotechnologist includes: -Cytotechnologist A 3. During an interview on June 21, 2022 at 4:15 PM these findings were confirmed by Cytology Supervisor.

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 the microscopic review of 236 negative gynecologic cytology cases/slides from April 1, 2022 through April 22, 2022 and confirmation by Technical Supervisor A on June 22, 2022 the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. 1. P2022-011946 04/05/2022 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory, Scant Cellularity TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory, Bloody Smear, Radiation Changes 2. P2022-011924 04/04/2022 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory, Scant Cellularity TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory, Scant Cellularity (Menstrual Smear) 3. P2022-013996 04/19/2022 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS; Unsatisfactory, Scant Cellularity TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory, Scant Cellularity (EMs unknown LMP)

D9999

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