Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2007457	02/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates Ne Baptist Hospital	8811 Village Drive, San Antonio, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on the review of laboratory records and interviews it was determined that the Facility A laboratory (CLIA #45D2007457) failed to enroll in an approved cytology proficiency testing (PT) program for gynecologic examination (refer to D2001). The cumulative effect of this systemic problem resulted in the laboratory's failure to meet certification requirements to accurately and reliably evaluate patients gynecologic cytology specimen slides for 2016, 2017 and to the date of the survey in 2018.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;

	This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that the Facility A laboratory failed to enroll in an approved cytology PT program for the years 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide records of enrollment in an approved cytology PT program for 2016, 2017 and to the date of the survey in 2018. 2. During an interview on 2/28/18 at 9:00 AM, the Facility B (CLIA #45D0505003) Laboratory Manager stated that the Facility A laboratory was not enrolled in an approved cytology PT program for 2016, 2017 and to the date of the survey in 2018. The Facility B Laboratory Manager further stated that Facility A staff participated in the PT at Facility B. 3. The Facility A Laboratory Director/Technical Supervisor #1 confirmed these findings during an interview on 2/28/18 at 1:45 PM .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of written laboratory policies and procedures, laboratory records, and interview, it was determined that the Facility A laboratory failed to establish written policies and procedures to assess the competency of seven of seven Technical Supervisors who performed the microscopic evaluation of cytology specimens in 2016 and 2017. Findings include: 1. The written procedure titled PROFESSIONAL COMPETENCY OF PATHOLOGISTS (not signed or dated by the Facility A Laboratory Director/Technical Supervisor #1) stated that the "pathologists participate in quality assurance activities as required by institutional policies to assure competency." The written procedure did not detail how these quality assurance activities were performed and documented for seven of seven Technical Supervisors in 2016 and 2017. 2. The Survey Team requested and the Facility A laboratory failed to provide records of competency assessment for seven of seven Technical Supervisors that performed the microscopic examination and reporting of cytology test results in 2016 and 2017. Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #5 Technical Supervisor #7 Technical Supervisor #8 Technical Supervisor #9 Technical Supervisor #10 3. During an interview on 2/28 /18 at 1:45 PM the Facility A Laboratory Director/Technical Supervisor #1 confirmed these findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by:

	Based on the review of written laboratory policies and procedures and interview it was determined that the Facility A laboratory failed to establish written policies or procedures to document the conditions required for the transportation of cytology specimen slides from Facility A to Facility B for the years 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide written policies and procedures for the documentation of the conditions required for the transport of cytology slides between Facility A and Facility B. 2. All cytology specimen slides were accessioned, processed, stained and examined by cytotechnologists at Facility B. Slides that required a Technical Supervisor review were then transported from Facility B to Facility A for final microscopic examination and reporting by a Technical Supervisor. All slides were transported back to Facility B for storage. 3. The Facility B Laboratory Manager and the Facility A Laboratory Director/Technical Supervisor #1 confirmed these findings during an interview on 2/28/18 at 1:45 PM.
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 four written laboratory procedures and interview it was determined that the Facility A laboratory failed to have two written policies and procedures. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide a written policy or procedure to describe the laboratory's gynecologic cytology PT program. 2. The Survey Team requested and the Facility A laboratory failed to provide a written policy or procedure to describe the laboratory's slide storage and retention process. 3. These findings were confirmed by the Facility A Laboratory Director/Technical Supervisor #1 during an interview on 2/26/18 at 3: 45 PM.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on the review of four written laboratory procedures and interview it was determined that the Facility A laboratory failed to ensure that three written procedures were approved, signed, and dated by the Laboratory Director. Findings include: 1. The Facility A Laboratory Director/Technical Supervisor #1 failed to sign and date three written procedures. Procedures include: - Microscopic Examination of Anatomic Pathology Specimens - Professional Competency of Pathologists - Quality Control and Quality Assurance. 2. These findings were confirmed by the Facility A Laboratory Director/Technical Supervisor #1 during an interview on 2/26/18 at 12:10 PM.
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 the review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test, and interviews it was determined that the Facility A laboratory failed to ensure that three of seven Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Findings include: 1. The Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, CYTYC Part Number 70354-001, states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." a. The Survey Team requested and the Facility A laboratory failed to provide morphology training records for three of seven Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. There were no training records for: - Technical Supervisor #2 - Technical Supervisor #5 - Technical Supervisor #8. 2. These findings were confirmed by the Facility B Laboratory Manager during an interview on 2/28/18 at 9:00 AM and by the Facility A Laboratory Director/Technical Supervisor #1 during an interview on 2/28/18 at 1:45 PM. B. Based on the review of the Becton Dickinson (BD) SUREPATH IMPLEMENTATION GUIDE, review of certification records for the BD SurePath Pap Test, and interviews it was determined that the Facility A laboratory failed to ensure that six of seven Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the BD SurePath Pap Test, according to the manufacturer's instructions. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states that the "BD Surepath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD Surepath prepared slides. a. The Survey Team requested and the Facility A laboratory failed to provide morphology training records for six of seven Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. There were no training records for: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #5 - Technical Supervisor #7 - Technical Supervisor #9 - Technical

	Supervisor #10. 2. These findings were confirmed by the Facility B Laboratory Manager during an interview on 2/28/18 at 9:00 AM and by the Facility A Laboratory Director/Technical Supervisor #1 during an interview on 2/28/18 at 1:45 PM.
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 the review of written laboratory policies and procedures and interviews it was determined that the Facility A laboratory failed to establish written policies and procedures to ensure that the cytology diagnosis and the histopathology diagnosis were compared to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide written policies and procedures to describe the laboratory's process to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. The Facility A laboratory did not perform the comparison of cytology and histopathology reports. 3. The Facility B Laboratory Manager stated during a phone interview on 2/26/18 at 12:00 PM that the comparison of cytology reports and corresponding histopathology reports was performed at Facility B. 4. The Facility A Laboratory Director/Technical Supervisor #1 confirmed during an interview on 2/26/18 at 3:45 PM that there were no laboratory procedures to describe the laboratory's process to ensure that the review, along with the cause for discrepancies, was performed and documented.
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 the review of written laboratory policies and procedures and interviews it was determined that the Facility A laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current High Grade Lesion (HSIL) or Malignancy was performed. Findings include: 1. The

	Survey Team requested and the Facility A laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or Malignancy. 2. The Facility A laboratory did not perform the review of previous negative gynecologic specimens from patients with a current HSIL or Malignancy. 3. The Facility B Laboratory Manager stated in a phone interview on 2/26/18 at 12:00 PM that the review of previous negative slides was performed at Facility B. a. The Facility A Laboratory Director/Technical Supervisor #1 confirmed during an interview on 2/26/18 at 3:45 PM that Facility B performed the search and review of all prior negative gynecologic specimens. 4. The Facility A Laboratory Director/Technical Supervisor #1 confirmed during an interview on 2/26 /18 at 3:45 PM that there were no written laboratory procedures to describe the laboratory's process to ensure the review was performed and documented.
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 the review of written laboratory policies and procedures, laboratory records, and interviews it was determined that the Facility A laboratory failed to establish written policies and procedures to maintain statistics for a program to include an annual evaluation of six of six required statistics. The laboratory failed to provide documentation for five of six statistics in 2016 and four of six statistics in 2017. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide written policies or procedures for an annual statistical laboratory evaluation of six of six required statistics for cytology specimens. 2. The Survey Team requested and the Facility A laboratory failed to provide documentation that the required annual statistics had been compiled and evaluated in 2016 for five of six statistics: - The number of patient cases reported by diagnosis, (including the number reported as unsatisfactory for diagnostic interpretation); -The number of specimens processed by specimen type; - Gynecologic cases where cytology and histology are discrepant; - Gynecologic cases with a diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; - 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. The Survey Team requested and the Facility A laboratory failed to provide documentation that the required annual statistics had been compiled and evaluated in 2017 for four of six statistics: - The number of patient cases reported by diagnosis (including the number

	reported as unsatisfactory for diagnostic interpretation); - Gynecologic cases where cytology and histology are discrepant; - Gynecologic cases with a diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; - 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. 4. The Facility A laboratory did not perform the annual statistical evaluation. 5. The Facility B Laboratory Manager stated in an interview on 2 /28/18 at 9:00 AM that the statistical analysis was performed at Facility B. 6. These findings were reviewed with and confirmed by the Facility B Laboratory Manager and the Facility A Laboratory Director/Technical Supervisor #1 during an interview on 2 /28/18 at 1:45 PM.
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 written laboratory policies and procedures, laboratory records, and interviews it was determined that the Facility A laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Facility A Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance and oversight with applicable regulations (refer to D6079); failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT event (refer to D6088); failed to ensure that three of seven Technical Supervisors had received appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test and that six of seven Technical Supervisors had received appropriate training to evaluate the BD SurePath Pap Test (refer to D6102); and failed to ensure the competency of seven of seven Technical Supervisors who reported cytology test results (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on the review of written laboratory policies and procedures, laboratory records, and interviews it was determined that the Facility A Laboratory Director (who was also Technical Supervisor #1) failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5311, D5403, D5407, D5411, D5623, D5625, and D5629
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that the Facility A Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT event for the years 2016, 2017 and prior to the date of the survey in 2018. Cross refer to D2001
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 the review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, the BD SUREPATH IMPLEMENTATION GUIDE, review of certification records, and interviews it was determined that the Facility A Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. Three of seven Technical Supervisors had not received the appropriate training to evaluate the ThinPrep Pap Test. Six of seven Technical Supervisors had not received the appropriate training to evaluate the BD SurePath Pap Test. Cross Refer to D5411
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by:

	Based on the review of written laboratory policies and procedures, laboratory records, and interview it was determined that the Facility A Laboratory Director failed to ensure that policies and procedures were established to monitor the competency of seven of seven Technical Supervisors that performed the microscopic evaluation and reporting of gynecologic cytology test results in 2016 and 2017. Cross refer to D5209
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review, glass slides and corresponding test reports, and interviews it was determined that the Technical Supervisor failed to verify the accuracy of 42 gynecologic test reports (refer to D6115) and failed to ensure the competency of one Technical Supervisor (refer to D6120). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
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 review of 1459 consecutive gynecologic cases (1467 slides) from February 2016 to July 2016 and October 2016 to November 2017 and confirmation by the Survey Team Pathologist on March 30, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of 42 gynecologic tests. 1. YZ427786 3/23/17 Imaged ThinPrep Pap Test (I-TPPT) FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 2. YZ149455 3/8/17 SurePath Pap Test (SPPT) FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 3. YU409563 4/14/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 4. YU424560 4/14/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 5. YU197078 4/1/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 6. YU091032 3/24/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 7. YV150545 6/1/16 Imaged SurePath Pap Test (I-SPPT) FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion

/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 8. YV081045 5/31/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Endocervical Cells favor Neoplasia 9. YU501598 4/21/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Endometrial Cells Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 10. YY761873 2/7/17 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 11. YY822905 2/9/17 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 12. YZ474614 3/30/17 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 13. YU884149 5/12/16 TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 14. YU708311 5/6/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 15. YU810145 5/6/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion Rare Atypcial Squamous Cells, cannot rule out High Grade Squamous Intraepithelial Lesion 16. YU017465 5/3/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 17. YU862778 5/11/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 18. YU512751 4/21/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 19. YU465938 4/18/16 TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 20. YU501032 4/21/16 TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 21. YU282606 4/5/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 22. YU437380 4/15/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 23. YU269220 4/5/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 24. YT821149 3/8/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 25. YV221075 6/6/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 26. YV252518 6/7/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM

	PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion Atypical Squamous Cells, cannot rule out High Grade Squamous Intraepithelial Lesion 27. YV351875 6/14/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 28. YV400666 6/24/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion /Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 29. YV474946 6/20/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 30. YV077795 5/25/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 31. YV198262 6/3/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 32. YV313730 6/13/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 33. YV445711 6/21/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 34. YZ427759 3/23/17 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 35. YU622403 5/3/16 SPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 36. YU322309 4/7/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 37. YU985615 5/19/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 38. YV200469 6/3/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 39. YT876782 3/10/16 I-TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Low Cellularity 40. YT853536 3/8/16 TPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Low Cellularity 41. YU746017 6/22/16 I-SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Low Cellularity 42. YV583305 7/12/16 Conventional Smear FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Obscuring Inflammation and Blood
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of gynecologic cytology glass slides and corresponding test reports and interviews it was determined that Facility A Technical Supervisor #1 failed to identify training needs and failed to ensure the competency of Technical Supervisor #7 to accurately report gynecologic cytology test results in 2016 and 2017. Cross Refer to D6115 Findings include: 1. The Survey Team Pathologist confirmed forty-two discrepant gynecologic cytology cases. a. Thirty-seven of the forty-two cases identified were reported by Technical Supervisor #7. 2. Technical Supervisor #7 failed to accurately report three cases of Atypical Squamous Cells, cannot rule out High Grade Squamous Intraepithelial Lesion (ASC-H); nineteen cases of Low Grade Squamous Intraepithelial Lesion (LSIL); ten cases of High Grade Squamous Intraepithelial Lesion (HSIL); two cases of Atypical Glandular Cells (AGC); and three Unsatisfactory (UNSAT) cases. ASC-H cases include: YV198262 YV313730 YV445711 LSIL cases include: YY761873 YY822905 YZ474614 YU884149 YU708311 YU810145 YU017465 YU862778 YU512751 YU465938 YU501032 YU282606 YU437380 YU269220 YT821149 YV221075 YV252518 YV351875 YV400666 HSIL cases include: YZ427786 YZ149455 YU409563 YU424560 YU197078 YU091032 YV150545 YZ427759 YU622403 YV200469 AGC cases include: YV081045 YU501598 UNSAT cases include: YT876782 YT853536 YU746017 3. The Facility A Laboratory Director/Technical Supervisor #1 confirmed in an interview on 3/30/18 at 10:45 AM that the Facility A Laboratory Director /Technical Supervisor #1 failed to identify training needs and failed to ensure the competency of Technical Supervisor #7 to accurately report gynecologic cytology test results.
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