Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D2002387	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Consultants, Pc Physician Office Lab	900 E Broadway, Bismarck, ND	

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 review of laboratory records and interviews it was determined that Facility B (CLIA 35D2002387) failed to enroll in an approved cytology proficiency testing (PT) program for gynecologic examination (refer to D2001); failed to meet the specified requirements for testing of samples for the gynecologic cytology PT program by engaging in inter-laboratory communications with Facility A (CLIA 35D0408903) prior to the date the proficiency testing results were reported to the program (refer to D2011); failed to examine cytology PT samples (slides) received from the PT program as required by the PT provider; and failed to meet the specified requirements in accordance with 493.801(b)(4) including the failure to notify CMS of the receipt of PT samples (slides) from another laboratory (refer to D2013). 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 2017 and 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 interview it was determined that Facility B failed to enroll in an approved cytology PT program for 2017 and 2018. Findings include: 1. The Survey Team requested and Facility B failed to provide records of enrollment in an approved cytology PT program for 2017 and 2018. 2. During an interview on October 21, 2019 at 10:00 AM, the Laboratory Director/Technical Supervisor A stated that Facility B was not enrolled in an approved cytology PT program for 2017 and 2018.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on interviews and review of PT records it was determined that Facility B failed to meet the specified requirements for testing of samples for the gynecologic cytology PT program by engaging in inter-laboratory communications with Facility A prior to the date the proficiency testing results were reported to the program in 2017 and 2018. Findings include: 1. During an interview on October 21, 2019 at 10:00 AM, the Laboratory Director/Technical Supervisor A stated that there were two laboratories under the pathology group that performed gynecologic cytology testing and that each facility had a separate cytology CLIA certificate. The Laboratory Director/Technical Supervisor A further stated: a. Facility A was the main laboratory where cytology specimens were accessioned, processed and screened by Cytotechnologists. Cases requiring technical supervisory review were sent to Facility B. b. The PT samples (slides) were received at Facility A. c. Staff B (located at Facility A) was the proctor and administered the PT test to the Cytotechnologists at Facility A, submitted the test result forms and cleaned the slides. d. The PT samples (slides) were referred from Facility A to Facility B for testing. e. A Cytotechnologist from Facility A went to Facility B to screen and dot the slides for the Technical Supervisors at Facility B. f. Staff B administered the PT test to the Technical Supervisors and submitted the test results. 2. During an interview on October 22, 2019 at 3:00 PM, Technical Supervisor D stated that Facility A and Facility B had "always done it (PT testing) that way." 3. During an interview on October 22, 2019 at 3:15 PM, Technical Supervisor E stated "thought we could take the PT like we do the rest of gyn testing." 4. During an interview on October 23, 2019 at 8:45 AM, Staff B stated that Staff B administered the PT test to the Cytotechnologists at Facility A and submitted the test results. Staff

	B then transported the PT samples (slides) to Facility B and administered the test to the Technical Supervisors. 5. The Survey Team reviewed PT testing records from 2017 for six Technical Supervisors that took the PT test event at Facility B. The PT testing records stated the CLIA number was for Facility A. a. Three of six Technical Supervisors tested on slideset #34426. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor C - Technical Supervisor E b. Three of six Technical Supervisors tested on slideset #34423. Technical Supervisors include: - Technical Supervisor B - Technical Supervisor D - Technical Supervisor F 6. The Survey Team reviewed PT testing records from 2018 for five Technical Supervisors that took the PT test event at Facility B. The PT testing records stated the CLIA number was for Facility A. a. Three of five Technical Supervisors tested on slideset #33989. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor C - Technical Supervisor D b. Two of five Technical Supervisors tested on slideset #34006. Technical Supervisors include: - Technical Supervisor B - Technical Supervisor E 7. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A confirmed Facility B received PT samples (slides) improperly referred from Facility A for testing and Facility B failed to notify CMS that gynecologic cytology samples (slides) were received from another laboratory for testing. a. There was inter-laboratory communication between Facility B and Facility A during participation in gynecologic cytology PT testing.
D2013	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 interviews and review of PT records it was determined that Facility B failed to meet the specified requirements for testing of samples for the gynecologic cytology PT program in 2017 and 2018, including the receipt of PT samples (slides) from another laboratory for testing. Cross refer to D2011
D5032	CYTOLOGY CFR(s): 493.1221 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.

	This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that Facility B failed to establish written procedures for three laboratory processes (refer to D5403); failed to ensure that one of five Technical Supervisors had received the appropriate training to evaluate Hologic ThinPrep gynecologic specimens (refer to D5411); failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy (refer to D5625); failed to establish policies and procedures for the annual evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual gynecologic statistics and two of three required annual nongynecologic statistics (refer to D5629); failed to follow written policies and procedures to ensure that Facility B would maintain records of the total number of hours spent examining slides (refer to D5645); failed to establish written policies and procedures to ensure that final gynecologic reports signed by Technical Supervisors reflected an electronic signature authorized by the Technical Supervisor (refer to D5651); failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory, and failed to identify and report one gynecologic cytology case as being "Unsatisfactory for Evaluation" (refer to D5655); and failed to maintain the dates of all testing (refer to D5787). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that Facility B failed to establish written policies and procedures to assess the competency of five of five Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures to describe the laboratory's process for assessing the diagnostic competency of five of five Technical Supervisors. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 2. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that Facility B failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross refer to D5209
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 18 laboratory policies and procedures and interviews it was determined that Facility B failed to establish written procedures for three laboratory processes. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures to describe the storage of gynecologic cytology slides. a. During an interview on October 21, 2019 at 8:50 AM, the Laboratory Director/Technical Supervisor A stated that Facility B's gynecologic cytology slides were stored at Facility A. 2. The Survey Team requested and Facility B failed to provide written policies and procedures to describe the transport and receipt of cytology specimens between Facility A and Facility B. 3. The Survey Team requested and Facility B failed to provide written policies and procedures to describe the process for sending cytology slides to other facilities for consultation. a. During an interview on October 23, 2019 at 9:25 AM, Staff A described Facility B's process for sending nongynecologic slides to other laboratories for outside consultation: The slides were retrieved from Facility A and sent to Facility B. Facility B entered case information into a spreadsheet and the laboratory information system (LIS) and the case was sent out. When the case was returned Facility B entered the return information into the spreadsheet and LIS. Staff A further stated that Facility A was the responsible laboratory for sending gynecologic cases to other laboratories for outside consultation. b. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A stated that Facility B was responsible for sending

	gynecologic and nongynecologic cases to other laboratories for outside consultation. 4. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director /Technical Supervisor A confirmed these findings.
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: Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of laboratory records and interview it was determined that Facility B failed to ensure that one of five 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 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 Facility B failed to provide the training records for one of five Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests during 2017, 2018 and to the date of the survey in 2019. Technical Supervisor includes: - Technical Supervisor A 2. During an interview on October 21, 2019 at 2:40 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interviews and laboratory records it was determined that Facility B failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures to describe Facility B's current process for the search and review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm reported by the laboratory. 2. During

	an interview on October 21, 2019 at 4:20 PM, the Laboratory Director/Technical Supervisor A stated that Facility A performed the search and review of prior negative gynecologic specimens. The Laboratory Director/Technical Supervisor A further stated that if there were prior negative specimens Facility A staff would complete a form titled REVIEW OF PRIOR NEGATIVE SPECIMENS. If there were no prior negative specimens, Facility A staff would document that on the test requisitions. 3. During an interview on October 22, 2019 at 1:15 PM, the Cytology Supervisor stated that Facility A staff would write "no prior negatives" on the test requisitions when a search was performed and there were no prior negative specimens. The Cytology Supervisor further stated that the comment "HSIL review" on the test requisitions did not indicate that there were no prior negative specimens. 4. The Survey Team reviewed laboratory records titled REVIEW OF PRIOR NEGATIVE SPECIMENS and test requisitions for 52 cases reported as HSIL or malignancy from January through August 2019. a. Seventeen of 52 cases did not have a documented search for prior negative specimens on the test requisition. Cases include: - GYN19-753 - GYN19-834 - GYN19-1247 - GYN19-2254 - GYN19-2309 - GYN19-2967 - GYN19-2993 - GYN19-3472 - GYN19-3518 - GYN19-5585 - GYN19-5817 - GYN19-6145 - GYN19-6399 - GYN19-8556 - GYN19-8578 - GYN19-8691 - GYN19-8695 b. One of 52 cases had a prior negative specimen that was not identified and reviewed. Case includes: - GYN19-3518 5. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that Facility B failed to establish written policies and procedures for the annual evaluation and comparison of six of six required statistics for gynecologic cytology specimens. Facility B failed to document six of six required statistics for gynecologic cytology specimens in 2017 and 2018. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures for an annual statistical evaluation of six of six required statistics for gynecologic specimens. 2. The Survey Team requested and Facility B failed to provide records of the six required gynecologic statistics for 2017 and 2018 for Facility B. 3. During interviews on October 21, 2019 at 9:05 AM and 11:55 AM, the Laboratory Director/Technical Supervisor A confirmed these findings and stated that Facility B's statistics included cases reported at Facility A. B. Based on review of laboratory policies and procedures, laboratory records and interviews it was

	determined that Facility B failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic cytology specimens. Facility B failed to document two of three required statistics for nongynecologic cytology specimens in 2017 and 2018. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic specimens: a. The number of nongynecologic cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. The Survey Team requested and Facility B failed to provide records of two of three required nongynecologic statistics for 2017 and 2018 for Facility B: a. The number of specimens processed by specimen type; b. The number of patient cases reported by diagnosis, to include unsatisfactory. 3. During interviews on October 21, 2019 at 9:05 AM and 11:55 AM, the Laboratory Director/Technical Supervisor A confirmed these findings and stated that Facility B's statistics included cases reported at Facility A.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interviews and review of laboratory records it was determined that Facility B failed to follow written policies and procedures to ensure that Facility B would maintain records for four of five Technical Supervisors of the number of hours spent examining slides. Findings include: 1. Facility B failed to follow the procedure CLIA '88 PERSONNEL QUALIFICATION STANDARDS which stated: "If personally responsible for screening not previously evaluated cytology slides, he or she must document the number of slides screened in 24 hours and the number of hours devoted to screening." 2. During an interview on October 22, 2019 at 3:00 PM, Technical Supervisor D stated that Technical Supervisor D did not record the number of hours spent examining slides when performing primary nongynecologic slide examinations. 3. During an interview on October 22, 2019 at 3:15 PM, Technical Supervisor E stated that Technical Supervisor E did not record the number of hours spent examining slides when performing primary nongynecologic slide examinations. 4. During an interview on October 22, 2019 at 3:30 PM, Technical Supervisor C stated that Technical Supervisor C did not record the number of hours spent examining slides when performing primary nongynecologic slide examinations. 5. During an interview on October 23, 2019 at 9:50 AM, the Survey Team reviewed records titled NONGYN SLIDE COUNT (PREVIOUSLY UNSCREENED NON-GYN SLIDES INCLUDING FNA, WRIGHT'S STAIN, CYTOSPIN, DIFF-QUICK AND PAP STAIN) with the Laboratory Director/Technical Supervisor A. The records documented the number of slides the Technical Supervisors examined during each 24-hour period and the number of hours spent examining slides. a. The Laboratory Director/Technical Supervisor A stated that the Cytology Supervisor completed the records and entered 15 minutes per slide for the number of hours spent examining slides. The Laboratory Director/Technical Supervisor A confirmed that the five Technical Supervisors failed

	to document the number of hours spent examining slides. b. The Laboratory Director /Technical Supervisor A failed to document the number of hours spent examining slides on 73 of 73 days that slides were examined from January 2018 through September 2019. Dates include: - January 2018: 2, 5, 26 - February 2018: 8, 20, 26 - March 2018: 5, 13 - April 2018: 4, 5, 11, 13 - May 2018: 4, 7, 11, 31 - June 2018: 5, 13, 15, 22 - July 2018: 6, 9, 25, 26, 27 - August 2018: 3, 22 - September 2018: 12 - October 2018: 10, 11, 19, 24, 30 - November 2018: 2, 6, 14, 16, 19, 22 - December 2018: 12, 17, 31 - January 2019: 7, 18 - February 2019: 6, 13, 18 - March 2019: 11, 19, 21 - April 2019: 1, 5, 9, 24 - May 2019: 3, 6, 8, 17 - June 2019: 3, 11, 19 - July 2019: 5, 12, 18, 29 - August 2019: 7, 19, 21, 27 - September 2019: 10, 17, 27, 30 c. Technical Supervisor C failed to document the number of hours spent examining slides on 50 of 50 days that slides were examined from January 2018 through September 2019. Dates include: - January 2018: 18, 23 - February 2018: 23 - March 2018: 6, 27 - April 2018: 3, 10, 19, 27 - May 2018: 1, 10, 15, 17 - June 2018: 8, 13, 19, 28 - July 2018: 3, 24 - August 2018: 7, 14 - September 2018: 7, 18, 25 - October 2018: 2, 18, 23 - November 2018: 16, 23 - December 2018: 18, 27 - January 2019: 15, 29 - March 2019: 5, 20, 29 - April 2019: 2, 16, 17, 30 - May 2019: 16, 21 - June 2019: 18, 21 - July 2019: 2, 9, 23, 30 - August 2019: 13 - September 2019: 24 d. Technical Supervisor D failed to document the number of hours spent examining slides on 81 of 81 days that slides were examined from January 2018 through September 2019. Dates include: - January 2018: 17, 22, 24 - February 2018: 7, 13, 15, 19, 26 - March 2018: 2, 7, 12, 21, 26 - April 2018: 2, 3, 12, 20, 25 - May 2018: 8, 17, 18, 21 - June 2018: 1, 15 - July 2018: 5, 11, 18, 30 - August 2018: 9, 14, 21 - September 2018: 6, 10, 17 - November 2018: 8 - December 2018: 3, 4, 5, 6, 7, 11, 13, 26 - January 2019: 8, 14, 31 - February 2019: 7, 20, 22, 26, 28 - March 2019: 4, 8, 25 - April 2019: 4, 19 - May 2019: 7, 13, 14 - June 2019: 7, 13, 24, 27 - July 2019: 3, 8, 10, 11, 22, 31 - August 2019: 2, 6, 8, 15, 16, 22, 23, 29 - September 2019: 6, 9, 12, 16 e. Technical Supervisor E failed to document the number of hours spent examining slides on 55 of 55 days that slides were examined from January 2018 through September 2019. Dates include: - January 2018: 12, 19, 30 - February 2018: 2, 5, 14, 22, 27 - March 2018: 19, 30 - April 2018: 9 - May 2018: 9, 14, 22, 25, 29 - July 2018: 2, 10, 20, 23 - September 2018: 11, 20, 24, 28 - October 2018: 5, 8, 9, 17, 22, 31 - November 2018: 7, 13 - January 2019: 11, 16, 28 - February 2019: 1, 5, 8, 9, 21 - March 2019: 8, 13 - April 2019: 3 - May 2019: 1, 10, 15, 22 - June 2019: 12, 14, 25 - July 2019: 1, 30 - August 2019: 2, 29 - September 2019: 4
D5651	CYTOLOGY CFR(s): 493.1274(e)(2) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interviews and review of laboratory records it was determined that Facility B failed to establish written policies and procedures to ensure that final gynecologic reports signed by five of five Technical Supervisors reflected an electronic signature authorized by the Technical Supervisor. Sixty of 60 final gynecologic reports from September 2019 failed to have

	an electronic signature authorized by the Technical Supervisor. Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures to ensure that an authorized electronic signature for five of five Technical Supervisor's was protected from use by unauthorized individuals. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 2. During an interview on October 21, 2019 at 4:20 PM, the Laboratory Director/Technical Supervisor A described the reporting process for gynecologic specimens: - The test requisitions were printed with cytology diagnostic codes. The Technical Supervisors circled the codes to match their diagnosis and initialed the requisition. - The test requisitions were sent to Facility A and data entry personnel entered the Technical Supervisor's results and electronic signature into the LIS. The results were then released by staff at Facility A. - The following day the Technical Supervisors at Facility B received a list of the cases that were resulted for them to verify. - The Laboratory Director/Technical Supervisor A confirmed that the Technical Supervisor's electronic signature was not protected from use by other individuals. 3. During an interview October 22, 2019 at 1:15 PM, the Cytology Supervisor confirmed that the Technical Supervisors were not the individuals authorizing the electronic signature for reports requiring technical supervisory review. 4. The Survey Team reviewed 60 random final gynecologic reports from September 2019. Sixty of 60 final gynecologic reports failed to have an electronic signature authorized by the Technical Supervisors. Reports include: - GYN19-9570 - GYN19-9571 - GYN19-9579 - GYN19-9589 - GYN19-9597 - GYN19-9606 - GYN19-9609 - GYN19-9616 - GYN19-9618 - GYN19-9620 - GYN19-9649 - GYN19-9658 - GYN19-9662 - GYN19-9679 - GYN19-9680 - GYN19-9681 - GYN19-9692 - GYN19-9693 - GYN19-9696 - GYN19-9697 - GYN19-9699 - GYN19-9705 - GYN19-9708 - GYN19-9712 - GYN19-9714 - GYN19-9719 - GYN19-9725 - GYN19-9728 - GYN19-9741 - GYN19-9761 - GYN19-9775 - GYN19-9778 - GYN19-9878 - GYN19-9897 - GYN19-9899 - GYN19-9900 - GYN19-9904 - GYN19-9907 - GYN19-9909 - GYN19-9925 - GYN19-9936 - GYN19-9943 - GYN19-9952 - GYN19-9957 - GYN19-9962 - GYN19-9964 - GYN19-10113 - GYN19-10115 - GYN19-10117 - GYN19-10122 - GYN19-10126 - GYN19-10178 - GYN19-10179 - GYN19-10372 - GYN19-10382 - GYN19-10396 - GYN19-10401 - GYN19-10404 - GYN19-10432 - GYN19-10436 5. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, gynecologic cytology slides and interview it was determined that Facility B failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. Facility B failed to identify and report one gynecologic cytology case from January through September 2019 as being "Unsatisfactory for Evaluation." Findings include: 1. The Survey Team requested and Facility B failed to provide written policies and procedures to define the minimum number of cells required for an adequate Hologic ThinPrep slide preparation. 2. Facility B failed to

	identify and report one gynecologic cytology case as being "Unsatisfactory for Evaluation." Case includes: - GYN19-8575 3. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that Facility B failed to maintain the date the Technical Supervisors examined cytology cases for 17 of 17 cases from January through August 2019. Findings include: 1. The Survey Team reviewed cytology test requisitions. The requisitions were used to document the Technical Supervisors diagnosis and the identity of the Technical Supervisor examining the case. a. Seventeen of 17 test requisitions failed to indicate the date the Technical Supervisor performed the slide examination. Requisitions include: - GYN19-753 - GYN19-834 - GYN19-1247 - GYN19-2254 - GYN19-2309 - GYN19-2967 - GYN19-2993 - GYN19-3472 - GYN19-3518 - GYN19-5585 - GYN19-5817 - GYN19-6145 - GYN19-6399 - GYN19-8556 - GYN19-8578 - GYN19-8691 - GYN19-8695 2. During an interview on October 22, 2019 at 3:00 PM, Technical Supervisor D confirmed that Technical Supervisor D did not document the date cases were reviewed. 3. During an interview on October 22, 2019 at 3:15 PM, Technical Supervisor E confirmed that Technical Supervisor E did not document the date cases were reviewed. 4. During an interview on October 22, 2019 at 3:30 PM, Technical Supervisor C confirmed that Technical Supervisor C did not document the date cases were reviewed. 5. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director/Technical Supervisor A 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, review of laboratory records and interviews it was determined that Facility B failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Cross refer to D5403, D5411, D5625, D5629, D5645, D5651, D5655, D5787
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on interviews and review of laboratory records it was determined that 17 of 17 final gynecologic test reports from January through August 2019 failed to accurately indicate the correct test report date. Findings include: 1. During an interview on October 22, 2019 at 1:15 PM, the Cytology Supervisor stated that the test report date on gynecologic test reports reported by Technical Supervisors was the date the results were entered into the LIS by Staff B or the Cytology Supervisor. The Cytology Supervisor further stated that there were no records of the date the Technical Supervisors reported gynecologic test results. 2. The Survey Team reviewed 17 test requisitions from January through August 2019 used to document the Technical Supervisors test results. Seventeen of 17 test requisitions failed to indicate the date the Technical Supervisors reported the results. Records include: - GYN19-753 - GYN19-834 - GYN19-1247 - GYN19-2254 - GYN19-2309 - GYN19-2967 - GYN19-2993 - GYN19-3472 - GYN19-3518 - GYN19-5585 - GYN19-5817 - GYN19-6145 - GYN19-6399 - GYN19-8556 - GYN19-8578 - GYN19-8691 - GYN19-8695 3. During an interview on October 23, 2019 at 9:50 AM, the Laboratory Director /Technical Supervisor A 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, laboratory records and interviews it was determined that Facility B failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the postanalytic phases of cytology testing. Cross refer to D5805
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that Facility B failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of Facility B and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that Facility B enrolled in an annual gynecologic cytology PT event for 2017 and 2018 (refer to D6088); failed to ensure enrollment and testing of samples for the gynecologic cytology proficiency testing program in 2017 and 2018 in accordance with 493.801(b)(3) which prohibits inter-laboratory communication between laboratories, and 493.801(b)(4) which prohibits the receipt of proficiency testing samples from another laboratory for testing (refer to D6089); failed to ensure that quality control programs were established and maintained (refer to D6093); and failed to ensure that quality assessment programs were established and maintained (refer to D6094). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of Facility B, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5403, D5411, D5645, D5651, D5655, D5787, D5805
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 interview it was determined that the Laboratory Director failed to ensure that Facility B enrolled in an annual gynecologic cytology PT event for 2017 and 2018. Cross refer to D2001
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 PT records and interviews it was determined that the Laboratory Director failed to ensure testing of samples for the gynecologic cytology proficiency testing program in 2017 and 2018 in accordance with 493.801(b)(3) which prohibits inter-laboratory communication between laboratories; and 493.801(b)(4) which prohibits the receipt of proficiency testing samples from another laboratory for testing. Cross refer to D2011, D2013
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5625, D5629
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5291, D5791, D5891
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on review of laboratory records and interview it was determined that the Laboratory Director failed to ensure that one of five Technical Supervisors that performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training and certification. 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 review of laboratory polices and procedures and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of five of five Technical Supervisors performing cytology test procedures. Cross refer to D5209
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of 102 random negative gynecologic cases/slides from January through September 2019 and confirmation by Technical Supervisor A on October 23, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic test. 1. GYN19-8575 08/12/19 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on the review of laboratory records and interviews it was determined that four

	of five Technical Supervisors failed to document the number of hours spent examining slides during each 24-hour period from January 2018 through September 2019. Cross refer to D5645
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.