Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449919	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Peterson Laboratory Services Pa	1133 College Ave, B131, Manhattan, KS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	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, observation and interviews it was determined the laboratory failed to provide written policies and procedures to describe the laboratory's process for sending gynecologic cytology tests to an outside laboratory for testing (refer to D5403); failed to ensure three of three Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (refer to D5411); failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens (refer to D5619); failed to establish written policies and procedures to ensure cases in the 10% quality control review would be randomly selected (refer to D5621); failed to establish written policies and procedures to ensure individual workload limits were established, reassessed, pro-rated and documented for three of three Technical Supervisors (refer to D5633, D5637, D5641, D5647); and failed to maintain records of the total number of slides examined and the total number of hours spent examining slides (refer to D5645).
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, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the diagnostic competency of three of three Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for three of three Technical Supervisors who performed microscopic evaluations in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04 /28/21 at 10:15 AM.
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 43 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for sending gynecologic cytology tests to an outside laboratory for testing. 2. During an interview on 04/26/2021 at 11:45 AM, the Cytology Preparatory Technician stated that the gynecologic cytology tests were sent to an outside laboratory for testing when the Cytotechnologist was not available to review cases. 3. The Laboratory Director confirmed these findings on 4/28/2021 at 10:15 AM.
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 manufacturer's instructions, laboratory records and interview it was determined the laboratory failed to ensure three of three Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep test in accordance with the manufacturer's instructions in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The HOLOGIC THINPREP PROCESSOR OPERATOR'S MANUAL states "Evaluation of microscope slides produced with the ThinPrep processor should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep-prepared slides by Hologic or by organizations or individuals designated by Hologic." 2. The Survey Team requested and the laboratory failed to provide training records for three of three Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep gynecologic tests in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04/28/21 at 10:15 AM.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interview it was determined that the laboratory failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. During an observation of nongynecologic specimen staining and interview on 04/26/2021 at 11:45 AM the Cytology Preparatory Technician stated there were separate stains inserted into the automated stainer specifically for nongynecologic specimens but there was no procedure or method used to prevent cross-contamination between these specimens which were stained together. 3. The Laboratory Director confirmed these findings on 04/28/21 at 10:15 AM.
D5621	CYTOLOGY CFR(s): 493.1274(c)(1)

	(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)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews it was determined the laboratory failed to establish written policies and procedures to ensure cases selected for 10% quality control review were selected randomly and unknown to the Cytotechnologist. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the cases selected for 10% quality review were randomly selected, to ensure these cases were unknown to the Cytotechnologist who performed the primary evaluation of cases. 2. During an interview on 04/28/21 at 9:10 AM, the Cytotechnologist stated the cases chosen for 10% random review were not selected randomly by the computer but by the Cytotechnologist at the time the diagnosis is entered in the computer. 3. The Laboratory Director confirmed these findings on 04/28/21 at 10:15 AM.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that an individual maximum workload limit was established for three of three Technical Supervisors during the years 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that an individual maximum workload limit was established for three of three Technical Supervisors who performed the primary evaluation of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide established workload limits for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04/28/21 at 10:15 AM.

D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for three of three Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of a workload reassessment at least every six months for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04/28/21 at 10: 15 AM.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure workload limits for three of three technical supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5645 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for three of three Technical Supervisors when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. 2. The Survey Team requested and the laboratory failed to provide records of a prorated workload limit for three of three Technical Supervisors in 2019, 2020 and to the date of the survey 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B - Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04/28 /21 at 10:15 AM.
D5645	CYTOLOGY

	CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and the total number of hours spent examining nongynecologic slides during each 24-hour period. The laboratory failed to maintain records of the total number of slides examined and the total number of hours spent examining nongynecologic slides during each 24-hour period for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of nongynecologic slides examined and the total number of hours spent examining nongynecologic slides during each 24-hour period for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. The Laboratory Director confirmed these findings on 04/28 /21 at 10:15 AM.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of established workload limits for three of three Technical Supervisors in 2019, 2020, and to the date of the survey in 2021. 2. The Laboratory Director confirmed these findings on 04/28/21 at 10:15 AM.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, observation and interviews it was determined that the laboratory 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, D5619, D5621, D5633, D5637, D5641, D5645, D5647
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, observation and interviews it was determined that 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure three of three Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (refer to D6102); and failed to ensure written policies and procedures were established to assess the competency for three of three Technical Supervisors (refer to D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, observation and interviews it was determined that the Laboratory Director 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 D5403, D5619, D5621, D5633, D5637, D5641, D5645 and D5647

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory records and interview it was determined the laboratory failed to ensure three of three Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in accordance with the manufacturer's instructions in 2019, 2020 and to the date of the survey in 2021. 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 policies and procedures, laboratory records 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 three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209
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.