Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449919	01/29/2025
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 and interviews the laboratory failed to ensure procedures were approved, signed and dated by the current Laboratory Director (refer to D5407); failed to assess the stain quality of the Diff Quick stain each day of use (D5473); failed to follow written policies and procedures to determine the causes of discrepancies between the cytology and histopathology diagnosis (refer to D5623); failed to establish and follow written procedures for the annual evaluation and comparison of two of six gynecologic cytology statistics, and failed to document two of six required annual statistics (refer to D5629); and failed to indicated the basis of correction for four of five corrected cytology reports (refer to D5659).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 51 laboratory policies and procedures and interview the laboratory

	failed to follow one written policy. Findings include: 1. The laboratory failed to follow the policy PREFACE which stated: "1. b) If there is a change in laboratory directorship, the new medical director must re-approve, sign, and date each individual procedure." 2. The Survey Team reviewed CYTOLOGY LABORATORY MANUAL. Laboratory Director A failed to approve, sign and date 51 of 51 cytology procedures from January 1, 2024 through July 31, 2024. (Refer to D5407) 3. The Survey Team reviewed CYTOLOGY LABORATORY MANUAL. Laboratory Director B failed to approve, sign and date 41 of 51 cytology procedures from August 1, 2024 through January 6, 2025. (Refer to D5407) 4. During an interview on January 28, 2025 at 8:43 AM these findings were confirmed by Laboratory Consultant.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 51 laboratory policies and procedures and interview with the Cytotechnologist the laboratory failed to establish and follow written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the Diff Quick stain maintenance protocol. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the stain assessment each day of use for the Diff Quick stain process. 3. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Cytotechnologist.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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:

A. Based on review of laboratory policies and procedures and interview with the Laboratory Consultant the laboratory failed to ensure procedures were approved, signed and dated by the current laboratory director. The laboratory failed to ensure 51 of 51 cytology procedures were approved, signed and dated by Laboratory Director A from January 1, 2024 through July 31, 2024. Findings include: 1. The Survey Team reviewed CYTOLOGY LABORATORY MANUAL. Laboratory Director A failed to approve, sign and date 51 of 51 cytology procedures. Laboratory Director A served in the role from January 1, 2024 through July 31, 2024. Procedures include: -PREFACE -SPECIMEN RETENTION -COLLECTING AND PROCESSING OF GYNECOLOGICAL SPECIMENS -REPROCESSING OF UNSATISFACTORY GYNECOLOGICAL SPECIMENS -CYTOLOGY PAP TEST SEND-OUT TESTING -CYTOLOGY ANCILLARY SEND-OUT TESTING -LABELING SPECIFICATIONS FOR NON-GYN CYTOLOGY SLIDES -CROSS-CONTAMINATION PREVENTION BETWEEN NON-GYNECOLOGIC SPECIMENS -COLLECTION AND PROCESSING OF BODY CAVITY FLUIDS -COLLECTION AND PROCESSING OF BREAST NIPPLE DISCHARGES -COLLECTION AND PROCESSING OF BRUSHINGS -COLLECTION AND PROCESSING OF CELL BLOCKS -COLLECTION AND PROCESSING OF FINE NEEDLE ASPIRATIONS -COLLECTION AND PROCESSING OF RESPIRATORY SPUTUMS -COLLECTION AND PROCESSING OF URINE -CRITERIA FOR CYTOLOGICAL SPECIMEN REJECTION -PAPANICOLAOU STAINING AND COVERSLIPPING -EVALUATION OF PAPANICOLAOU STAIN QUALITY -DIFF-QUICK STAINING PROCEDURE -STAIN CHANGING AND FILTERING -STAIN TROUBLESHOOTING -GYNECOLOGICAL SPECIMEN ADEQUACY -GYNECOLOGICAL CYTOLOGY DIAGNOSTIC CRITERIA -GYNECOLOGICAL CYTOLOGY REPORTING -FINE NEEDLE ASPIRATION SPECIMEN ADEQUACY -CYTOLOGY QUALITY ASSURANCE PLAN -CYTOLOGY DAILY WORKLOAD -10% NEGATIVE REVIEW OF GYNECOLOGICAL SLIDES -5-YEAR RETROSPECTIVE REVIEW OF PRIOR NEGATIVE CASE(S) ON CURRENT ABNORMAL CASE -ABNORMAL GYNECOLOGICAL CYTOLOGY FOLLOW-UP -CYTOLOGY NORMAL PAP TEST LETTERS-APEASY CLOUD -HISTOLOGY-CYTOLOGY CORRELATION OF GYNECOLOGICAL SPECIMENS -CYTOLOGY PROFICIENCY MONITORING AND TESTING -THINPREP 2000 PROCESSING SYSTEM FOR GYNECOLOGICAL AND NON-GYNECOLOGICAL CYTOLOGY SPECIMENS -SAKURA TISSUE-TEK PRISMA STAINER FOR GYNECOLOGICAL AND NON-GYNECOLOGICAL CYTOLOGY SPECIMENS -SAKURA TISSUE-TEK AUTOMATED COVERSLIPPER -THINPREP IMAGER -HOLOGIC THINPREP REVIEW SCOPE MANUAL + -REFRIGERATOR TEMPERATURE MONITORING -AMBIENT TEMPERATURE AND HUMIDITY MONITORING -FREEZER TEMPERATURE MONITORING -CYTOLOGY AMBIENT, REFRIGERATOR, AND FREEZER THERMOMETER CALIBRATION -CYTOLOGY ROTOFIX 32A CENTRIFUGE CALIBRATION AND MAINTENANCE -CYTOLOGY TIMER VERIFICATION PROCEDURE -SAFETY PRECAUTIONS FOR CYTOLOGICAL PROCESSING -NEEDLE STICK DURING CYTOLOGICAL PROCESSING -EYE WASH STATION USE AND MAINTENANCE -ACCESSIONING GYNECOLOGICAL CYTOLOGY SPECIMENS-APEASY CLOUD -ACCESSIONING NON-GYNECOLOGICAL CYTOLOGY SPECIMENS IN APEASY CLOUD -GYNECOLOGICAL CYTOLOGY RESULTS ENTRY-APEASY CLOUD -REVISED AND CORRECTED GYNECOLOGICAL CYTOLOGY REPORTS-APEASY CLOUD 2. During an interview on January 28, 2025 at 8:43 AM these findings were confirmed by Laboratory Consultant. B. Based on review of laboratory policies and procedures

	and interview with the Laboratory Consultant the laboratory failed to ensure procedures were approved, signed and dated by the current laboratory director. The laboratory failed to ensure 41 of 51 cytology procedures were approved, signed and dated by Laboratory Director B from August 1, 2024 through January 6, 2025. Findings include: 1. The Survey Team reviewed CYTOLOGY LABORATORY MANUAL. Laboratory Director B failed to approve, sign and date 41 of 51 cytology procedures. Laboratory Director B served in the role from August 1, 2024 through January 6, 2025. Procedures include: -PREFACE -SPECIMEN RETENTION - COLLECTING AND PROCESSING OF GYNECOLOGICAL SPECIMENS - REPROCESSING OF UNSATISFACTORY GYNECOLOGICAL SPECIMENS - LABELING SPECIFICATIONS FOR NON-GYN CYTOLOGY SLIDES -CROSS-CONTAMINATION PREVENTION BETWEEN NON-GYNECOLOGIC SPECIMENS -COLLECTION AND PROCESSING OF BODY CAVITY FLUIDS - COLLECTION AND PROCESSING OF BREAST NIPPLE DISCHARGES - COLLECTION AND PROCESSING OF BRUSHINGS -COLLECTION AND PROCESSING OF FINE NEEDLE ASPIRATIONS -COLLECTION AND PROCESSING OF RESPIRATORY SPUTUMS -COLLECTION AND PROCESSING OF URINE -CRITERIA FOR CYTOLOGICAL SPECIMEN REJECTION -PAPANICOLAOU STAINING AND COVERSLIPPING - EVALUATION OF PAPANICOLAOU STAIN QUALITY -DIFF-QUICK STAINING PROCEDURE -STAIN CHANGING AND FILTERING -STAIN TROUBLESHOOTING -GYNECOLOGICAL SPECIMEN ADEQUACY - GYNECOLOGICAL CYTOLOGY DIAGNOSTIC CRITERIA -GYNECOLOGICAL CYTOLOGY REPORTING -FINE NEEDLE ASPIRATION SPECIMEN ADEQUACY -CYTOLOGY QUALITY ASSURANCE PLAN -CYTOLOGY DAILY WORKLOAD -10% NEGATIVE REVIEW OF GYNECOLOGICAL SLIDES -5-YEAR RETROSPECTIVE REVIEW OF PRIOR NEGATIVE CASE(S) ON CURRENT ABNORMAL CASE -HISTOLOGY-CYTOLOGY CORRELATION OF GYNECOLOGICAL SPECIMENS -CYTOLOGY PROFICIENCY MONITORING AND TESTING -THINPREP 2000 PROCESSING SYSTEM FOR GYNECOLOGICAL AND NON-GYNECOLOGICAL CYTOLOGY SPECIMENS - SAKURA TISSUE-TEK PRISMA STAINER FOR GYNECOLOGICAL AND NON-GYNECOLOGICAL CYTOLOGY SPECIMENS -SAKURA TISSUE-TEK AUTOMATED COVERSLIPPER -THINPREP IMAGER -HOLOGIC THINPREP REVIEW SCOPE MANUAL + -REFRIGERATOR TEMPERATURE MONITORING -AMBIENT TEMPERATURE AND HUMIDITY MONITORING - CYTOLOGY AMBIENT, REFRIGERATOR, AND FREEZER THERMOMETER CALIBRATION -CYTOLOGY ROTOFIX 32A CENTRIFUGE CALIBRATION AND MAINTENANCE -CYTOLOGY TIMER VERIFICATION PROCEDURE - SAFETY PRECAUTIONS FOR CYTOLOGICAL PROCESSING -NEEDLE STICK DURING CYTOLOGICAL PROCESSING -EYE WASH STATION USE AND MAINTENANCE 2. During an interview on January 28, 2025 at 8:43 AM these findings were confirmed by Laboratory Consultant.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by:

	Based on lack of laboratory records and interview with the Cytotechnologist the laboratory failed to test Diff Quick staining materials for intended reactivity each day of use. The laboratory failed to test the Diff Quick stain process each day of use in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide records to document the stain assessment for the Diff Quick stain process each day of use in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. (Refer to D5403) 2. During an interview on January 27, 2025 at 3:40 PM these findings were confirmed by Cytotechnologist.
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (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 review of laboratory policies and procedures, histopathology final test reports and interview with the Laboratory Consultant the laboratory failed to follow written policies and procedures to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. The laboratory failed to ensure gynecologic cytology reports with a diagnosis of high grade squamous intraepithelial lesion (HSIL) or malignancy were compared with the histopathology report in seven of eleven gynecologic cytology cases with a diagnosis of high grade squamous intraepithelial lesion in 2024. Findings include: 1. The laboratory failed to follow the procedure HISTOLOGY-CYTOLOGY CORRELATION OF GYNECOLOGICAL SPECIMENS which stated: -"3. If a recent gynecological cytology report is available, the pathologist should then correlate the histological diagnosis with the diagnosis on the cytology report. 5. If the diagnoses are concordant, the pathologist will make a comment on the surgical report indicating as such. 6. If the diagnoses are disconcordant, the pathologist will review the pap slide in question to determine whether the pap smear was properly diagnosed. a. If there is no discrepancy...the pathologist will make a comment on the surgical report...b. Should there be a discrepancy between the initial screen of the pap smear and the re-screen, the pathologist will make a comment on the surgical report..." 2. The Survey Team reviewed 11 gynecologic cytology cases with a diagnosis of HSIL for which histopathology reports were available for comparison in 2024. The laboratory failed to document the correlation on seven of eleven histopathology final test reports. Cases include: -Cytology P24-00293 Histopathology H25-00186 -Cytology P24-01701 Histopathology H24-12743 -Cytology P24-01773 Histopathology H24-02942 -Cytology P24-02897 Histopathology H24-06338 -Cytology P24-03701 Histopathology H24-06242 -Cytology P24-05035 Histopathology H24-09487 -Cytology P24-06071 Histopathology H24-09483 3. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Laboratory Consultant.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology

	cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Laboratory Consultant the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of six required gynecologic laboratory statistics. The laboratory failed to provide one of six required annual gynecologic statistics in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six required gynecologic statistics. 2. The Survey Team requested and the laboratory failed to provide one of six required gynecologic statistics for 2023 and 2024. Statistic includes: -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison. 3. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Laboratory Consultant. B. Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Laboratory Consultant the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of six required gynecologic laboratory statistics. The laboratory failed to provide one of six required gynecologic statistics in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six required gynecologic statistics. 2. The Survey Team requested and the laboratory failed to provide one of six required gynecologic statistics for 2024. Statistic includes: -The number of gynecologic cases where cytology and histology are discrepant 3. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Laboratory Consultant.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Cytotechnologist the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on January 28, 2025 at 3:00 PM these findings were confirmed by Cytotechnologist.

D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, corrected cytology test reports and interview with the Laboratory Consultant the laboratory failed to follow written policies and procedures to ensure corrected cytology test reports indicated the basis for correction on the corrected test report. The laboratory failed to indicate the basis for correction on four of five corrected gynecologic cytology test reports from December 16, 2024 through January 16, 2025. Findings include: 1. The laboratory failed to follow the procedure REVISED AND CORRECTED GYNECOLOGICAL CYTOLOGY REPORTS-APEASY CLOUD which stated: -"Procedure: 5. Another pop-up screen will appear asking for a Reason for the Amendment. Write a brief statement documenting why the case is being revised. This will appear in the Revised Report." 2. The Survey Team reviewed five corrected gynecologic cytology test reports from December 16, 2024 through January 16, 2025. a. Four of five corrected gynecologic cytology test reports failed to indicate the basis for correction on the corrected test report. Reports include: -P24-08253 December 16, 2024 Amendment reason: Update pathologist No pathologist name was included on the corrected test report. -P24-08366 December 18, 2024 Amendment reason: Updating result There was no reference to the original result. -P25-00029 January 13, 2025 Amendment reason: Update diagnosis There was no reference to the original diagnosis. -P25-00092 January 16, 2025 Amendment reason: Update diagnosis There was no reference to the original diagnosis. 3. During an interview on January 29, 2025 at 11: 30 AM these findings were confirmed by Laboratory Consultant.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on microscopic review of 305 random negative gynecologic cytology cases/319 slides and the corresponding final cytology test reports from December 5, 2024 through December 31, 2024 and confirmation by Technical Supervisor A on January 29, 2025 the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. P24-08585 12/31/2024 Hologic ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for intraepithelial lesion or malignancy SURVEY TEAM DIAGNOSIS: Low grade squamous intraepithelial lesion TECHNICAL SUPERVISOR A DIAGNOSIS: Low grade squamous intraepithelial lesion
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) 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; (b)(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: A. Based on lack of laboratory records and interview with the Cytotechnologist the Technical Supervisor failed to ensure each individual who performed cytology testing received regular continuing education and training. The Technical Supervisor failed to ensure continuing education and training in cytology were maintained for two of two Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide records to document continuing education and training activities in cytology for two of two Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 2. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Cytotechnologist. B. Based on lack of laboratory records and interview with the Cytotechnologist the Technical Supervisor failed to ensure each individual who performed cytology testing received regular continuing education and training. The Technical Supervisor failed to ensure continuing education and training in cytology were maintained for one of one Cytotechnologist in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide records to document continuing education and training activities in cytology for one of one Cytotechnologist in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Cytotechnologist included: -Cytotechnologist 2. During an interview on January 29, 2025 at 11:30 AM these findings were confirmed by Cytotechnologist.
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.