Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410407	01/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	2475 Broadway, Helena, MT	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 37 laboratory policies and procedures, lack of gynecologic stain maintenance records and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to follow one written procedure. Findings include: 1. The procedure titled PAPINICOLAOU (PAP) STAIN, MODIFIED (Actual Laboratory Title) stated: "8.2 Change the first 95% alcohol after each full rack. 8.3 Change distilled water rinses after each rack. 8.4 Filter hematoxylin weekly, change monthly. 8.5 Change and rotate other alcohols as needed. 8.6 Change Cyto Stain as needed. 8.7 Change and rotate xylene weekly, filter as needed." 2. The Survey Team requested and the laboratory failed to provide gynecologic stain maintenance records for 2021, 2022, and to the date of the survey in 2023. 3. During an interview on January 11, 2023 at 11:00 AM these findings were confirmed by Anatomic Pathology Technical Supervisor.
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, morphology certification records and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Becton Dickinson (BD) SurePath Pap Test in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of three Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: - Technical Supervisor B 3. During an interview on January 9, 2023 at 2:00 PM these findings were confirmed by Anatomic Pathology Technical Supervisor.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to test staining materials for intended reactivity of two of two "Diff Quick" stain processes used for nongynecologic slide preparations for each day of use in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of two of two "Diff Quick" stain processes used for nongynecologic slide preparations were assessed each day of use in 2021, 2022 and to the date of the survey in 2023. Locations of the stain processes include: -Fine Needle Aspiration Tray -Under the Hood 2. During an interview on January 9, 2023 at 2:05 PM these findings were confirmed by Anatomic Pathology Technical Supervisor.
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, laboratory records and

	interview with the Anatomic Pathology Technical Supervisor the laboratory failed to follow written policies and procedures to ensure that the review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy was documented. The laboratory failed to document the review of prior negative gynecologic cases for two of two HSIL or malignant cases from January 2021 to June 2022. Findings include: 1. The procedure titled GYN CYTOLOGY RESCREENING AND REVIEW stated: "3.5 Staff Cytotechnologist screens...3.5.5 Negative smears available at this facility from previous five years when there is a current interpretation of HSIL." "4. Evidence of Compliance...4.3 Documentation on HSIL spreadsheet and look back." 2. The Survey Team reviewed records titled 2021 5 YEAR LOOK BACK and 2022 5 YEAR LOOK BACK. The laboratory failed to document the review of prior negative gynecologic cases for two of two HSIL or malignant cases from January 2021 to June 2022. Cases include: -C-270-21 -C-1957-22 3. During an interview on January 9, 2023 at 2:30 PM these findings were confirmed by Anatomic Pathology Technical Supervisor.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to follow written policies and procedures for an annual statistical evaluation of two of six required gynecologic cytology statistics. The laboratory failed to document two of six required gynecologic statistics for 2021 and 2022. Findings include: 1. The procedure titled GYN CYTOLOGY RESCREENING AND REVIEW stated: "9.3.2.2 For gynecologic cases, records are maintained that include the following: 9.3.2.2.2 Number of cases with significant cytologic-histologic discrepancies. 9.3.2.2.4 Number of cases where histopathology results are unavailable to compare with high-grade or malignant cytopathology results." 2. The Survey Team requested and the laboratory failed to provide two of six required gynecologic annual statistics for 2021 and 2022. Statistics include: -Number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -Number of gynecologic cases where cytology and histology are discrepant 3. During an interview on January 9, 2023 at 11:00 AM these findings were confirmed by Anatomic Pathology Technical Supervisor.
D5657	CYTOLOGY

	CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic 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 gynecologic cytology test results. 2. During an interview on January 11, 2023 at 11:00 AM these findings were confirmed by Anatomic Pathology Technical Supervisor. B. Based on review of laboratory policies and procedures and interview with the Anatomic Pathology Technical Supervisor the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on January 11, 2023 at 11:00 AM these findings were confirmed by Anatomic Pathology Technical Supervisor.
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 certification records and interview with the Anatomic Pathology Technical Supervisor the Laboratory Director failed to ensure that one of three Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests had received the required morphology certification prior to reporting patient specimens in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5411. Findings include: 1. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of three Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests in 2021, 2022 and to the date of the survey in 2023.
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, lack of competency assessment records and interview the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors, Anatomic Pathology Technical Supervisors and Cytotechnologists who conduct preanalytic, analytic and postanalytic phases of cytology testing. The Laboratory Director failed to provide documentation of a competency assessment for three of three Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of Technical Supervisors who conduct analytic and postanalytic phases of cytology testing. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for three of three Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of Anatomic Pathology Technical Supervisors who conduct preanalytic, analytic and postanalytic phases of cytology testing. 3. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor, and maintain the competency of Cytotechnologists who conduct preanalytic, analytic and postanalytic phases of testing. 4. During an interview on January 11, 2023 at 11:00 AM these findings were confirmed by Director of Laboratory Services and Anatomic Pathology Technical Supervisor.
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.