Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0692679	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Sutter Bay Medical Foundation	**Street Address, City, State** 795 El Camino Real, Ames Bldg 2nd Fl, Palo Alto, CA	

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, cytology specimen slides and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors, and failed to assess the competency of six of six Technical Supervisors (refer to D5209); failed to establish written policies and procedures to describe the laboratory's process for labeling nongynecologic specimen slides with a unique patient identifier (refer to D5311); failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test (refer to D5411); failed to follow written policies and procedures to detect errors in the performance of cytologic examinations and the reporting of results (refer to D5623 and D5625); and failed to follow written policies and procedures for an annual statistical evaluation of four of six required laboratory statistics (refer to D5629).
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 the Technical Supervisors. The laboratory failed to assess the competency of six of six Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. a. The Survey Team reviewed the written procedure STAFF COMPETENCY ASSESSMENT, which stated: "Annual competency assessments will be given to all technical and non-technical staff. This is to help assure that staff show competency in processing specimens, performing test procedures and reporting test results promptly and proficiently." "Competency assessments include documentation of direct observation of routine test performance, patient preparation, specimen handling, processing, and written tests." b. The procedure failed to describe the documentation used to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for six of six Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on March 30, 2022 at 10:50 AM, these findings were confirmed with the Pathology Manager and Cytology Supervisor.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, nongynecologic specimen slides and the corresponding final test reports and interviews it was determined that the laboratory failed to establish written policies and procedures to describe the laboratory's process for labeling nongynecologic specimen slides with a unique patient identifier. The laboratory failed to label nongynecologic specimen slides from 15 of 15 consecutive cases from February 2022 with a unique patient identifier. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's current process for labeling nongynecologic specimen slides with a unique patient identifier. 2. The Survey Team reviewed nongynecologic specimen slides and the corresponding final test reports from 15 consecutive cases from February 2022. Fifteen of 15 cases failed to have slides labeled with a unique patient identifier that corresponded to the unique patient identifier on the final test report. Cases include: Test report: PAN-22-00444 Specimen slide: 22-444 Adhesive label: N-22-00444 Test report: PAN-22-00445 Specimen slide: 22-445 Adhesive label: N-22-00445 Test report: PAN-22-00446 Specimen slide: 22-446 Adhesive label: N-22-00446 Test report: PAN-22-00447 Specimen slide: 22-447 Adhesive label: N-22-00447 Test report: PAN-22-00448 Specimen slide: 22-448 Adhesive label: N-22-00448 Test report: PAN-22-00449

	Specimen slide: 22-449 Adhesive label: N-22-00449 Test report: PAN-22-00450 Specimen slide: 22-450 Adhesive label: N-22-00450 Test report: PAN-22-00451 Specimen slide: 22-451 Adhesive label: N-22-00451 Test report: PAN-22-00452 Specimen slide: 22-452 Adhesive label: N-22-00452 Test report: PAN-22-00453 Specimen slide: 22-453 Adhesive label: N-22-00453 Test report: PAN-22-00454 Specimen slide: 22-454 Adhesive label: N-22-00454 Test report: PAN-22-00455 Specimen slide: 22-455 Adhesive label: N-22-00455 Test report: PAN-22-00456 Specimen slide: 22-456 Adhesive label: N-22-00456 Test report: PAN-22-00457 Specimen slide: 22-457 Adhesive label: N-22-00457 Test report: PAN-22-00458 Specimen slide: 22-458 Adhesive label: N-22-00458 3. During an interview on March 29, 2022 at 11:00 AM, Staff A stated the nongynecologic specimen slides were labeled with the last two digits of the year, the specimen number, patient's last name and first initial, and the specimen source. After processing an adhesive label was placed on the nongynecologic specimen slides with the specimen number and patient name. a. The Survey Team observed Staff A label four nongynecologic specimen slides. Staff A failed to label four of four nongynecologic specimen slides with a unique patient identifier. Slides include: Accession number: PAN-22-00726 Slide labeled: 22-726 Accession number: PAN-22-00727 Slide labeled: 22-727 Accession number: PAN-22-00728 Slide labeled: 22-728 Accession number: PAN-22-00729 Slide labeled: 22-729 4. During an interview on March 30, 2022 at 9:40 AM, the Cytology Supervisor confirmed these findings and reviewed the procedure SPECIMEN ACCESSIONING with the Survey Team, which stated: "Each case is assigned a unique accession number, which is written on the slide or specimen container and the requisition form or EPIC order. The unique identifier includes the prefix PAC"...", the year, and the accession number." a. The Cytology Supervisor stated that the laboratory was revising the procedure and confirmed that the procedure failed to describe the laboratory's process for labeling nongynecologic specimen slides with a unique patient identifier. The Cytology Supervisor further stated that the nongynecologic specimen slides should be labeled with the prefix PAN, year and specimen number.
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 81 laboratory policies and procedures, interview, microscopic review of gynecologic specimen slides and review of laboratory records it was determined that the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure HISTOLOGY AND CYTOLOGY CORRELATIONS, which stated: "A retrospective review is done on all prior pap tests diagnosed as negative or reactive/reparative within the previous five years that have not previously been reviewed. The retrospective review is performed and documented as described in the section titled "Gyn Retrospective Rescreen Protocol and Documentation."" 2. During an interview on March 28, 2022 at 12:30 PM, the Cytology Supervisor stated that the laboratory reviewed prior negative gynecologic cytology cases within the past five years when a gynecologic histopathology case was reported as high-grade squamous intraepithelial lesion

	(HSIL) or malignant. a. The Survey Team reviewed records titled RETROSPECTIVE REVIEWS for 16 histopathology cases reported as HSIL from January 2020 through October 2021 that had prior negative gynecologic cytology cases. b. The Survey Team identified and Technical Supervisor B confirmed on April 1, 2022 that the laboratory failed to identify six of 16 prior negative gynecologic cases as having a more significant lesion than was originally reported. Cases include: -PAC-20-00857 -PAC-20-09327 -PAC-21-03553 -PAC-21-12335 -PAC-21-13106 -PAC-21-22140
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 that the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope 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 HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for two of six Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Technical Supervisor E -Technical Supervisor F 3. During an interview on March 30, 2022 at 10: 15 AM, these findings were confirmed with the Pathology Manager and Cytology 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, microscopic review of gynecologic specimen slides and review of laboratory records it was determined that the laboratory failed to follow written policies and procedures to identify three of 11 previous negative gynecologic cases from seven current cases of HSIL from March 2020 through October 2021 as having a more significant lesion. Findings include: 1.

	The laboratory failed to follow the procedure CYTOLOGY QUALITY CONTROL AND QUALITY ASSURANCE, which stated: "Whenever gynecologic cytology material reveals a HSIL or malignant findings, all previous WNL/NIL and reactive /reparative cytologic cases within the past 5 years, which are not documented as to having been retrospectively reviewed, are rescreened by a cytology supervisor. Any discrepancies noted on review are sent to the pathologist for reconciliation and documentation." 2. The Survey Team reviewed 11 previous negative gynecologic cases from seven current cases of HSIL from March 2020 through October 2021. a. The Survey Team identified and Technical Supervisor C confirmed on April 1, 2022 that the laboratory failed to identify three of 11 prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative cases include: -PAC-18-23239 -PAC-19-25519 -PAC-20-24645
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 records and interview it was determined that the laboratory failed to follow written policies and procedures for an annual statistical evaluation of four of six required laboratory statistics. The laboratory failed to document four of six required annual statistics for 2020 and 2021. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY STATISTICS, which stated: "CLIA REQUIRED ANNUAL STATISTICS" "The total number of cytology (gynecologic + non-gynecologic) cases examined." "Specimens processed by specimen type, including gynecologic and all the various categories of non-gynecologic specimens." "The number of GYN cases reported by diagnosis." "The number of gynecologic cases where any rescreen (QC-prospective and retrospective) of negative cases resulted in the reclassification to LGSIL, HGSIL, or carcinoma." 2. The Survey Team requested and the laboratory failed to provide four of six required annual statistics for 2020 and 2021. Statistics include: -The number of cytology cases examined -The number of specimens process by specimen type -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms 3. During an interview on March 29, 2022 at 9:35 AM, these findings were confirmed with the Pathology Manager and Cytology Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the workload limit for individuals, 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. 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 individuals when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. 2. During an interview on March 29, 2022 at 9:35 AM, these findings were confirmed with the Pathology Manager and Cytology Supervisor.
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, microscopic review of gynecologic specimen slides, review of laboratory records 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 D5401, D5625, D5629 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the laboratory's program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. a. The Survey Team reviewed records titled RETROSPECTIVE REVIEWS for 16 histopathology cases reported as HSIL from January 2020 through October 2021 that had prior negative gynecologic cytology cases. b. The 16 prior negative gynecologic cases were confirmed as negative by the Cytology Supervisor. c. The Survey Team identified and Technical Supervisor B confirmed on April 1, 2022 that the laboratory failed to identify six of 16 prior negative gynecologic cases as having a more significant lesion than was originally reported. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the laboratory's program to identify three of 11 previous negative gynecologic cases as having a more significant lesion than

	originally reported. a. The Survey Team reviewed 11 previous negative gynecologic cases from seven current cases of HSIL from March 2020 through October 2021. b. The 11 previous negative gynecologic cases were confirmed as negative by the Cytology Supervisor. c. The Survey Team identified and Technical Supervisor C confirmed on April 1, 2022 that the laboratory failed to identify three of 11 prior negative gynecologic cases as having a more significant lesion than was originally reported. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the annual evaluation of four of six required laboratory statistics.
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 that the Laboratory Director failed to ensure that two of six Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5411 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of appropriate training to accurately report cytology test results prior to performing Hologic ThinPrep Pap test evaluations.
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 six of six Technical Supervisors performing cytology test procedures. Cross refer to D5209 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess the competency of the Technical Supervisors, and when necessary identify methods to improve the skills of the Technical Supervisors. 2. The Survey Team requested and

	the Laboratory Director failed to provide documentation of competency assessments for six of six Technical Supervisors in 2020, 2021 and to the date of the survey in 2022.
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.