Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0998287	06/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Yosemite Pathology	3000 Sillect Ave, Bakersfield, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on review of 14 laboratory policies and procedures and interview, the laboratory failed to ensure that four of 14 written procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date four of 14 laboratory procedures. Procedures include: - QUALITY ASSURANCE PROGRAM FOR SURGICAL PATHOLOGY - ASSESSING PROFESSIONAL COMPETENCY - NON-GYN PAPANICOLAOU STAIN: MANUAL METHOD - PATHOLOGIST CYTOLOGY WORKLOAD MONITORING AND LIMITS 2. During an interview on June 29, 2022 at 10:00 AM, these findings were confirmed with the Practice Manager.
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, lack of records and interview, the laboratory failed to establish written policies and procedures for identifying non-

	gynecologic specimens with a high potential for cross-contamination and staining them separately from other non-gynecologic specimens and filtering or changing the stains following staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying non-gynecologic specimens with a high potential for cross-contamination and staining them separately from other non-gynecologic specimens and filtering or changing the stains following staining. 2. The Survey Team requested and the laboratory failed to provide documentation of cases with a high potential for cross-contamination which had been stained separately and the stains and reagents changed following staining in 2020, 2021 and to the date of survey in 2022. 3. During an interview on June 28, 2022 at 1:00 PM, these findings were confirmed with the Practice Manager.
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, lack of records and interview, 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 the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisors' workload limits would be reassessed at least every six months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide records of a workload reassessment at least every six months for five of five Technical Supervisors in 2020, 2021 and to the date of the survey 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview on June 28, 2022 at 1:30 PM, these findings were confirmed with the Practice Manager.
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, the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Technical Supervisors would be prorated when examining cytology slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to

	prorate the workload limits for the Technical Supervisors when examining non-gynecologic cytology slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for five of five Technical Supervisor when examining slides in less than an eight-hour work day. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview on June 28, 2022 at 1:30 PM, these findings were confirmed with the Practice Manager.
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 establish written policies and procedures to assess the competency of the laboratory assistants performing preparation of cytology specimens. The Laboratory Director failed to assess the competency of two of two laboratory assistants in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to describe the process for assessing the competency of the laboratory assistants. 2. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for two of two laboratory assistants who prepared cytology specimens in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on June 28, 2022 at 9:50 AM, these findings were confirmed with the Practice Manager.
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.