Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1098267	12/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Omnipathology Solutions	968 S Fair Oaks Ave, Pasadena, 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
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 review of policies and procedures, lack of laboratory staining records and interview with the Laboratory Director, the laboratory failed to follow it's procedure to test staining materials for intended reactivity of the Papanicolaou stain used for gynecologic and nongynecologic slide preparations for each day of use in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The laboratory procedure CYTOLOGY SPECIMEN PROCESSING stated "Each rack of slides is brought to the Laboratory Director for QC evaluation." 2. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used for gynecologic and nongynecologic slide preparations were assessed each day of use in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on December 14, 2022 at 9:00 AM the Laboratory Director confirmed these findings.
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, lack of laboratory records and interview with the Laboratory Director, the laboratory failed to follow written policies and procedures for the documentation of a search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current High Grade Lesion (HSIL) or malignancy. The laboratory failed to document the search for prior negative gynecologic cytology cases for current HSIL and malignant cases from January 2021 through the date of the survey in 2022. Findings include: 1. The procedure QUALITY MANAGEMENT stated "Current CIN 2 or above diagnosis triggers a search in the system for previous negative Paps. Any such cases are pulled and reviewed by the Laboratory Director." 2. The Survey Team requested and the laboratory failed to provide documentation of a search for prior negative cases for current HSIL or malignant cases for 2021 to the date of the survey in 2022. 3. During an interview on December 14, 2022 at 9:00 AM the Laboratory Director confirmed these findings.
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, statistical records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures for the evaluation and comparison of two of six statistics. The laboratory failed to document three of six required annual statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of two of six annual statistics. Annual statistics include: - Gynecologic cases with a diagnosis of HSIL, adenocarcinoma or other malignant neoplasm for which histology results were available. - Gynecologic cases where any rescreen of a normal or negative resulted in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma or other malignant neoplasms. 2. The Survey Team requested and the laboratory failed to provide documentation of three of six required annual statistics for 2020 and 2021. Annual statistics include: - Gynecologic cases with a diagnosis of

	HSIL, adenocarcinoma or other malignant neoplasm for which histology results were available. - Gynecologic cases where cytology and histology were discrepant. - Gynecologic cases where any rescreen of a normal or negative resulted in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma or other malignant neoplasms. 3. During an interview on December 14, 2022 at 9:00 AM, the Laboratory Director confirmed these findings.
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, lack of workload limit records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to ensure maximum workload limits were established for each individual performing primary examination of gynecologic and nongynecologic cytology specimens. Cross refer to D6130 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established maximum workload limits for each individual performing primary examination of cytology specimens. 2. During an interview on December 14, 2022 at 9:00 AM, the Laboratory Director confirmed these findings.
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 workload limit records and interview with the Laboratory Director, 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 Supervisor. Cross refer to D6130 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. During an interview on December 14, 2022 at 9:00 AM, the Laboratory Director confirmed these findings.
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 workload limit records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Technical Supervisor would be prorated when examining cytology slides in less than an eight-hour work day. The laboratory failed to prorate the workload limits for one of one 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 prorate the workload limits for the Technical Supervisor when examining gynecologic and non-gynecologic cytology slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records of prorated workload limits for one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - The Technical Supervisor 3. During an interview on December 14, 2022 at 9:00 AM, the Laboratory Director confirmed these findings.
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 workload limit records and interview with the Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisor. The laboratory failed to provide records of workload limits for one of one Technical Supervisors during 2020, 2021 and through 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 ensure records were available to document the workload limit for the Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisors during 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - The Technical Supervisor 3. During an interview on December 12, 2022 at 3:00 PM, the Technical Supervisor confirmed these findings.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by:

	A. Based on the review of 196 negative gynecologic cases from June 1, 2022 to November 30, 2022 and confirmation by the Technical Supervisor, the Technical Supervisor failed to verify the accuracy of two gynecologic cytology reports. Cases include: 1. CG22-470 May 4, 2022 Cervical LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous intraepithelial Lesion 2. GC22-828 October 31, 2022 Cervical LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous intraepithelial Lesion B. Based on review of 67 nongynecologic cases from January 11, 2022 to December 13, 2022 and confirmation by the Technical Supervisor on December 13 and 14, the Technical Supervisor failed to verify the accuracy of two nongynecologic cytology reports. Cases include: 1. FN22-018 February 24, 2022 Anal/Rectal LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous intraepithelial Lesion 2. FN22-046 April 18, 2022 Anal/Rectal LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous intraepithelial Lesion
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, lack of workload limit records and interview with the Technical Supervisor, the Technical Supervisor failed to establish an individual workload limit and failed to reassess workload limits at least every six months for one of one Technical Supervisors 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - The Technical Supervisor 2. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - The Technical Supervisor 3. During an interview on December 12, 2022 at 3:00 PM, the Technical Supervisor confirmed these findings.
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.