

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0563772	(X3) Date Survey Completed 03/02/2022
Name of Provider or Supplier Sun Clinical Laboratories	Street Address, City, State 9349 Telstar Ave Ste A & B, El Monte, 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	<p>CYTOLOGY CFR(s): 493.1221</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation of four of six annual statistics (refer to D5629); failed to establish written policies and procedures for the establishment of individual workload limits (refer to D5633); failed to reassess workload limits at least every six months (refer to D5637); failed to follow written policies and procedures to ensure the laboratory maintained records of the total number of hours spent examining slides per 24-hour period (refer to D5645); and failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report (refer to D5659).</p>
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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</p>

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 establish written policies and procedures for an annual statistical evaluation of four of six required cytology statistics. The laboratory failed to document four 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 an annual statistical evaluation of four of six required cytology statistics. Statistics include: - The number of patient cases reported by diagnosis, including the number reported as unsatisfactory; - Gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma or other malignant neoplasm for which histology results were available for comparison; - Gynecologic cases where cytology and histology are discrepant; - Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low grade intraepithelial lesion (LSIL), HSIL, adenocarcinoma or other malignant neoplasms. 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 patient cases reported by diagnosis, including the number reported as unsatisfactory; - Gynecologic cases with a diagnosis of HSIL, adenocarcinoma or other malignant neoplasm for which histology results were available for comparison; - Gynecologic cases where cytology and histology are discrepant; - Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma or other malignant neoplasms. 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor .

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, laboratory documents and interview it was determined that the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established. The laboratory failed to ensure workload limits were established for five of five cytotechnologists and one of one Laboratory Director/Technical Supervisors when performing primary screening for 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 ensure the Technical Supervisor established individual maximum workload limits for five of five cytotechnologists and one of one Laboratory Director/Technical Supervisors who performed primary screening. 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for five of five cytotechnologists and one of one Laboratory Director /Technical Supervisors for 2020, 2021 and to the date of the survey in 2022.

Cytotechnologists include: -Cytotechnologist #1 -Cytotechnologist #2 - Cytotechnologist #3 -Cytotechnologist #4 -Cytotechnologist #5 Technical Supervisors include: -Laboratory Director/Technical Supervisor 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director /Technical Supervisor.

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:
A. Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that 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 Laboratory Director/Technical Supervisor. The laboratory failed to reassess workload limits for one of one Laboratory Director /Technical Supervisor who performed primary screening of nongynecologic cytology specimens in 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Laboratory Director/Technical Supervisor's 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 a reassessment of a workload limit for the Laboratory Director/Technical Supervisor in 2020 and 2021. 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor. B. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow the procedure for reassessment of workload limits for four of five cytotechnologists every six months in 2020 and 2021. Findings include: 1. The laboratory failed to follow the written procedure CYTOTECHNOLOGIST SEMI-ANNUAL REVIEW, PERFORMANCE EVALUATION which stated: "These standards are based on CLIA 88 guidelines which require documentation of established workloads, results of all slides reviewed, proof of six-month reassessment and adjustment ..." 2. The cytotechnologist's semi-annual, performance evaluation forms from 2020 and 2021 did not include reassessed workload limits for four of five cytotechnologists. Cytotechnologists and dates without reassessed workload limits include: - General Supervisor/Cytotechnologist #1 August-December 2020 - Cytotechnologist #2 August-December 2020 August-December 2021 - Cytotechnologist #3 August-December 2020 January-July 2021 August-December 2021 - Cytotechnologist #4 August-December 2021 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director /Technical Supervisor.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of

the site or laboratory.

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 to ensure that the laboratory maintained records of the total number of hours one of one Laboratory Director/Technical Supervisors spent examining slides per 24-hour period for 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The laboratory failed to follow the procedure GYN AND NON-GYN PRIMARY REVIEW WORKLOAD SURVEILLANCE PROCEDURE, which stated: "Cytotechnologists and pathologists doing primary screening are given Workload Surveillance charts on which they are to write the date, hours of review and number of primary review cases". 2. The Laboratory Director/Technical Supervisor's monthly Workload Surveillance charts from the years 2020, 2021 and to the date of the survey in 2022 failed to include the hours spent examining slides. 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director /Technical Supervisor.

D5659

CYTOLOGY

CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (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, laboratory records and interview it was determined that the laboratory failed to establish a written policy or procedure to indicate the basis for the correction on the test reports and failed to follow the laboratory procedure for corrected test reports. The laboratory failed to indicate the basis for the correction on two of two corrected test reports from January and February, 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy or procedure for indicating the basis for the correction on a corrected test report. 2. The laboratory failed to follow the written procedure AMENDED PAP SMEAR REPORT PROCEDURE which stated: "The new report will contain the words "THIS IS AN AMENDED REPORT". Under this phrase there will be the words "PREVIOUSLY REPORTED AS...". 3. Two of two reports were identified as not having a statement as to why they were corrected and as not following the laboratory procedure policy to correct the reports. Reports include: - 220045270 - 220048360 4. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor.

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.

	<p>This STANDARD is not met as evidenced by: Based on review of written policies and procedures, laboratory records and interview it was determined that the Technical Supervisor failed to establish individual workload limits and to reassess the workload limits in 2020 and 2021 for four of five cytotechnologists and one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Finding include: 1. The Technical Supervisor failed to establish individual workload limits for five of five cytotechnologists and one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. 2. The Technical Supervisor failed to reassess workload limits for four of five cytotechnologists and one of one Laboratory Director/Technical Supervisors in 2020 and 2021. 3. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that one of one Technical Supervisors failed to document the number of hours devoted to performing primary screening of nongynecologic cytology slides during each 24-hour period in 2020, 2021 and to the date of survey in 2022. Cross refer to D5645 Findings include: 1. The Laboratory Director/Technical Supervisor failed to provide records of the total number of hours spent screening nongynecologic cytology slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. 2. During an interview on March 2, 2022 at 11:45 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
<p>D9999</p>	<p>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.</p>