

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0508312	(X3) Date Survey Completed 04/17/2024
Name of Provider or Supplier Clinical Pathology Associates	Street Address, City, State 1150 N 18th Suite 102, Abilene, TX	
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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Technical Operations Manager/Pathology Assistant, the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of one of six required gynecologic laboratory statistics. The laboratory failed to document one of six required gynecologic laboratory statistics for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of one of six required annual gynecologic laboratory statistics. Statistic includes: - The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 2. The Survey Team requested and the laboratory failed to provide records of one of six required annual gynecologic statistics for 2022 and 2023. Statistic includes: - The number of gynecologic cases where any rescreen of a normal or</p>

negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview on April 16, 2024 at 4:00 PM, these findings were confirmed by the Technical Operations Manager/Pathology Assistant.

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, workload limit records and interview with the Technical Operations Manager/Pathology Assistant, the laboratory failed to establish and follow written policies and procedures to ensure that workload limits for the Technical Supervisors and the Cytotechnologist would be prorated when examining 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 workload limits for the Technical Supervisors and the Cytotechnologist when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for three of three Technical Supervisors and one of one Cytotechnologists when examining slides in less than eight hours. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 Cytotechnologist includes: - The Cytotechnologist 3. During an interview on April 16, 2024 at 09:40 AM, these findings were confirmed by the Technical Operations Manager/Pathology Assistant.

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 workload records and interview with the Technical Operations Manager/Pathology Assistant, the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of hours each individual spent examining slides during each 24-hour period. The laboratory failed to maintain records of the number of hours three of three Technical Supervisors spent examining slides in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies

and procedures to ensure that the laboratory maintained records of the number of hours each individual spent examining slides per 24-hour period. 2. Three of three Technical Supervisors failed to document the number of hours spent examining slides during each 24-hour period in 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D6133 3. During an interview on April 15, 2024 at 03:14 PM these findings were confirmed by the Technical Operations Manager/Pathology Assistant.

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 microscopic review of 329 random negative gynecologic slides and corresponding final cytology test reports from February 2, 2024 through April 5, 2024 and confirmation by Technical Supervisor #2 on April 17, 2024 the Technical Supervisor failed to verify the accuracy of six gynecologic cytology tests. 1. OG24-01922 03/21/2024 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR #2 DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. OG24-02027 03/29/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR #2 DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 3. OG24-00716 02/02/2024 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory: Limited Cellularity TECHNICAL SUPERVISOR #2 DIAGNOSIS: Unsatisfactory: Scant Cellularity 4. OG24-01983 03/25/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory: Limited Cellularity TECHNICAL SUPERVISOR #2 DIAGNOSIS: Unsatisfactory: Scant Cellularity 5. OG24-01992 03/25/2024 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory: Limited Cellularity TECHNICAL SUPERVISOR #2 DIAGNOSIS: Unsatisfactory: Scant Cellularity 6. OG24-02073 03/27/2024 ImagedThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory: Limited Cellularity TECHNICAL SUPERVISOR #2 DIAGNOSIS: Unsatisfactory: Scant Cellularity B. Based on microscopic review of 47/57 non-negative gynecologic cases /slides and corresponding final cytology test reports from February 2, 2024 through April 5, 2024 and confirmation by Technical Supervisor #2 on April 17, 2024 the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 3. OG24-01921 03/21/2024 ThinPrep Pap Test LABORATORY DIAGNOSIS: Atypical Squamous Cells cannot rule out High Grade Squamous Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy TECHNICAL SUPERVISOR #2 DIAGNOSIS: Benign Cellular Changes 4. OG24-01974 03/26/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS:

Atypical Squamous Cells cannot rule out High Grade Squamous Intraepithelial Lesion
SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy
TECHNICAL SUPERVISOR #2 DIAGNOSIS: Benign Cellular Changes

D6133

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(c)(6)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory workload records and interview with the Technical Operations Manager/Pathology Assistant, three of three Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. Three of three Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in January through December 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 -Technical Supervisor #3 2. During an interview on April 15, 2024 at 03:14 PM, these findings were confirmed by the Technical Operations Manager /Pathology Assistant.

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.