

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2144376	(X3) Date Survey Completed 10/21/2022
Name of Provider or Supplier Cytopath At Uab Medical West	Street Address, City, State 995 9th Avenue South West, Bessemer, AL	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 38 laboratory policies and procedures, final test reports and interviews the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure QUALITY MANAGEMENT /QUALITY CONTROL PLAN, which stated: "The original report will be scanned into the LIS under documents for that particular case." a. The Survey Team requested and the laboratory failed to provide the original final test report from four of four corrected reports from January through July 2020 and February 2022. Reports include: -CMWO2020-000036 -CMWO2020-000505 -CMWO2020-000778 -CMWO2022-000263 b. During an interview on June 13, 2022 at 10:45 AM, these findings were confirmed with the Laboratory Manager. c. During an interview on June 14, 2022 at 1:15 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.</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</p>

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:

A. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics. The laboratory failed to document six of six required gynecologic 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 six of six required gynecologic statistics. 2. The Survey Team requested and the laboratory failed to provide six of six required gynecologic annual statistics for 2020 and 2021. a. The Survey Team reviewed records titled ANNUAL STATISTICS REPORT and PAP SMEAR STATISTICS. The statistics on the records were combined statistics for the laboratory being surveyed and other laboratories. b. During an interview on June 13, 2022 at 4:15 PM, the Laboratory Director/Technical Supervisor A stated that the statistics were for multiple laboratories. 3. During an interview on June 14, 2022 at 1:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. The laboratory failed to document three of three required nongynecologic 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 three of three required nongynecologic cytology statistics. Statistics include: -The number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide the three required nongynecologic annual statistics for 2020 and 2021. Statistics include: -The number of cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory. a. The Survey Team reviewed records titled ANNUAL STATISTICS REPORT. The statistics on the records were combined statistics for the laboratory being surveyed and other laboratories. b. During an interview on June 13, 2022 at 8:40 AM, the Laboratory Director/Technical Supervisor A stated that the laboratory did not perform nongynecologic cytology testing. 3. The Survey Team identified one nongynecologic case from 2021. Case includes: -CMWO2021-001504 a During an interview on June 14, 2022 at 9:30 AM, the Laboratory Director/Technical Supervisor A stated that the laboratory stopped nongynecologic cytology testing in approximately November 2020. The Laboratory Director/Technical Supervisor A further stated that the laboratory received and reported results on the nongynecologic case by mistake. 4. During an interview on June 14, 2022 at 1:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on June 14, 2022 at 1:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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, laboratory records, specimen slides and interview the laboratory failed to establish written policies and procedures for an effective ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. The laboratory failed to identify and document failures of the analytic systems in 2021 and to the date of the survey in 2022. Cross refer to D6115 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define an effective quality assessment program to monitor, assess and correct diagnostic interpretation errors identified in cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of any problems identified in the accuracy of reporting gynecologic cytology test results in 2021 and to the date of the survey in 2022. 3. The laboratory failed to verify the accuracy of 12 gynecologic cytology tests. Refer to D6115 4. During an interview on June 15, 2022 at 12:25 PM, the Survey Team asked the Laboratory Director/Technical Supervisor A if there were any programs to identify diagnostic interpretation errors. The Laboratory Director/Technical Supervisor A stated six gynecologic cases were randomly reviewed per quarter from multiple laboratories. a. The Survey Team reviewed records titled MONTHLY QUALITY ASSURANCE RETROSPECTIVE REVIEW for 2021 through June 2022. The records failed to identify any diagnostic interpretation errors.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if

applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on review of final test reports and interviews the laboratory failed to maintain duplicates of four of four original final test reports from January through July 2020 and February 2022 when a correction was made to the original final test report.

Findings include: 1. The Survey Team requested and the laboratory failed to provide a duplicate of the original final test report for four of four reports that were corrected.

Reports include: -CMWO2020-000036 -CMWO2020-000505 -CMWO2020-000778 -

CMWO2022-000263 2. During an interview on June 13, 2022 at 10:45 AM, the

Laboratory Manager stated the laboratory did not maintain duplicates of the original final test report when a correction was made to the original final test report. 3. During

an interview on June 14, 2022 at 1:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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:

Based on microscopic review of 1235 gynecologic cases/1289 slides and the corresponding final test reports from January 2019 through October 7, 2022 and confirmation by the Survey Team Pathologist on October 21, 2022 the Technical

Supervisor failed to verify the accuracy of 12 gynecologic cytology tests. Findings include: 1. CMWO2021-000663 06/17/2021 Imaged ThinPrep Pap Test (I-TPPT)

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 2. CMWO2021-000892 08/20/2021 ThinPrep Pap

Test (TPPT) LABORATORY DIAGNOSIS: Atypical Squamous Cells of

Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High

Grade Squamous Intraepithelial Lesion 3. CMWO2021-001476 12/13/2021 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 4. CMWO2021-001568 12/29/2021 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 5. CMWO2021-001611 01/05/2022 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 6. CMWO2022-000746 06/07/2022 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 7. CMWO2022-001247 10/07/2022 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 8. CVSO2020-002363 11/03/2020 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 8. CVSO2020-002363 11/03/2020 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade

Squamous Intraepithelial Lesion 8. CVSO2020-002363 11/03/2020 I-TPPT

LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined

Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 9. CVSO2022-001003 05/05/2022 TPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 10. CVSO2022-001701 09/16/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 11. CMWO2020-000376 03/20/2020 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 12. CVSO2020-002094 10/09/2020 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion

D9999

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