

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2151225	<b>(X3) Date Survey Completed</b>  02/02/2022
<b>Name of Provider or Supplier</b>  Red Mountain Diagnostics	<b>Street Address, City, State</b>  140 Oxmoor Blvd Suite 140, Homewood, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5625</b>	<p>CYTOLOGY CFR(s): 493.1274(c)(3)</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) (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, microscopic review of gynecologic cytology slide preparations and interview it was determined that the laboratory failed to follow written policies and procedures to review prior gynecologic cases and identify cases with a more significant lesion. The laboratory failed to identify one of two prior negative gynecologic cases as having a more significant lesion than originally reported from January 2021 to December 2021. Findings include: 1. The laboratory failed to follow the procedure FIVE YEAR RETRO REVIEW which stated: "When a GYN case (Pap Smear) is signed out by a Pathologist as HSIL, AIS or Malignant a records search will be done to identify any (which includes unsatisfactory) cases signed out at Red Mountain Pathology in the past five years from the collection date of the current high grade case." 2. The Survey Team reviewed records titled FIVE YEAR GYN PULL LIST from January 2021 to December 2021 that included two current cases of High-grade Intraepithelial Lesion (HSIL). The Survey Team reviewed two prior negative gynecologic cases from two cases of HSIL and determined that the laboratory failed to identify one of two prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative case includes: -CBBO-20-001019 3. During an interview on</p>

February 2, 2022 at 11:30 AM the Laboratory Director/Technical Supervisor A confirmed these findings. p

**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, lack of laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures for an annual statistical evaluation of six of six required laboratory statistics. The laboratory failed to document the six of six required annual statistics for 2019 and 2020. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY STATISTICAL RECORDS which stated: "A. Statistics maintained yearly for the entire laboratory are: a). # of specimens by specimen type b). # of specimens by diagnosis c). # of unsatisfactory specimens by diagnosis and client d). # of total cytology cases examined e). # of gyn cases where cytologic and histologic diagnoses are discrepant f). # of cases where rescreen of a normal (WNL) resulted in reclassification as malignant or pre-malignant (LGSIL or greater) result g). # of pre-malignant or malignant cases where histology results are unavailable for comparison." 2. The Survey Team requested and the laboratory failed to provide the six of six required annual statistics for 2019 and 2020. 3. During an interview on February 2, 2022 at 9:30 AM, the Laboratory Manager confirmed these findings. 4. During an interview on February 2, 2022 at 11:30 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

**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, laboratory records, microscopic review of gynecologic cytology slide preparations and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to microscopically identify one of

one gynecologic cytology slide preparation from November 2021 as being "UNSATISFACTORY FOR EVALUATION." Findings include: 1. The laboratory failed to follow the procedure UNSATISFACTORY SPECIMENS which stated: "Specimen adequacy is at least 5000 well visualized and preserved squamous cells when using the ThinPrep method of processing." 2. The laboratory failed to identify and report one of one gynecologic cytology slide preparation from November 2021 as being "UNSATISFACTORY FOR EVALUATION." Case includes: - CBBO-21-006181 3. During an interview on February 2, 2022 at 11:30 AM the Laboratory Director/Technical Supervisor A confirmed these findings.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, lack of laboratory records, microscopic review of gynecologic cytology slide preparations and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were followed and maintained to assure the quality of cytology services and identify failures in quality as they occur. Cross refer to D5625 and D5629 Findings include: 1. The Laboratory Director failed to ensure the quality of microscopic examinations as part of a program to review prior negative specimens on current HSIL patients. 2. The Laboratory Director failed to ensure six of six annual statistics were documented and reviewed as part of a program to evaluate and monitor annual laboratory statistics.

**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 the microscopic review of 403 random negative gynecologic cases/405 slides and the corresponding final test reports from November and December 2021 and confirmation by the Laboratory Director/Technical Supervisor A on February 2, 2022 it was determined that the Technical Supervisor failed to verify the accuracy of three gynecologic tests. 1. CBBO-21-06283 11/10/21 Hologic Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Low-Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Low-Grade Squamous Intraepithelial Lesion 2. CBBO-21-003244 11/05/21 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Low-Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Low-Grade Squamous Intraepithelial Lesion 3. CBBO-21-006181 11/02/21 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS:

Unsatisfactory for Evaluation. Too few epithelial cells LABORATORY DIRECTOR /TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Evaluation.

**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.