

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2147750	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Mawd Pathology Group Pa	Street Address, City, State 1201 Corporate Drive, Parsons, KS	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of annual gynecologic cytology proficiency testing (PT) enrollment records and interview with the Laboratory Director/Technical Supervisor A, the laboratory failed to enroll in an annual CMS-approved PT program for gynecologic cytology examination in 2019, 2020 and 2021. Findings Include: 1) The survey team requested and the laboratory failed to provide gynecologic cytology proficiency testing enrollment records for 2019, 2020, and 2021. 2) The Laboratory Director /Technical Supervisor A confirmed on May 24, 2022 at 4:05 PM the laboratory performed gynecologic cytology testing in 2019, 2020, and 2021 and did not enroll in an approved proficiency testing program for any years.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on lack of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures to assess the competency of three of three 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 describe the process for assessing the competency of the Technical Supervisors. 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:
Based on lack of a policy and procedures manual and interview, the laboratory failed to have a written procedures manual for all cytology test processes performed by the laboratory available to laboratory personnel. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedures manual for all cytology test processes performed at the laboratory. 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on lack of laboratory policies and procedures and interview, the laboratory

failed to establish written policies and procedures for two laboratory cytology test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's requirements for microscopic examination of gynecologic and nongynecologic cytology specimens, including the detection of inadequately prepared slides. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's system for data entry and reporting of cytology results in the patient record and reporting patient results. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5623

CYTOLOGY
CFR(s): 493.1274(c)(2)

(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) (2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

This STANDARD is not met as evidenced by:
Based on lack of laboratory policies and procedures, laboratory records and interviews, the laboratory failed to establish written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL) or malignant neoplasms with available histopathology. The laboratory failed to provide current records for a correlative review program to determine the causes of any discrepancies in 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 for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology to determine the causes of any discrepancies. 2. The Survey Team requested and the laboratory failed to provide current records of a laboratory comparison of clinical information with cytology reports and a comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology for 2021 and to the date of the survey in 2022. 3. During an interview on May 24, 2022 at 1:00 PM, the Survey Team observed Technical Supervisor B performing the process of correlating the cytology diagnosis with patient clinical information and the corresponding histopathology diagnosis. Technical Supervisor B stated there was no policy or procedure to describe these activities. 4. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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 lack of laboratory policies and procedures and interviews, the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed in 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 describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy reported by the laboratory in 2021 and to the date of the survey in 2022. 2. During an interview on May 24, 2022 at 1:30 PM, Technical Supervisor B stated that Facility B performed the search for and the review of prior negative specimens for each patient with a current HSIL or malignancy. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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 lack of laboratory policies and procedures, lack of laboratory records and interview, the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required cytology 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 cytology statistics. 2. The Survey Team requested and the laboratory failed to document six required annual statistics for 2020 and 2021. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

<p>D5655</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack 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 a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.</p>
<p>D5657</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(5)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and nongynecologic cytology test results. 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory policies and procedures and interview, the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>

<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on lack of laboratory policies and procedures, laboratory records, observation and interviews, the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure the laboratory enrolled in a CMS-approved annual gynecologic cytology PT program (refer to D6088); failed to ensure that quality control programs were established and maintained (refer to D6093); failed to ensure that a written quality assessment program was established and maintained (refer to D6094); failed to ensure two of three Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (refer to D6102); failed to ensure written policies and procedures were established to assess the competency for three of three Technical Supervisors (refer to D6103); and failed to ensure that an approved procedure manual was available to all personnel. (refer to D6106).</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of PT enrollment records, lack of laboratory policies and procedures and interview, the Laboratory Director failed to ensure that the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2019, 2020 and 2021. Cross refer to D2000 Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an annual CMS-approved PT program for 2019, 2020 and 2021. 2. The Laboratory Director failed to ensure written policies and procedures were available to describe the laboratory's process for cytology proficiency testing enrollment of personnel that perform gynecologic cytology testing. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory policies and procedures, laboratory records and interview, the Laboratory Director failed to ensure quality control programs were established and</p>

maintained in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Laboratory Director failed to ensure the establishment and maintenance of written policies and procedures for a quality control program for all phases of cytology testing. 2. The Laboratory Director failed to provide records of an established quality control program and failed to identify failures in quality in 2020, 2021 and to the date of the survey in 2022. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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 lack of laboratory policies and procedures, laboratory records and interview, the Laboratory Director failed to ensure quality assessment programs were established and maintained in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide the establishment and maintenance of written policies and procedures for a quality assessment program for all phases of cytology testing. 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality in 2020, 2021 and to the date of the survey in 2022. 3. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, laboratory records and interview, the Laboratory Director failed to ensure that two of three Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to evaluating and reporting patient specimens using the HOLOGIC THINPREP Pap Test in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Laboratory Director failed to ensure appropriate training prior to evaluating and reporting Hologic ThinPrep Pap tests. a. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." b. The Survey Team requested and the laboratory failed to provide the required morphology certification for two of three Technical Supervisors

	<p>who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Technical Supervisor B -Technical Supervisor C 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory policies and procedures, laboratory records and interview, the Laboratory Director failed to ensure policies and procedures were established to assess, monitor and maintain the competency of three of three Technical Supervisors performing cytology test procedures. Cross refer to D5209 Findings include: 1. Laboratory Director failed to ensure that three of three technical supervisors were monitored to assess their competency to perform cytology test procedures in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a policy and procedure manual and interview, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Cross refer to D5401 Findings Include: 1. The Laboratory Director failed to ensure an approved procedure manual was available to all personnel. 2. During a telephone interview on May 24, 2022 at 4:05 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</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>