| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 17D1027743 | 06/23/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Heartland Pathology, Pa | 9300 East 29th St North, Suite 208, Wichita, 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 |
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| **D5205** | COMPLAINT INVESTIGATIONS<br>CFR(s): 493.1233<br><br>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish a system for the documentation of complaints reported to the laboratory during the years 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for documentation of complaints made to the laboratory. 2. The Survey Team requested and the laboratory failed to provide documentation of complaints made to the laboratory for 2019, 2020 and to date of the survey in 2021. 3. During an interview with the Survey Team at 10:00 AM on June 23, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 11 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test procedure. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for gynecologic cytology Proficiency Testing enrollment and participation of personnel that perform gynecologic cytology testing. 2. During an interview with the Survey Team at 10:00 AM on June 23, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5629** | CYTOLOGY<br>CFR(s): 493.1274(c)(5)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>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 the evaluation and comparison of six of six laboratory statistics and failed to document two of six required annual statistics for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six required statistics. 2. The Survey Team requested and the laboratory failed to provide two of six required annual statistics for 2019 and 2020. Statistics include: a. Gynecologic cases where cytology and histology are discrepant; and b. 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 with the Survey Team at 10:00 AM on June 23, 2021 Technical Supervisor #2 confirmed these findings. |
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| **D5633** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>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 ensure that individual maximum workload limits were established for five of five Technical Supervisors during the years 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that individual maximum workload limits were established for five of five Technical Supervisors.. 2. The Survey Team requested and the laboratory failed to provide an individual workload limit for five of five Technical Supervisors for 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview with the Survey Team at 2:15 PM on June 21, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5637** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)(ii)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>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 ensure that the workload limit for five of five Technical Supervisors was reassessed and adjusted when necessary at least every six months during 2019, 2020 and to date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment and adjustment when necessary of workload limits at least every six months for five of five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of a reassessed workload limit for five of five Technical Supervisors during 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview with the Survey Team at 2:15 PM on June 21, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5641** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(ii)<br><br>(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 |

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| | (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;<br><br>This STANDARD is not met as evidenced by:<br>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 ensure that the workload limits for five of five Technical Supervisors would be prorated when examining slides in less than eight hours. The laboratory failed to document prorated workload limits for five of five Technical Supervisors when examining slides in less than an eight-hour day in 2020 and 2021 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for five of five Technical Supervisors when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for five of five Technical Supervisors when examining slides at the laboratory in less than eight hours. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview with the Survey Team at 2:15 PM on June 21, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5645** | CYTOLOGY<br>CFR(s): 493.1274(d)(3)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to ensure that the laboratory maintained records for five of five Technical Supervisors of the total number of slides and the total number of hours spent evaluating slides per 24-hour period in 2020 to the date of the survey in 2021. 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 total number of slides and total number of hours spent evaluating slides in 2020 and to the date of the survey in 2021. 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides and total number of hours five of five Technical Supervisors spent evaluating slides during each 24-hour period in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview with the Survey Team at 2:15 PM on June 21, 2021 Technical Supervisor #2 confirmed these findings. |
| **D5647** | CYTOLOGY<br>CFR(s): 493.1274(d)(4) |

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| | (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.<br><br>This STANDARD is not met as evidenced by:<br>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 ensure that records were available to document the workload limit for five of five Technical Supervisors for 2020 and to the date of the survey in 2021. Cross refer to D5633 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for five of five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records to document the workload limit for five of five Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. During an interview with the Survey Team at 2:15 PM on June 21, 2021 Technical Supervisor #2 confirmed these findings. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079). |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5205, D5403, D5629, D5633, D5637, D5641, D5645 and D5647. |
| **D6130** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(2)(3)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor #1 failed to establish and reassess the workload limits at least every six months and make adjustments when necessary for five of five Technical Supervisors in 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637 |
| **D6133** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(6)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor #1 failed to document the total number of slides and total number of hours devoted to examining slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5645 |
| **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. |