Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1027743	01/16/2025
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of the cytology procedure manual, lack of current laboratory director (LD) approval and interview with the cytology general supervisor (CT/GS), the laboratory failed to have 19 of 47 cytology procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Review of the laboratory cytology procedures revealed the current LD did not approve, sign, and date 19 of 47 of the laboratory procedures at the time of survey. 2. The following procedures were not signed by the current LD: a. Pathologist Qualifications. b. Quality Assurance Program. c. QA Program for Heartland Pathology Pathologists. d. Maintaining Proper Quality Assurance During the Pre-analytical, Analytical and Post-analytical Phases. e. Imminently Life=Threating Test Results Significant and Unexpected Findings. f. Specimen Rejection Procedure. g. Cytology Microscope Evaluation. h. Course of Action When the Novopath System or Server Becomes Inoperable (Fail-Safe). i. Cytopathologic Interlaboratory Comparison Program. j. Cytology Workload Limits Primary Screening. k. Non-Gynecologic Specimens with a High Potential for Cross-Contamination. l. Collection and Receipt of Specimens. m. Esophageal Brushings. n. Gastric Washing & Brushings. o. Fine Needle Aspiration - General. p. Fine Needle Aspiration - Thyroid. q. Fine Needle Aspiration - Breast. r. Cell Block Preparation. s. Interpreting Results and Reporting on Non Gyn Cytology Cases. 3. Interview with the CT/GS on 1/16/25at 11:50 a.m. confirmed, the laboratory failed to have 19 of 47 cytology procedures approved, signed, and dated by the current laboratory director before use.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on the review of the CMS-116 test lists, tour of the laboratory, lack of comparison study documents, and interview with the Director of Laboratory Services (DLS), the laboratory failed to perform comparison studies on Immuno Histochemical (IHC) stains performed on three of three Ventana Benchmark staining instruments for 2023, 2024, and to date of survey 2025. Findings: 1. Review of the CMS116 test lists revealed that 77 IHC stains are performed in the laboratory. 2. During a tour of the laboratory, the surveyor noted that the IHC stains are performed by three Ventana Benchmark staining instruments. Serial numbers are 319259, 319258, 320951. All three instruments can perform all 77 stains. 2. The surveyor requested documentation of twice a year comparisons of the 77 stains on the three Ventana Benchmark instruments. No documentation of twice a year comparison studies for 2023, 2024, and to date of survey 2025 was provided at the time of survey. 3. Interview with the DLS on 1/26/25at 11:40 a.m. confirmed, the laboratory failed to perform comparison studies on IHC stains performed on three of three Ventana Benchmark staining instruments for 2023, 2024, and to date of survey 2025.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS-209 Laboratory Personnel Report, competency assessment documentation, and interview with the DLS, the technical supervisor (TS) failed to perform competency assessment on one of one cytologist (CT) with the required six elements for 2023, 2024 and to date of survey 2025. Findings: 1. Review of the CMS-209 Laboratory Personnel Report found one cytologist as high complexity testing personnel (TP). 2. The surveyor requested competencies for review. The competencies provided for 2023, and 2024 failed to include the following required elements. a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f. Assessment of problem solving

	skills. 3. Interview with the DLS 1/16/25 at 10:05 a.m. confirmed the TS failed to perform competency assessment on one of one CT with the required six elements for 2023, 2024.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on the review of the CMS 209 personnel form, annual competency documentation, and interview with the DSL, the general supervisor (GS) failed to perform the annual competency assessment which included the six required elements for 11of 11 high complexity TP for 2023 and 2024. Findings: 1. Review of the CMS209 personnel form revealed that 11of 11 TP had performed high complexity testing for more than one year in histology and hematology. 2. The surveyor requested competencies of the 11of 11 TP for review. The competencies provided for 2023 and 2024 failed to include the following required elements. a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f. Assessment of problem solving skills. 4. Interview with the DLS on 1/16/25 at 10:05 a.m. confirmed, the GS failed to perform the annual competency assessment which included the six required elements for 11of 11 high complexity TP for 2023 and 2024.