| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D2093824 | 08/03/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Heartland Pathology Diagnostics, Llc | 9300 E 29th St N Ste 209, 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 |
|---|---|
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system and the College of American Pathologists (CAP) PT summary reports, the laboratory failed to successfully participate in the CMS approved PT 2026 program under the specialty of Routine Chemistry, for two consecutive testing events. Refer D2096. |
| **D2096** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(f) |

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| | (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a desk review of proficiency testing (PT) and the provider College of American Pathologists (CAP) for Routine Chemistry, the laboratory failed to achieve an acceptable score of 80% or higher for two consecutive testing events for the regulated routine chemistry analytes: 0435 - LDH. Findings: 1. Review of the CAP PT scores for 2026 for the analyte 0435 - LDH: a. Event 1 revealed a 0% performance score for 0435 - LDH. b. Event 2 revealed a 0% performance score for 0435 - LDH. 2. A email with the laboratory supervisor on August 3, 2025 at 12:15 p.m. and review of the provider College of American Pathologists (CAP) for Routine Chemistry confirmed, the laboratory failed to achieve an acceptable score of 80% or higher for two consecutive events for the regulated routine chemistry analyte: 0435 - LDH, |