

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D1026068	(X3) Date Survey Completed 09/05/2019
Name of Provider or Supplier Heartland Diagnostic Services Llc	Street Address, City, State 3290 20th St S, Fargo, ND	
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on American Proficiency Institute proficiency testing record review and laboratory director communication, the laboratory failed to achieve satisfactory performance in white blood cell differential proficiency testing for two consecutive testing events in 2019 (Event 1 and Event 2), resulting in unsuccessful performance. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on proficiency testing record review and laboratory director communication, the laboratory failed to achieve satisfactory performance in proficiency testing for white blood cell differential for two consecutive events in 2019 (Event 1 and Event 2), resulting in unsuccessful performance. Findings include: 1. Review of 2019 American Proficiency Institute (API) proficiency testing reports on 09/05/19 for the analyte white blood cell differential revealed the following results: Event 1 - 0% Basophils % Sample Lab results Acceptable Range #1 0.0 4.6 - 7.8 #2 0.0 4.1 - 7.2 #3 0.0 5.2 - 8.6 #4 0.0 4.7 - 7.9 #5 0.0 4.5 - 7.6 Eosinophils % Sample Lab results Acceptable Range #1 0.0 7.7 - 12.3 #2 0.0 6.8 - 11.2 #3 0.0 8.2 - 13.0 #4 0.0 7.5 - 12.0 #5 0.0 7.6 - 12.0 Lymphocytes % Sample Lab results Acceptable Range #1 1.7 31.1 - 35.4 #2 0.7 35.3 - 41.6 #3 3.1 27.6 - 30.6 #4 0.7 31.1 - 37.6 #5 1.6 31.5 - 35.6 Monocytes % Sample Lab results Acceptable Range #1 0.2 7.7 - 11.1 #2 0.0 7.4 - 11.7 #3 0.8 8.4 - 11.0 #4 0.2 7.3 - 11.9 #5 1.1 8.2 - 11.5 Neutrophils % Sample Lab results Acceptable Range #1 4.8 38.2 - 44.1 #2 2.2 34.1 - 40.7 #3 14.1 40.8 - 46.6 #4 2.4 36.7 - 43.3 #5 5.6 38.0 - 43.6 Event 2 - 4% Basophils % Sample Lab results Acceptable Range #6 0.0 4.5 - 7.4 #7 0.0 4.0 - 7.1 #8 0.0 5.3 - 8.5 #9 0.0 4.4 - 7.5 #10 0.0 4.6 - 7.8 Eosinophils % Sample Lab results Acceptable Range #6 0.1 7.4 - 11.9 #7 0.7 6.8 - 10.9 #8 0.0 8.4 - 13.0 #9 0.1 7.4 - 11.9 #10 0.0 7.4 - 11.9 Lymphocytes % Sample Lab results Acceptable Range #6 21.6 33.0 - 36.8 #7 23.1 36.6 - 42.6 #8 16.5 27.8 - 31.1 #9 26.0 33.3 - 37.7 #10 27.2 32.7 - 39.0 Monocytes % Sample Lab results Acceptable Range #6 13.5 7.8 - 10.8 #7 10.2 7.0 - 11.3 #8 0.1 7.6 - 10.4 #9 2.5 7.6 - 10.8 #10 1.2 6.8 - 11.0 Neutrophils % Sample Lab results Acceptable Range #6 64.8 37.4 - 43.0 #7 66.0 33.7 - 40.0 #8 83.4 41.3 - 46.7 #9 71.4 36.8 - 42.6 #10 71.6 36.1 - 42.8 The specialty of hematology requires a score of 80% or greater for satisfactory performance. 2. Through electronic communication received at 10:03 a.m. on 08/20/19 and written communication received on 09/05/19, the laboratory director (#1) stated the laboratory had failed hematology proficiency testing for the second time.