

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2147454	(X3) Date Survey Completed 02/10/2020
Name of Provider or Supplier Heritage Labs Db a Ion Diagnostics Laboratories	Street Address, City, State 4512 Breton Rd Se, Kentwood, MI	
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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of hematology for 2 (1st and 3rd) of 3 testing events in 2019. Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 2 of 3 proficiency testing events for the specialty of hematology. Refer to D2130. .</p>
D2130	HEMATOLOGY

CFR(s): 493.851(f)

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 review of the CMS database and review of the American Proficiency Institute (API) graded proficiency testing reports, the laboratory failed to achieve satisfactory performance for the hematology white blood cell differential for 2 out of 3 consecutive testing events. Findings include: Unsatisfactory performance for 2 out of 3 consecutive proficiency events constitutes unsuccessful performance for white blood cell differential: White Blood Cell Differential PT Event Score 3rd event 2019 0% 1st event 2019 32%