

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2147454	(X3) Date Survey Completed 05/11/2020
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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, It was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the specialty of hematology. Findings include: Review of the CMS database and the API proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the specialty of hematology. Refer to D2121 and D2130. **Repeat deficiency form 2/10/2020**</p>
D2121	HEMATOLOGY

	<p>CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve at least 80 percent for hematology cell identification or white blood cell differential for 3 (1st and 3rd events in 2019 and the 1st event in 2020) out of 4 consecutive testing events. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed the following scores for 3 out of 4 consecutive proficiency for cell identification or white blood cell differential: Cell Identification or White Blood Cell Differential PT Event Score 1st event 2019 32% 3rd event 2019 0% 1st event 2020 32%</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the hematology cell identification or white blood cell differential for 3 (1st and 3rd events in 2019 and the 1st event in 2020) out of 4 consecutive testing events. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed unsatisfactory performance for 3 out of 4 consecutive proficiency for cell identification or white blood cell differential: Cell Identification or White Blood Cell Differential PT Event Score 1st event 2019 32% 3rd event 2019 0% 1st event 2020 32% **Repeat deficiency from 2/10/2020**</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. Failure to ensure that the proficiency testing samples were tested as required under Subpart H. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. . Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program as required under Subpart H for 3 (1st and 3rd events in 2019 and the 1st event in 2020) out of 4 consecutive testing events. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed unsatisfactory performance for 3 out of 4 consecutive proficiency for cell identification or white blood cell differential: Cell Identification or White Blood Cell Differential PT Event Score 1st event 2019 32% 3rd event 2019 0% 1st event 2020 32%