Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D2194915	**(X3) Date Survey Completed** 08/15/2023
Name of Provider or Supplier Phenomics Health Inc	**Street Address, City, State** 46701 Commerce Center Dr, Plymouth, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: . Based on record review of the CMS database and the College of American Pathologists' proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the toxicology analyte valproic acid. Findings include: 1. The laboratory failed to achieve satisfactory performance in proficiency testing for the toxicology analyte valproic acid. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(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. This STANDARD is not met as evidenced by: . Based on record review of the CMS database and the College of American Pathologists' proficiency testing reports, the laboratory failed to achieve satisfactory performance in proficiency testing for the toxicology analyte valproic acid for 3 (3rd event of 2022 and 1st event of 2023, and 2nd event of 2023) of 3 consecutive testing events reviewed. Findings include: 1. A record review of the College of American Pathologists' proficiency testing records revealed the laboratory had not provided its results to the proficiency testing company, resulting in a score of 0 for valproic acid. 2. A record review of the CMS database revealed the laboratory failed to achieve satisfactory performance for three consecutive proficiency testing events: Valproic Acid PT Event Score 3rd event 2022 0% 1st event 2023 0% 2nd event 2023 0%
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on review of the CMS database and review of the College of American Pathologists (CAP) proficiency testing reports, the Laboratory Director failed to provide overall management and direction. Findings include: 1. Laboratory Director failed to ensure that the laboratory successfully participated in a proficiency testing program as required under subpart H. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: . Based on review of the CMS database and review of the College of American Pathologists (CAP) proficiency testing reports, the Laboratory Director failed to ensure that the laboratory successfully participated in a proficiency testing program as required under subpart H. Findings include: The laboratory failed to achieve satisfactory performance for valproic acid. Refer to D2016 and D2118.