Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2194915	02/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Phenomics Health Inc	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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to to maintain monitoring policies and procedures to ensure contamination with genomic deoxyribonucleic acid (DNA) or amplicons was minimized (refer to D3003), failed to utilize a uni-directional workflow for its pharmacogenomic testing using molecular amplification procedures (refer to D3005 A), and failed to have separate areas for reagent preparation and amplification (refer to D3005 B).
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Laboratory Director, the laboratory failed to maintain monitoring policies and procedures to ensure contamination with genomic deoxyribonucleic acid (DNA) or amplicons was minimized for 8 (June 2023 to February 2024) of 8 months since the laboratory started molecular testing. Findings include: 1. A review of the laboratory's "Wipe Test Procedure" approved for use by the Laboratory Director on 6/20/23 revealed a section stating, "The purpose of the monthly wipe test is to detect possible sources of contaminations with genomic DNA or amplicons within the PGx workflow workstations, and laboratory equipment." 2. A review of the laboratory's "Wipe Test Log" revealed wipe tests were not performed monthly and had only been performed on the following dates: a. 11/15/23 b. 2/12/24 3. An interview on 2/26/24 at 3:08 pm with the Laboratory Director confirmed the laboratory had not performed wipe tests in accordance with the established procedure.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: A. Based on observation and interview with the Laboratory Director, the laboratory failed to utilize a uni-directional workflow for its pharmacogenomic testing using molecular amplification procedures for 8 (June 2023 to February 2024) of 8 months since the laboratory started testing. Findings include: 1. An interview on 2/26/24 at 9: 19 am with the Laboratory Director revealed the laboratory started its pharmacogenomic testing in June 2023. 2. A verbal walkthrough of the laboratory's molecular workflow on 2/26/24 at 9:46 am with the Laboratory Director and the Manager revealed specimen preparation is performed to the left of the dead air box, then is transported through the reagent preparation area to the King Fisher Flex extraction analyzer for nucleic acid extraction. Once completed, the extracted specimens are brought back to the dead air box to add the reagents prior to loading on the Eppendorf Mastercycler x50h to the left of the dead air box. During the amplification process with the Eppendorf Mastercycler x50h, the plate is taken off and brought back to the dead air box to add additional reagents. 3. The surveyor observed Testing Personnel #5 preparing the master mix reagents for the plate that was running on the Eppendorf Mastercycler x50h and left the dead air box to go to the specimen preparation area to use the vortex, then went back to the dead air box to continue preparing the master mix on 2/26/24 at 9:56 am. 4. An interview on 2/26/24 at 9:46 am with the Laboratory Director and General Supervisor confirmed the workflow was not unidirectional. B. Based on observation and interview with the Laboratory Director, the laboratory failed to have separate areas for reagent preparation and amplification for 8 (June 2023 to February 2024) of 8 months since the laboratory started testing. Findings include: 1. An interview on 2/26/24 at 9:19 am with the Laboratory Director revealed the laboratory started its pharmacogenomic testing in June 2023. 2. An interview on 2/26/24 at 9:46 am with the Laboratory Director revealed the Eppendorf Mastercycler x50h runs three different programs for the amplification process and the plate is taken off in-between to add reagents. 3. The surveyor observed Testing Personnel #5 preparing the master mix reagents for the plate that was running on the Eppendorf Mastercycler x50h in the dead air box where the post-amplification plate is brought for the addition of more reagents before running the next program on 2/26/24 at 9:56 am. The same area is used in both

	reagent preparation and amplification. 4. An interview on 2/26/24 at 10:08 am with the Laboratory Director confirmed the laboratory did not have separate areas for amplification and reagent preparation.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to verify the accuracy of analytes not formally graded for 2 (Toxicology event C-C 2023 and Pharmacogenomics event PGX-B 2023) of 4 events reviewed. Findings include: 1. A review of the laboratory's proficiency testing documentation revealed the Toxicology event C-C 2023 response "was not graded due to insufficient peer group data" and the Pharmacogenomics event PGX-B 2023 was an "educational challenge" with a lack of formal scores. 2. A review of the laboratory's "Proficiency Testing Policy-Ungraded PT Test Results Review" revealed a section stating, "Corrective action is required whenever an unacceptable response is obtained. Investigation and evaluation are required whenever a test result is un-graded due to no consensus." 3. An interview on 2/26/24 at 12:19 pm with the Laboratory Director revealed the laboratory had not verified the accuracy of the analytes tested in the proficiency testing events listed above and corrective action was not performed in accordance with the established policy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to verify the accuracy at least twice annually for 181 of 318 analytes on the laboratory's test menu. Findings include: 1. A review of the laboratory's College of American Pathologists' Proficiency Testing documentation revealed a lack of documentation showing the following analytes on the laboratory's test menu were challenged in the toxicology and pharmacogenomics testing events in 2022 and 2023: a. ABCB1 b. ADRA2A c. BDNF d. CACNA1C e. COMT f. CPS1 g. CYP2B6 h. CYP1A2 i. DRD2 j. GRIK1 k. GRIK4 l. HLA-A m. HLA-B n. HTR2A o. HTR2C p. MC4R q. MTHFR r. UGT2B15 s. VKORC1 t. 6-Beta-Naltrexol u. Asenapine v. Atomoxetine w. Brexpiprazole x. Buspirone y. Chlorpromazine z. Clonidine aa. Desvelafaxine bb. Fluvoxamine cc. Fluphenazine dd. Guanfacine ee. haloperidol ff. Iloperidone gg. Lurasidone hh. Milnacipran ii. Naloxone jj. Naltrexone kk. Norhydrocodone ll. Noroxymorphone mm. Norquentiapine nn. Paliperidone oo. Perphenazine pp. Risperidone qq. Ritalinic Acid rr. Thioridazine ss. Thiothixene tt. Vilazodone uu. Vortioxetine vv. Ziprasidone ww. Eszopiclone xx. 6-

	Hydroxybuspirone yy. Acebutolol zz. Acetazolamide aaa. Alfuzosin bbb. Alpha-Hydroxymetoprolol ccc. Amiodarone ddd. Amlodipine eee. Amoxapine fff. Atorvastatin ggg. Atorvastatin Lactone hhh. Baclofen iii. Benzaprilat jjj. Bisoprolol kkk. Budesonide lll. Buspirone mmm. Candesartan nnn. Canrenone ooo. Carvedilol ppp. Celecoxib qqq. Cetirizine rrr. Chlorothiazide sss. Cilostazol ttt. Clopidogrel uuu. Colichicine vvv. Lisinopril www. Loratadine xxx. Losartan yyy. Meloxicam zzz. Metformin A Methocarbamol B. Metoclopramide C. Montelukast D. Nadolol E. Nateglinide F. N-Desmethylvenlafaxine G. Nifredipine H. Nitrofurantoin I. Nordazepam J. Olmesartan Acid K. Olopatadine L. Omeprazole N. Ondansetron O. Oxypurinol P. Pantoprazole Q. Pentoxifylline R. Dabigatran S. Darifenacin T. Dehydroaripiprazole U. Desethylamiodarone V. Desloratadine W. Dexamethasone X. Diclofenac Y. Dipyridamole Z. Donepezil AA. Doxazosin BB. Dronedarone CC. Eletriptan DD. Enalaprilat EE. Etodolac FF. Ezetimibe GG. Famoltidine HH. Febuxostat II. Fenofibric Acid JJ. Rexofenadine KK. Flecainide LL. Furosemide MM. Gemfibrozil NN. Flimepiride OO. Flipizide PP. Glyburide QQ. Pioglitazone RR. Piroxicam SS. Prednisone TT. Promethazine UU. Raloxifene VV. Ranitidine WW. Ranolazine XX. Repaglinide YY. Rivaroxaban ZZ. Ropinirole AAA. Rosiglitazone BBB. Saxagliptin CCC. Sitagliptin DDD. Sumatriptan EEE. Telmisartan FFF. Terazosin GGG. Ticagrelor HHH. Tofacitinib III. Torsemide JJJ. Triamterene KKK. Valsartan LLL. Vardenafil MMM. Warfarin NNN. Hydrochlorothiazide OOO. Hydroxyxhloroquine PPP. Hyoscuamine QQQ. Imdapamide RRR. Indomethacin SSS. Eszopiclone TTT. Irbesarten UUU. Itraconazole VVV. Labetalol WWW. Lansoprazole XXX. Linagliptin 2. A review of the laboratory's "Proficiency Testing: Alternative Assessment" policy revealed a section stating, "Unregulated analytes are those within a clinical test(s) not listed in the CFR. It can occur that unregulated analytes does not have commercial products available or the commercial product does not challenge all aspects of the test. CLIA requires tat, in these cases, at least twice annually, the lab verifies th accuracy of unregulated tests or procedures through another mechanism. Drug analysis employing LC/MS/MS methodology falls into the category of unregulated clinical testing for which there is no comprehensive commercial product currently available to confirm testing accuracy for all drugs and metabolites reported. Phenomics Health, Inc., will make use of "intra laboratory split sample testing" as a mechanism to confirm testing accuracy and meet the CAP-CLIA requirements for proficiency testing of drug analytes presently covered in the Comprehensive Drug Assay." 3. An interview on 2/26/24 at 12:19 pm with the Laboratory Director revealed the laboratory had not performed twice annual verification of accuracy testing for the analytes listed above in accordance with the established procedure for 2022 and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to ensure all reagents were labeled to indicate storage requirements and expiration dates for 9 reagents observed. Findings include: 1. The surveyor

	observed the following reagents that failed to have the storage requirements and expiration dates indicated: a. A glass bottle with a blue screw top labeled with "0.1% FORMIC ACID in ACE." b. A smaller glass bottle with a blue screw top had yellow tape with "hydroxide 7/20/23" written on it. c. A plastic squirt bottle labeled with "2-propanol 100% 2/16/24" written on it. d. A 100 mL beaker with aluminum foil on the top labeled with "97:3 Recon." e. A small glass bottle with a white screw top with a label stating "Noviplex collection discs 850 disks." f. A 100 mL beaker with aluminum foil on the top labeled with "ACN 100%." g. A 100 mL beaker with "0.1% FA 5/4/23 in water" on the yellow label. h. A 100mL beaker with "DN80 100% 5/4 /23" on the yellow label. i. A 25 mL beaker with parafilm on the top labeled with "MeOH filled 2/26/24." 2. A review of the laboratory's "Reagent Management Policy" revealed a section stating, "Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled, as applicable and appropriate, with the following elements: a. Content and quantity/concentration b. Storage requirements c. Date prepared by laboratory d. Expiration date" 3. An interview on 2/26/24 at 9:32 am with the Laboratory Director confirmed the reagents listed above did not include the storage requirements and expiration dates.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the Technical Supervisor failed to perform direct observations of patient test performance when conducting competency assessments for 1 (Testing Personnel #2) of 5 testing personnel listed on Form CMS-209. Findings include: 1. A review of competency assessments revealed the competency assessments for Technical Supervisor #2 were performed by Technical Supervisor #2 on 12/1/23. 2. An interview on 2/26/24 at 12: 52 am with the Laboratory Director revealed Technical Supervisor #2 had never been to the laboratory and the competency assessment for Testing Personnel #2 did not include direct observation of patient testing.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, personnel performing the duties of the General Supervisor were not qualified. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which

the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
. Based on record review and lack of documentation, personnel performing the duties of a General Supervisor were not qualified for 3 (General Supervisor #1-#3) of 6

	personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's competency assessments revealed General Supervisor #1-#3 had performed competency assessments for high complexity testing personnel, a duty that can be delegated to General Supervisors by Technical Supervisors. 2. A review of qualifications for General Supervisor #1-#3 revealed a lack of documentation of at least one year of laboratory training or experience in high complexity testing for the three personnel. 3. The surveyor requested the training and experience documentation on 2/26/24 at 12:52 pm and it was not made available. 4. The laboratory was granted an additional 7 days to provide the missing documentation and it was not received.