Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D1036625	02/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Of Personalized Health	67 Jefferson St, 1st Flr, Hartford, CT	

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
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 staff interview, the laboratory failed to verify accuracy bi-annually for testing performed in the specialty of Hematology and the sub-specialty of Toxicology. Findings include: 1. Record review of the proficiency testing (PT) records from the College of American Pathologists (CAP) on 2/28/19 revealed: a. The laboratory did not enroll in PT testing in 2017. Biannual verification of test accuracy was not performed in 2017. b. The laboratory participated in PT testing with CAP in only one event in 2018. No further records for biannual verification of test accuracy were available for 2018. 2. Staff interview with the laboratory director on 2/28/19 at 9: 25 AM confirmed the above findings. 3. The laboratory performs 900 tests in the sub-specialty of Toxicology and 240 tests in the specialty of Hematology annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to use in date reagents in the specialty of Hematology and sub-specialty of Toxicology.. Findings include: 1. Surveyor observation of the laboratory freezer on 2/28/19 at 10:45 AM

	revealed 27 reagents with expiration dates ranging from 01/2014 through 01/2019 were in use. 2. During staff interview with the testing personnel and the laboratory director (LD) on 2/28/19 the LD stated: a. 26 of 27 expired reagents were only used for research purpose but were not labeled as such. b. 1 of 27 expired reagents is currently used for patient testing and no other in date reagent was available. 3. The laboratory performs 900 tests in the sub-specialty of Toxicology and 240 tests in the specialty of Hematology annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: (A) Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the sub-specialty of Toxicology. Findings include: 1. Record review of the maintenance log for Auto-Genomics Infinity Plus (asset tag 1045) instrument for pharmacogenetics testing on 2 /28/19 revealed the lack of daily, weekly and monthly maintenance documentation. 2. Record review of the operator manual for the above instrument on 2/28/19 revealed daily, weekly and monthly maintenance is required to obtain accurate test results. 3. Staff interview with testing personnel (TP) on 2/28/19 at 10:40 AM confirmed the laboratory failed to document daily, weekly and monthly maintenance and function checks for the above equipment as required by the manufacturer. TP further stated he /she was not aware routine maintenance and function checks were required by the manufacturer. 4. The laboratory performs 900 tests in the sub-specialty of Toxicology annually. (B) Based on record review and staff interview, the laboratory failed to perform and document preventive maintenance for the laboratory equipment(s) to ensure accurate and reliable test results. Findings include: 1. Record review on 2/28 /19 of the equipment(s) preventive maintenance (PM) logs for 2017 and 2018 revealed the following: a. Annual PM of the 'Luminex 200' {serial number (SN#) LX10012320401} was not performed and documented in 2018 as recommended by the manufacturer. b. Annual PM of the 'GenMark Dx' (SN# L100564) was not performed and documented in 2017 and 2018 as recommended by the manufacturer. c. Annual PM of the 'Capt air ultra violet' equipment (unit ID: DNA 103-2012-a) was not performed and documented in 2017 and 2018 as recommended by the manufacturer. 2. Staff interview with the testing personnel (TP) on 2/28/19 at 11:00 AM confirmed that annual PM and function checks for the above laboratory equipment were overlooked and not performed since 2017 for item listed in (a) above and since 2015 for items listed in (b) and (c) above. 3. The laboratory performs 900 tests in the sub-specialty of Toxicology and 240 tests in the specialty of Hematology annually.