Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1041308	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Princeton Longevity Medical Group	104 Carnegie Center Drive, Princeton, NJ	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of analyzer Quality Control Records (QC), review of the Manufacturer QC Directions For Use (DFU) and interview with the Techincal Consultant (TC), the laboratory failed to follow the DFU for QC for Hematology testing performed on the Sysmex XN-430 from 7/13/21 to 9/25/24. The findings include: 1. The directions for use stated "XN-L Check is stored at 2-8C before and after opening. The period of use is 12 weeks per lot, with an open vial stability of 15 days if stored at 2 - 8 C. The volume is 3.0 mL per vial." 2. The TC stated "QC is used over 15 working days not calendar days" 3. The TC confirmed on 9/25/24 at 11:40 am, the laboratory failed to follow the DFU.
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: Based on surveyor review of the Maintenance Records (MR) for the Tosoh AIA 360 analyzer, User Manual and interview with the Technical Consultant (TC) the

	laboratory failed to perform and document monthly maintenance as specified by the manufacturer for the Tosoh AIA 360 analyzer used for Endocrinology tests from March 1, 2023 to August 31, 2024. The finding includes: 1. There was no documented evidence for monthly maintenance performed in the months of March 2023, May 2023, September 2023, December 2023, Februrary 2024 and August 2024. 2. The TC confirmed on 9/25/24 at 1:15 pm there was no documented evidence for monthly maintenance performed for the Tosoh AIA 360 in the above mentioned months.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to establish a maintenance protocol for the Labomed CxL microscope used for Urine Microscopy tests from 7/13/21 to 9 /25/24. The findings include: 1. The PM did not have a maintenance protocol for the Labomed CxL microscope. 2. The TC confirmed on 9/25/24 at 11:00 am the laboratory did not have a maintenance protocol for the Labomed CxL microscope.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control Verification (QCV) records and interview with the Technical Consultant (TC) , the laboratory failed to verify QC material before use for Alfa Wassweman Ace Alera from 7/3/21 to 9/25/24. The findings include. 1) There was no documented evidenced that the QCV was performed on the current lot of Alfa Wassermsan Controls. 2) The TC confirmed 9/25 /24 at 11:15 am that QC material was not verified before putting in use.