

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1041308	<b>(X3) Date Survey Completed</b>  11/27/2018
<b>Name of Provider or Supplier</b>  Princeton Longevity Medical Group	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), review of Quality Control (QC) data and interview with the Laboratory Consultant (LC), the laboratory failed to verify assayed QC material was within the acceptable range before it was put into use for Chemistry tests from May 2018 to the date of survey. The finding includes: 1. Review of the QC records revealed the controls listed below were not verified before use: a. Mas Liquimmune Control Lot # LIA20042 currently in use. c. Point Scientific Control Level 1 Lot # 807301 and Level II Lot # 807302 currently in use. d. ELITechGroup ISE control level 1 lot # 17-1250 and level II lot # 17-1355 currently in use. 2. The LC confirmed on 11/27/16 at 11:40 AM that the QC lots listed above were not verified.</p>