

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1041308	<b>(X3) Date Survey Completed</b> 07/13/2021
<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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) vials and interview with the Technical Consultant (TC), the laboratory failed to put an appropriate expiration date on the ELITechGroup ISE QC reagents in use on the Selectra Pro S analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "After reconstitution: Stability of component: between 2-8 C for 7 days" 2. The laboratory failed to record expiration dates on the ELITechGroup ISE QC vials. 3. The TC confirmed on 7/13/21 at 11:00 am the laboratory failed to put appropriate expiration dates on the QC vials.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) Records and interview with the Technical Consultant (TC), the laboratory used expired ELITechGroup ISE QC</p>

material for electrolyte testing from 7/7/21 to the date of survey. The findings include: 1. QC material expiration date changes once opened. 2. The laboratory was unaware that ELITechGroup ISE QC material expired 7 days after opening. 3. QC material in use was opened 6/24/21 and expired 7/1/21. 4. Approximately 32 patients were run and reported after 7/1/21. 5. The TC confirmed on 7/13/21 at 12:30 pm that the laboratory used expired QC material.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of the Personnel Files (PF) and interview with Technical Consultant (TC), the Laboratory Director (LD) failed to have foreign education evaluated for one out of two Testing Personnel (TP) performing nonwaived tests from June 2021 to the date of the survey. The finding includes: 1. The laboratory did not have a foreign education evaluation for one out of two TP. 2. The TC confirmed 7/13/21 at 10:30 am that the LD did not have foreign education evaluated.