

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2328883	(X3) Date Survey Completed 09/28/2026
Name of Provider or Supplier Longevity Nutricare Llc	Street Address, City, State 6605 Cypresswood Drive, Suite 125, Spring, TX	
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
D0000	An announced survey of the laboratory was conducted on 09/28/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's policies/procedures, sample receipt documents and staff interview, the laboratory failed to follow its own policy and document specimen transport conditions and/or transport time to ensure samples' stability for nine of nine patient samples received by the laboratory for testing on the Piccolo Xpress chemistry analyzer from January through August 2026. Findings included: 1. Review of manufacturer instructions in the "Piccolo Xpress chemistry analyzer Operator's Manual" (document dated February 2025) revealed: "3.1 Sample Requirements ... Plasma or serum can be stored at room temperature for no longer than five hours after centrifugation. If storage for more than five hours is required, refrigerate the sample in the stoppered tube at 2-8C (36-46F) for no longer than 48 hours, or store it at -10C (14F) for up to five weeks in a freezer with no self-defrost cycle." 2. Review of the laboratory's "Standard Operating Procedure Specimen Transport" (effective 01/20/2026) revealed: "Patient specimens shall be transported in a manner that preserves specimen integrity, prevents leakage or contamination, and

maintains appropriate environmental conditions for the requested testing." And, "Specimens shall be transported under conditions appropriate for the requested testing unless otherwise specified by the assay manufacturer." And, "Upon receipt, laboratory personnel shall verify: ... " - Acceptable transport temperature (when applicable) " - Acceptable transport time" 3. Review of laboratory's sample receipt documents revealed the following seventeen samples were received in the laboratory for testing on the Piccolo Xpress from January through August 2026 without documentation of transport temperature and/or time: Date/time collected: 07/24/2026 at 12:30PM Date received: 07/24/2026 - No transport time documented Sample: LNC0104-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 07/29/2026 at 9:45AM Date received: 07/30/2026 - No transport time documented Sample: LNC0109-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 07/29/2026 at 9:15AM Date received: 07/30/2026 - No transport time documented Sample: LNC0110-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/03/2026 at 9:20AM Date received: 08/04/2026 - No transport time documented Sample: LNC0113-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/03/2026 at 9:50AM Date received: 08/04/2026 - No transport time documented Sample: LNC0114-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/03/2026 at 8:30AM Date received: 08/04/2026 - No transport time documented Sample: LNC0115-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/06/2026 at 8:30AM Date received: 08/07/2026 - No transport time documented Sample: LNC0116-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/06/2026 at 9:15AM Date received: 08/07/2026 - No transport time documented Sample: LNC0117-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented Date/time collected: 08/06/2026 at 8:30AM Date received: 08/07/2026 - No transport time documented Sample: LNC0118-26 Tests ordered: Magnesium, Phosphorus, Lactate Blood Test Transport temperature: Not documented 4. In an interview on 09/28/2026 at 1140 hours in the office, the Laboratory Director (as indicated on submitted Form CMS 209) stated that the facility tested samples from outside clinics and received samples only as serum in Serum Separator Tubes (SST), but did not document sample temperature or transport time, confirming the findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory's test menu, new test verification studies, patient test records and staff interview, the laboratory failed to document verification of patient

	normal ranges for magnesium, lactate and phosphorus testing with the MetLac12 cartridge, one of one moderate complexity testing Piccolo Xpress cartridge used by the laboratory from January through August 2026. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory tested magnesium, lactate and phosphorus using the MetLac12 Piccolo Xpress cartridge. 2. Review of the laboratory's new test verification studies revealed the laboratory did not have documentation of verification of patient normal ranges for magnesium, lactate and phosphorus. 3. Review of laboratory's patient test records revealed the laboratory tested magnesium, phosphorus and/or lactate on the following nine samples from January through August 2026: LNC0104-26 LNC0109-26 LNC0110-26 LNC0113-26 LNC0114-26 LNC0115-26 LNC0116-26 LNC0117-26 LNC0118-26 4. In an interview on 09/28/2026 at 1140 hours in the office, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's policies/procedures, sample receipt documents and staff interview Laboratory Director failed to ensure test systems provide quality lab services for preanalytic systems for one of one test platforms used by the laboratory, the Piccolo Xpress chemistry analyzer. Refer to D5311.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of laboratory's test menu, new test verification studies, patient test records and staff interview, Laboratory Director failed to ensure test verification studies included verification of patient normal ranges for one of one moderate complexity MetLac12 Cartridge tested on the Piccolo Xpress chemistry analyzer. Refer to D5421. Key: C - Degrees Celsius F - Degrees Fahrenheit CMS - Centers for Medicare and Medicaid Services