Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2233899	03/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Voruganti Laboratory At Unc Nutrition	500 Laureate Way Rm 3149, Kannapolis, NC	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based upon review of 2023 and 2024 Daily Temperature Logs and interview with TP#1 (Testing Personnel) on 3/1/24, the laboratory did not document the room temperature and humidity in the extraction room where two AnaPrep instruments are operated. Findings: Review of 2023 and 2024 Daily Temperature logs revealed the following: 1. The room temperature and humidity were documented daily in the main laboratory area. 2. No documentation was observed of the room temperature and humidity in the extraction room where two Anaprep instruments are operated. In interview at approximately 11:30 a.m., TP#1 confirmed the laboratory does not document the room temperature and humidity in the extraction room.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the

	performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based upon review of records to establish the performance specifications for DNA (deoxyribonucleic acid) genotyping and interview with the Laboratory Director on 3/1 /24, the laboratory failed to assess the impact of interfering substances in EDTA (ethylenediaminetetraacetic acid) anticoagulated whole blood and failed to assess the temperature and age requirements for the stability of saliva. Findings: Review of records to establish the performance specifications for DNA genotyping revealed the following: 1. No documentation of a study to assess the impact of interfering substances in EDTA anticoagulated whole blood was observed. 2. No documentation of a study to assess the age and temperature requirements for saliva was observed. In interview at approximately 10:00 a.m., the Laboratory Director confirmed the following: 1.The laboratory did not perform a study to assess the impact of interfering substances in EDTA anticoagulated whole blood. 2. The laboratory did not perform a study to assess the age and temperature requirements for saliva.
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 upon review of the Nanodrop One User Guide, review of 2023 and 2024 maintenance logs and interview with TP#1 (Testing Personnel) on 3/1/24, The laboratory failed to perform maintenance as required by the manufacturer of the Nanodrop instrument. Findings: Review of the Nanodrop One User Guide revealed in "4. Maintaining Your Instrument: Every 6 months:" 1. Recondition pedestals 2. Run intensity check 3. Run performance check 4. Run pedestal image check Review of 2023 and 2024 maintenance logs for the Nanodrop instrument did not reveal the documentation of biannual maintenance activities. In interview at approximately 11: 45 a.m., TP#1 stated he was unaware of these biannual maintenance requirements.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based upon review of laboratory records and interview with the LD (Laboratory Director) on 3/1/24, the laboratory does not utilize extraction quality controls for its molecular testing. Findings: The review of 2023 and 2024 laboratory records did not reveal documentation of the use of extraction control materials. In interview at approximately 9:45 a.m., the LD confirmed that the laboratory does not utilize extraction control materials.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based upon review of a result spreadsheet for a patient study group and interview with TP#1 (Testing Personnel) on 3/1/24, the laboratory does not disclose its address on the result spreadsheet that is provided to the study group managers. Findings: The review of a patient study spreadsheet revealed the absence of the laboratory's address. In interview at approximately 10:30 a.m., TP#1 confirmed the laboratory's address is not disclosed on result spreadsheets for patient study groups.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based upon review of the laboratory's QC (Quality Control) policy, review of 2023 QC records and interview with TP#1 (Testing Personnel) on 3/1/24, TP#1 failed to follow the laboratory's QC policy. Findings: Review of the laboratory's Quality Control policy revealed in "3.3 QC frequency... One negative QC should be run with each plate. Three Positive QC should be run with each plate. In brief, a plate of 3 Coriell samples Homo (homozygous) wild type, Hetero (heterozygous) and Homo (homozygous) mutated with a negative control should be run with each batch of samples." Review of the laboratory's 2023 QC records revealed the following: 1. Two positive and one negative QC materials were utilized during the patient run on the following dates: 5/5/23, 5/17/23, 6/21/23, 6/23/23. Approximately 248 patients were reported on these 4 dates. 2. One positive and one negative QC materials were utilized during the patient run on 6/16/23. Approximately 93 patients were reported on this date. In interview at approximately 1:15 p.m., TP#1 stated he does not utilize 3 positive QC materials with each patient run for every patient study.