Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2289204	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Nasa Nutritional Biochemistry Laboratory	2101 Nasa Parkway, Bldg 21, Houston, 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	A Federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an initial survey at the NASA NUTRITIONAL BIOCHEMISTRY LABORATORY from December 3, 2024, to December 4, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and found to be in compliance with condition level CLIA Requirements. The following standards level deficiencies were found on December 3, 2024.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on observation of chemicals in the laboratory and interview with the laboratory director (LD) and Technical Supervisor (TS) #2, the laboratory failed to label clinical chemicals with expiration dates for a sampling (8 of 8 bottle) of Sigma-Aldrich chemicals observed in the laboratory. Findings Include: 1. Observation of the laboratory on December 3, 2024 at 3:30 pm, revealed the following sampling of 8 out of 8 clinical chemicals without expiration dates: a. Three out of three bottles - Lanthanum oxide - batch#203556-100G b. One out of one bottle - Sodium Bicarbonate - Lot#20H0774 - opened March 31,1992. c. One out of one bottle - Sodium Phosphate dibasic - Lot#STBH2634 d. One out of one bottle - Sodium Tetraborate - batch# 028k0075 - received August 1,2008 e. One out of one bottle - Zinc Chloride - batch#206096-500Gf. One out of one bottle - Zinc Dust - Lot#2099-

	88-1009 - received October 13, 2008. 2. The LD and TS#2 confirmed the findings on December 3, 2024, at 3:35 pm, that the above chemicals used for clinical testing, did not have expiration dates.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Abbott i -stat procedure, review of the Abbott i-stat quality control (QC) records and interview with the laboratory director (LD) and Technical Supervisor (TS) #2, the laboratory failed to perform QC each day of patient testing for the Abbott i-stat GC8+ cartridges used to analyze Ionized Calcium for 11 out of 33 patients from September 28, 2023, to October 22, 2024. Findings Include: 1. Review of The Abbott i-stat procedure on December 3, 2024 at 12:30 pm, revealed the GC8+ cartridges used for Ionized Calcium are performed weekly. 2. The laboratory was unable to provide QC documentation for the Abbott i-stat GC8+ cartridges used to analyze Ionized Calcium performed each day of patient testing in 2023 and 2024. 3. From September 28, 2023, to October 22, 2024, the following 11 out of 33 patients were tested with the GC8+ cartridges used to analyze Ionized Calcium, when QC was not performed: a. 10/22/2024 - LIMS ID 98625 b. 10/17/2024 - LIMS ID 98624 c. 10 /02/2024 - LIMS ID 98328, LIMS ID98327 d. 08/20/2024 - LIMS ID 96753 e. 06/26 /2024 - LIMS ID 97590 f. 04/10/2023 - LIMS ID 96845 g. 04/09/2024 - LIMS ID 96837 h. 04/04/2024 - LIMS ID 96762 i. 04/03/2024 - LIMS ID 96761 j. 09/28/2023 - LIMS ID 95054 4. The LD and TS#2 confirmed the findings above on December 3, 2024, at 1:00 pm.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records, and interview with the laboratory director (LD) and Technical Supervisor (TS) #2, the TS failed to assess 5 out of 6 testing personnel (TP) for problem-solving skills on all six-month competency assessments for each test system in 2024. Findings Include: 1. Review of the laboratory competency assessment records on 12/3/2024 at 9:30 revealed, 5 out of 6 TP were not assessed for problem-solving skill on their 6-month competency for each test system performed in the laboratory. The TS#2 signed the six-month competency assessment records on September 25, 2024. 2. The following tests are performed by the laboratory: a. ISTAT 1 Blood analyzer b. Atomic absorption Spectrophotometry - Perkin Elmer PinAAcle 500 c. ICP-MS - Perkin Elmer NexION 350D d. ELISA kit - Serum-Intact PTH EIA kit - Biomerica e. ELISA kit - QUIDEL MicroVue Bone BAP EIA f. ELISA Kit - Zeus ELISA NTX Urine Test g. ELISA Kit

	- QUIDEL MicroVue Bone DPD h. ELISA kit - QUIDEL MicroVue Bone PYD EIA i. RIA kit - Osteocalcin 1 RIA kit- IBL America j. BNII System - Siemens Healthineers k. Dual Channel Ion Chromatography ICS600 - Thermo Fisher Scientific l. HPLC - Agilent 1260 Infinity II High-Performance Liquid Chromatography m. LC-MS/MS - Waters Quattro Micro Tandem Mass Spec with Electro Spray Ionization (ESI) n. Axcel - Alfa Wasserman 3. The LD and TS#2 confirmed the findings above on December 3, 2024, at 10:30 am.