

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2289204	(X3) Date Survey Completed 09/03/2026
Name of Provider or Supplier Nasa Nutritional Biochemistry Laboratory	Street Address, City, State 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 Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey on 09/03/2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be out of compliance with standard level CLIA requirements. The following standard level deficiencies were found.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of laboratory Proficiency Test (PT) records and an interview with the Technical Supervisor #2 (TS2), the laboratory failed to attest that PT samples were tested in the same manner as patient specimens for three of three PT events in 2025. Findings: 1. A review of three PT events revealed the following: 2025 CAP - BMV2-A Bone-Specific Alkaline Phosphatase CAP # 7197487 - 01 SEQ # 01 (04/22/2025) No attestation statement signature from the Laboratory Director (or Designee). 2025 UK NEQAS for Vitamin K Distribution 101 (07/31/2025) No Attestation Statement and no signatures for the Laboratory Director (or Designee) and Testing Personnel. 2025 UK NEQAS for Vitamin K Distribution 102 (10/31/2025) No Attestation Statement and no signatures for the Laboratory Director (or Designee) and Testing Personnel. 2. In an interview on 09/03/2026 at 12:50 PM, the TS2 confirmed the findings stated above.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of laboratory Proficiency Test (PT) records and an interview with the Technical Supervisor #2 (TS2), the laboratory failed to document the evaluation of PT results with reported exception codes for one of one PT event in 2025. Findings: 1. A review of PT, R-B 2025 Trace Metals (R), CAP # 7197487 - 01, Kit Sequence 1, revealed an Exception Code [30] = Scientific committee decision for analytes Copper and Zinc (sample R-05) and an unacceptable grade for Zinc (sample R-06) with no documentation of evaluation by the laboratory. 2. In an interview on 09/03/2026 at 12:45 PM, the TS2 confirmed the findings stated above.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:

Based on direct observation in the laboratory, review of Quality Control (QC) manufacturer's Instructions for Use (IFU), and an interview with the Technical Supervisor #2 (TS2), the laboratory failed to ensure 6 of 6 expired QC bottles were not available for use. 1. While touring the laboratory on 09/03/2026 at 3:05 PM, the following expired QC material for clinical testing was observed stored in the clinical use only refrigerator: BioRad Lyphocheck Urine Metals Control Level 1 Lot # 69261 Reconstituted bottle expiration date: 07/06/2026 BioRad Lyphocheck Urine Metals Control Level 2 Lot # 69262 Reconstituted bottle expiration date: 07/06/2026 UTAK NR Trace Elements Serum Control Lot # D7471 Reconstituted date: 08/03/2026 Reconstituted bottle expiration date: 08/28/2026 UTAK HR Trace Elements Serum Control Lot # D7015 Reconstituted date: 08/03/2026 Reconstituted bottle expiration date: 08/28/2026 UTAK NR Metals Urine Control Lot # D6251 Reconstituted date: 08/03/2026 Reconstituted bottle expiration date: 08/28/2026 UTAK HR Metals Urine Control Lot # D5343 Reconstituted date: 08/03/2026 Reconstituted bottle expiration date: 08/28/2026 2. A review of the QC manufacturer's IFU's revealed the following storage stability statements: BioRad Lyphocheck Urine Metals Control Level 1 (Lot# 69261) and Control Level 2 (Lot# 69262), "Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2C to 8C, this product will be stable as follows: All analytes: 5 days." UTAK NR Trace Elements Serum Control (Lot# D7471) and UTAK HR Trace Elements Serum Control (Lot# D7015), "Store reconstituted control material at 2-8C (35-46F). Reconstituted Stability (Days) 25 ..." for all analytes. UTAK NR Metals Urine Control (Lot# D6251) and UTAK HR Metals Urine Control (Lot # D5343), "Store reconstituted control material at 2-8C (35-46F). Reconstituted Stability (Days) 25 ..." for all analytes. 3. In an interview on 09/03/2026 at 3:05 PM, the TS2 confirmed the findings stated above.