Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0861539	06/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Usda Tufts University Nutrition Evaluation Lab	711 Washington St, Boston, MA	

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 announced CLIA recertification survey at Tuffs University Nutrition Evaluation Laboratory from June 24, 2025 to June 25, 2025.. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and found to not be in compliance with all condition-level CLIA requirements. The following condition and standard level deficiencies were found during CLIA recertification survey that concluded on June 25, 2025.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview with the technical consultants (TC), the laboratory failed to examine PT samples in the same manner as patient samples for two out of two years from 2023 to 2025. Findings Included: Refer to D2006:
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples

	it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the technical consultant (TC), the laboratory failed to examine CAP PT samples it received in the same manner as it tests patient specimens for two of two years. Findings Included: 1. The Hematology Policy on repeating results states, "Results that do not fall within the ranges established by the nutrition evaluation lab are repeated. The repeat is in agreement with the initial result, the result closet to the normal range is reported. If both results are normal, the two results are averaged and then reported. 2. Review of patient test records on June 25, 2025 revealed, patient specimens are run in duplicate when they fell outside of established ranges. a. ID58442711 (11/27/2024) - ALP 115 / 115 - UA 2.8 / 3.9 b. ID58431034 (03/12/2025) - UA 4.3 / 4.3 3. Review of a sampling of the CAP Event 1 2025 - Hematology Automated Differential Series survey result forms, showed the following documented test run values for the below samples: a. FH10-1: 8.5, 8.5, 8.7, 8.8, 9.4 for WBC. b. FH10-2: 4.31, 4.31, 4.36, 4.41, 4.42 for RBC. c. FH10-3: 48.1, 49.0, 49.1, 49.4, 49.7 for HCT. d. FH10-4: 2.5, 2.5, 2.6, 2.6, 2.6 for WBC. e. FH10-5: 12.7, 12.7, 12.7, 12.7, 12.8 for HGB 3. By interview on June 25, 2025 at 12:20 pm, the TC confirmed they re-ran samples multiple time until they were close to there accepted range and that PT samples are not always run like patient samples. Key: RBC = Red Blood Cells. WBC = White Blood Cells. HCT = Hematocrit. HGB = Hemoglobin.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the training and evaluation policy, lack of technical consultant competency assessment records, and interview with the technical consultant, the laboratory failed establish a procedure to assess the competency for one of one TC delegated responsibilities in 2023 and 2024. Findings Included: 1. Review of the training and evaluation policy on June 24, 2025 at 10:00 am, revealed the policy did not include the assessment for TC for their delegated responsibilities. 2. Review of the TC's personnel folder on June 24, 2025 revealed, the TC was not assessed for competency of their delegated responsibilities in 2023 or 2024. 3. By interview, the TC confirmed on June 24, 2024 at 10:30 am their TC responsibilities were not assessed for competency is 2023 and 2024.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)

	(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) program procedure, lack of QA documents and interview with the technical consultant (TC), the laboratory failed to establish a QA program to monitor and evaluate the requirements for the general laboratory system for two of two years (2023 to 2025). The findings include: 1. On June 24, 2025, at 10:00 a.m., the laboratory's QA program procedure was reviewed. For two of the two years (2023 to 2025), the procedure did not include the assessment of general laboratory systems. 2. The QA program procedure did not include the frequency of assessment for monitoring practices related to: a. Patient confidentiality. b. Specimen identification and integrity. c. Complaint investigations. d. Communications. e. Personnel competency. f. Proficiency testing performance. 3. By interview with the TC on June 25, 2025, at 1:00 pm, confirmed the QA procedure did not include a frequency to monitor the laboratory's general laboratory systems. .
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 observation of the laboratory collection tubes, review of the Horbia ABX Pentra 60 C+ manufactures manual and interview with the technical consultant, the laboratory failed to collect patient specimen in the correct vacutainer tubes for 2 of 2 year (2023 to 2025). Findings Included: 1. The Horbia ABX Pentra 60 C+ manufactures manual, specimen collections states, "In all cases, the anticoagulant used has to be EDTA K3". 2. Observation of the laboratory on June 24, 2025 at 10:00 am revealed, specimens are collected in BD vacutainer EDTA Blood collection tubes that contain K2 anticoagulant. 3. Per form CMS 116, that was signed by the laboratory director on June 12, 2025, the annual test volume for hematology is 456. 4. By interview on June 25, 2025 at 10:30 am, the TC confirmed the laboratory uses EDTA Blood collection tubes that contain K2 anticoagulant and the K3 EDTA is not available in the states. Key: BD = Becton Dickinson. EDTA = Ethylenediaminetetraacetic acid. K2 = Dipotassium. K3 = Tripotassium.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) program procedure, lack of QA documents and interview with the technical consultant (TC), the laboratory failed to establish a QA program to monitor and evaluate the requirements for pre-analytic systems for two of two years (2023 to 2025). The findings include: 1. On June 24, 2025, at 10:00 a.m., the laboratory's QA program procedure was reviewed. For two of the two years (2023 to 2025), the procedure did not include the assessment of pre-analytic systems. 2. The QA program procedure did not include the frequency of assessment for monitoring practice related to: a. Test requests. b. Specimen submission and handling. c. specimen referrals. 3. By interview with the TC on June 25, 2025, at 1:00 pm, confirmed the QA procedure did not include a frequency to monitor the laboratory's pre-analytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's analytical systems, observation of the laboratory and interview with the technical consultant (TC), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 from November 2, 2023 to June 25, 2025 Refer to: D5403 - Procedure manuals did not include Step-by-step performance of the procedure, including test calculations and interpretation of result, Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing, The reportable range for test results for the test system as established or verified in 493.1253, Corrective action to take when calibration or control results fail to meet the laboratory ' s criteria for acceptability. D5413 - Temperature monitoring. D5415 - Labeling quality control material with open, reconstitution and expiration dates. D5469 - Establish or verify the criteria for acceptability of all control materials.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective

	action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory and records, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to include in the ABX Pentra 60C+ and Beckman Coulter Olympus AU480 procedure manuals, step-by-step performance of the procedures, test calculations and interpretation of result and controls used in testing, and corrective action to take when calibration or control results fail to meet the laboratory ' s criteria for acceptability for two of two instrument procedures. Findings Include: 1. Based on the CMS 116 signed by the laboratory director on June 12, 2025, the laboratory performed Hematology testing on the Horbia ABX Pentra 60C+ and chemistry testing on Beckman Coulter Olympus AU480. 2. Review of laboratory procedures for the Horbia ABX Pentra 60C+ and Beckman Coulter Olympus AU480 on June 24, 2025 to June 25, 2035 revealed, the procedure did not include the following: a. Step-by-step performance of the procedures, including test calculations and quailty controls. b. Corrective action to take when calibration or control results fail to meet the laboratory 's criteria for acceptability. 3. The laboratory was unable to provide documenting for: - Verification of assayed quality control used on both analyzers, regarding westgard rules, means and standard deviations. - lot to lot verification of quality control used on both analyzers. - verification for repeating patient specimen, as what is the threshold of agreement for the initial to the repeated result. 4. On June 25, 2025 at 12:00 pm, the TC confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: A. Based on the review of manufacturers' documents, lack of monitored temperature records, observation of the blood collection tube storage areas, and an interview with the technical consultant (TC), the laboratory failed to monitor and document room temperatures for two of three areas where BD vacutainer EDTA Blood Collection tubes were stored. Findings Included: 1. On June 25, 2025, at 1:45 p.m., while on a tour of the laboratory, 45 BD vacutainer EDTA Blood Collection tubes were observed in the subject draw room. 2. The TC also mentioned that blood collection tubes were stored overnight in the senior staff nurse's room. 3. The manufacturer's document for

	BD vacutainer EDTA Blood Collection tubes states, "Store at 4 - 25 degrees Celsius. 4. The laboratory was unable to provide documentation of the monitored room temperature for both the subject's drawing room and the senior staff nurse's room. 5. On June 24, 2024, at 2:00 p.m., by interview, the TC confirmed that the two areas where blood collection tubes were stored were not monitored for room temperature, nor were temperatures documented. B. Based on the review of laboratory temperature records, observation of the laboratory room 805, and interview with the technical consultant (TC), the laboratory failed to monitor room temperatures consistent with the manufacturer's requirements for four out of four boxes of Horbia ABX diluents stored in the laboratory. Findings Included: 1. On June 25, 2025, at 9:30 a.m., while on a tour of the laboratory, four boxes of Horbia ABX diluents were observed in the laboratory under the bench top. 2. The manufacturer's requirements on the four boxes of Horbia ABX diluents stated, "Store at 18 - 25 degrees Celsius. 3. A review of the laboratory temperature log for multiple instruments revealed that an acceptable temperature range of 18 to 30 degrees Celsius was recorded on the log. 4. The following days' temperatures were out of range based on the manufacturer's acceptable ranges: a. February 3, 2025. b. February 19, 2025. c. April 25, 2025. d. April 29, 2025. e. May 8, 2025. f. May 19, 2025. 5. On June 24, 2024, at 9:45 a.m., the TC confirmed the findings above by interview.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's package inserts, direct observation of the laboratory refrigerator, and an interview with the technical consultant (TC), the laboratory failed to label two of two opened quality control (QC) materials with expiration dates based on their stability period once opened. Findings included: 1. The Bio-Rad Lyphochek Assayed Chemistry Controls 1 and 2 states package insert under, Reconstituted and refrigerated, "After reconstitution and storing tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: All analytes 7 days. 2. The Horbia Medical Difftrol package insert states, under stability and storage, "Opened tubes are stable for 15 days provided they are handled properly." 3. Observation of the laboratory on June 25, 2025, at 10:00 AM, revealed the following reagents that were not labeled with open date or stability expiration dates: a. 1 of 1 bottles of Bio-Rad Lyphochek Assayed Chemistry Controls 1 and 2, - Lot#89742 b. 1 of 1 vial of Horbia Medical Difftrol, Lot#5300100142 4. The above findings were confirmed by an interview with the TC on June 25, 2025, at 10:15 a.m.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of corrective action documentation, and interview with the technical consultant (TC), the laboratory failed to establish procedures for performing and documenting corrective action in a manner that ensures accurate and reliable patient test results for 403 out of 403 analyzer alarm in the Beckman coulter AU480 used for chemistry testing. Findings Included: 1. The Beckman coulter AU480 manufacturers manual, error flag summary states, It is important that the operator reviews each flag as it is generated and identifies the root cause. 2. On June 25, 2025, at 11:30 AM, a review of a sample of the Beckman Coulter AU480 alarm lists revealed that 403 alarm flags occurred between January 2, 2025, and January 31, 2025. 3. The TC was unable to provide documentation of corrective actions performed to show the root causes were identified for each alarm. 4. By interview on June 25, 2025 at 1:00 pm, the TC confirmed the root causes for each alarm were not identified and documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) program procedure, lack of QA documents and interview with the technical consultant (TC), the laboratory failed to establish a QA program to monitor and evaluate the requirements for analytic systems for two of two years (2023 to 2025). The findings include: 1. On June 24, 2025, at 10: 00 a.m., the laboratory's QA program procedure was reviewed. For two of the two years (2023 to 2025), the procedure did not include the assessment of analytic systems. 2. The QA program procedure did not include the frequency of assessment for monitoring: a. Test procedures. b. Test systems, equipment, instruments, reagents, materials, and supplies. c. Specimen and reagent storage condition. d. Equipment /instrument/test/system maintenance and function checks. e. Establishment and verification of method performance specifications. f. Calibration and calibration verification. g. Control procedures. h. Comparison of test result. i. Corrective actions. j. Test records. 3. By interview with the TC on June 25, 2025, at 1:00 pm, confirmed the QA procedure did not include a frequency to monitor the laboratory's analytic systems.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) program procedure, lack of QA documents and interview with the technical consultant (TC), the laboratory failed to establish a QA program to monitor and evaluate the requirements for postanalytic

	systems for two of two years (2023 to 2025). Findings Included: 1. Review of the laboratory's QA program on June 24, 2025 10:00 am revealed the QA procedure did not include the assessment of post analytic systems for two of two years (2023 to 2025). 2. The QA program procedure did not include the frequency of assessment for monitoring: a. Completeness of the laboratory ' s test reports. b. Laboratory ' s turn-around times and procedures for notification of test results. c. The accuracy of the laboratory's LIS. 3. By interview with the TC on June 25, 2025 at 1:00 pm confirmed the QA procedure include a frequency to monitor the laboratory's postanalytic systems. Key: LIS - Laboratory Information System.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on the review of testing personnel competency assessment records, and interview with the technical consultant, the laboratory failed to evaluate the competency for three of four TP for each test procedure performed in Hematology and Chemistry in 2023 and 2024. Finding Included: 1. Review of the competency evaluation forms on June 24, 2025 at 9:30 am revealed, three of four TP performing patient testing were not assessed for competency for each test procedure performed. 2. The laboratory performed the following test in 2023 and 2024: - Complete Blood Count (CBC) test on an ABX Pentra 60C+. - Chemistry tests on an Olympus AU480. - human chorionic gonadotropin (hCG) on OSOM hCG Genzyme test kits. 3. By interview, the TC confirmed the above findings on June 24, 2024 at 10:30 am.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records, TP educational credentials and interview with the technical consultant (TC), the laboratory failed to ensure one out of four TP was qualified to perform testing in 2025. Finding Included: Refer to D6065 - Testing personnel Qualifications.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements

	in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records, TP educational credentials and interview with the technical consultant (TC), the laboratory failed to ensure one out of four TP was qualified to perform testing in 2025. Findings Included: 1. The Laboratory Personnel Report (CLIA) Form CMS 209, lists five laboratory personnel. The fourth laboratory personnel is listed as TP#3, which was signed by the laboratory director on June 12, 2025. 2. Review of TP educational credentials on June 24, 2025 at 9:00 am revealed, TP#3 educational file had a translation document of their degree earned from Nanjing University from the People Republic of China, which conferred a degree of Bachelors of Science in Chemistry. 3. By interview with the TC on June 24, 2025, at 10:00 AM, confirmed TP#3 educational file did not include documentation of Foreign equivalency to validate their earned degree from the Republic of China.