Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0861539	11/02/2023
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Consultant #1 (TC#1) and Technical Consultant #2 (TC#2), the laboratory failed to ensure proficiency testing samples were tested by all testing personnel identified on the laboratory personnel CMS 209 form for six of six proficiency testing events. Findings include: 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Routine chemistry testing using the Beckman Coulter AU480 analyzer. b. Complete Blood Count (CBC) testing using the Horiba ABX Pentra 60+ analyzer. 2. Record review on 11/02/223 of the laboratory personnel CMS 209 form, completed by TC#1 prior to the survey, listed two testing persons (TP#1 and TP#2) performing the above testing. 3. Record review on 11/02/2023 of 2022 and 2023 proficiency testing records revealed that six of six events were tested by the same person (TP#1). 4. Interview with TC#2 on 11/02/2023 at 11:45 AM, confirmed the above findings.
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 on observation, manufacturer's instructions, temperature records, humidity records, and interviews with Technical Consultant #1 (TC#1) and Technical Consultant #2 (TC#2), the laboratory failed to ensure the room temperature and humidity were maintained as required by the manufacturer for two of two analyzers for three of three months and failed to ensure blood collection tubes were stored according to manufacturer's instructions for three of three months. Findings include: A. Beckman Coulter AU480 analyzer 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Routine chemistry testing using the Beckman Coulter AU480 analyzer. 2. Record review on 11/02/2023 of the manufacturer's environmental requirements titled, "2.3.1 System Specifications" (page 2-21) stated, "3. Operating environments" as follows: a. Temperature - 18 to 32C (Celsius) b. Humidity - 20 to 80% RH (Relative Humidity) 3. Record reviewon 11/02 /2023 of temperature records from August 2023 through October 2023, revealed no evidence of temperature or humidity monitoring for the Beckman Coulter AU480 analyzer for three of three months. 4. Interview with TC#2 on 11/02/23 at 02:30 PM, confirmed the findings above. B. Horiba ABX Pentra 60+ analyzer 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Complete Blood Count (CBC) testing using the Horiba ABX Pentra 60+ analyzer. 2. Record review on 11/02/2023 of the manufacturer's environmental requirements titled, "2. PHYSICAL SPECIFICATIONS" stated, "2.2. Operating temperature and humidity" as follows: a. Temperature - 18 to 34C b. Humidity - Maximum relative humidity of 80% 3. Record review on 11/02/2023 of temperature records from August 2023 through October 2023, revealed no evidence of temperature or humidity monitoring for the Horiba ABX Pentra 60+ analyzer for three of three months. 4. Interview with TC#2 on 11/02/23 at 02:30 PM, confirmed the findings above. C. Blood Collection Tubes 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Routine chemistry testing using the Beckman Coulter AU480 analyzer. b. Complete Blood Count (CBC) testing using the Horiba ABX Pentra 60+ analyzer. c. Blood collection tubes were stored in the nursing unit storage room. 2. Record review on 11/02/2023 of the manufacturer's environmental requirements for blood collection tubes on 11/02/2023, revealed a room temperature requirement between 4-25C. 3. Surveyor observation on 11/02 /2023 at 10:03 AM of blood collection tubes in the nursing storage room stored the following blood collection tubes: a. BD Vacutainer SST - 300 tubes of lot#3153030 b. BD Vacutainer K2 EDTA - 300 tubes of lot#2227128 4. Record review on 11/02/2023 of temperature records from August 2023 through October 2023, revealed no evidence of temperature monitoring for the blood collection tubes for three of three months. 5. Interview with TC#2 on 11/02/23 at 10:05 AM, confirmed the findings above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must

	be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review of, written laboratory policy and procedure, and interviews with Technical Consultant #1 (TC#1) and Technical Consultant #2 (TC#2), the laboratory failed to follow their defined function check protocol to ensure the centrifuge was functioning properly for one of two preventative maintenance function checks. Findings include: 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Routine chemistry testing using the Beckman Coulter AU480 analyzer. 2. Interview with TC#2 on 11/02/23 at 11:15 AM, confirmed the laboratory used the ThermoFisher Scientific Legend RT+ centrifuge to process chemistry testing. 3. Record review on 11/02/2023 of the written laboratory policy and procedure titled, "Policy for the Maintenance of the Laboratory Centrifuges" stated, "The Legend RT+ bench top ....will be serviced semi-annually for preventive maintenance and to ensure proper operation.". 4. Record review on 11/02/23 of the preventive maintenance records from 06/06/2022 through the day of the survey (11/02/2023) revealed no evidence of preventative maintenance between 06/06/2023 through 07/20/2023. 5. Interview with TC#1 and TC#2 on 11/02/2023 at 02:45 PM, confirmed the laboratory failed to ensure the centrifuge was functioning properly for one of two preventative maintenance checks.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Consultant #1 (TC#1), the technical consultant failed to ensure that evaluations included direct observation of patient test performance, including patient preparation, specimen handling, processing, and testing for two of two testing persons. Findings include: 1. Interview with TC#1 on 11/02/23 at 09:25 AM, confirmed the laboratory performed the following: a. Routine chemistry testing using the Beckman Coulter AU480 analyzer. b. Complete Blood Count (CBC) testing using the Horiba ABX Pentra 60+ analyzer. c. hCG serum pregnancy testing using the OSOM hCG test kit. 2. Record review on 11/02/2023 of 2022 personnel records for two of two people performing the testing above, revealed no evidence that direct observation of patient test performance, including patient preparation, specimen handling, processing, and testing was included as part of the evaluation. 3. Interview with TC#1 on 11/23/2023 at 4:10 PM, confirmed the above findings.