Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0678403	05/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Unt Student Health And Wellness Center Lab	1800 Chestnut St Room 295, Denton, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, PT corrective actions, and confirmed in staff interview, the laboratory failed to document the corrective action for 1 of 1 chemistry

	testing event with an unacceptable PT grade in 2021. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing" (Reviewed by the Laboratory Director in 06/25/2018) revealed the following: 2. Review of API PT Chemistry 3rd Event 2021 revealed the following unacceptable result: API PT 1st Event Chloride - 80% Further review of API 1st Event in 2022 revealed the Laboratory Director failed to document corrective actions for the unacceptable PT result in 2022. 3. During an interview with the Technical Consultant (TC-1) on 05/31/2022 at 11:12 AM in the facility conference room, TC-1 was asked to provide documentation of the laboratory director documenting corrective actions for the unacceptable PT event. No documentation was provided. This confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) Hematology events for 2021 (2nd and 3rd events), 2022 (1st event) and staff interview, the laboratory failed to provide documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 1 of 3 events reviewed in 2021 and 2022. Findings Included: 1. Review of laboratory records revealed the laboratory performed manual blood cell identification (ID) on hematology specimens if criteria were met for manual blood cell identification. 2. Review of API PT records from 2020 and 2021 revealed the following events with ungraded performance: a. Hematology 2nd Event 2021 Blood Cell ID: Sample BCl-07 Reported Result: Myelocyte Expected Result: See Data Summary Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed no documentation of verifying the accuracy of analytes not graded by the proficiency testing program. b. Hematology 3rd Event 2021 Blood Cell ID: Sample ECI-11 Reported Result: NRBC Expected Result: NRBC Performance: Not Graded Sample ECI-12 Reported Result: Target Cell Expected Result: Target Cell Performance: Not Graded Sample ECl-13 Reported Result: Sepherocyte Expected Result: Sepherocyte Performance: Not Graded Sample ECI-14 Reported Result: Monocyte Expected Result: Monocyte Performance: Not Graded Sample ECI-15 Reported Result: Lymph Expected Result: See Commentary Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed no documentation of verifying the accuracy of analytes not graded by the proficiency testing program. b. Hematology 3rd Event 2021 Blood Cell ID: Sample ECI-11 Reported Result: NRBC Expected Result: NRBC Performance: Not Graded Sample ECI-12 Reported Result: Target Cell Expected Result: Target Cell Performance: Not Graded Sample ECl-13 Reported Result: Sepherocyte Expected Result: Sepherocyte Performance: Not Graded Sample ECI-14 Reported Result: Monocyte Expected Result: Monocyte Performance: Not Graded Sample ECI-15 Reported Result: Lymph Expected Result: See Commentary Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed no documentation of verifying the accuracy of analytes not graded by the proficiency testing program. d. Hematology 1st Event 2022 Blood Cell ID: Sample ECl-01 Reported Result: Lymphocyte Expected Result: Lymphocyte Performance: Not Graded Sample ECl-02 Reported Result: Platelet Expected Result: Platelet

	Performance: Not Graded Sample ECl-03 Reported Result: Lymphocyte Expected Result: Lymphocyte Performance: Not Graded Sample ECl-04 Reported Result: Monocyte Expected Result: Monocyte Performance: Not Graded Sample BCl-05 Reported Result: Lymph Expected Result: Lymph Performance: Not Graded Further review of the API "Performance Review and Corrective Action" form revealed no documentation of verifying the accuracy of analytes not graded by the proficiency testing program. 3. During an interview with the Technical Consultant (TC-1) on 05 /31/2022 at 11:15 AM in the facility conference room, TC-1 was asked to provide documentation of the laboratory director verifying the accuracy of analytes not graded by the proficiency testing program. No documentation was provided. This confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 policy, patient final reports, and confirmed in staff interview, the laboratory failed to define in their policy the quantification of the terms "rare, few, moderate, many, 1+, 2+, 3+, 4+" when reporting urine microscopy results for 5 of 5 patients reviewed in May 2022. Findings Included: 1. Review of the laboratory's policy titled "Routine Urinalysis" (Reviewed by the Laboratory Director on 09/04/2012) revealed: "MICROSCOPIC ..2. Pour off the supernatant and resuspend the sediment in the urine that drains back down the sides of the tube. ..6. The cells which can be present in the urine include: erythrocytes, leukocytes, and epithelial cells from anywhere in the urinary tract, from the tubules to the urethra or as contaminants from the vagina or vulva. Scan the slide and observe for WBC's, Glitter Cells, WBC clumping, RBC's and bacteria. Reporting of sedimentation is listed below: Bacteria: None seen, Trace, 1+ - 4+/hpf Squamous/Transitional/Epithelial Cells: None Seen, Few, Moderate, Rare, Many/hpf Crystal/Cast: None Seen, Few, Moderate, Many/hpf The laboratory failed to define the quantification of the terms "1+, 2+, 3+, 4+, rare, few, moderate, many". 2. A random review of patient reports from October 19-21, 2021 revealed the following: 10/19/2021 Patient MR# 2080994; Urine Microscopy results: Epithelial: Few Bacteria: Few Patient MR# 2081031; Urine Microscopy results: Epithelial: Few Yeast: Few Patient MR# 2043446; Urine

	Microscopy results: Epithelial: Few Bacteria: Few Patient MR# 2010155; Urine Microscopy results: Epithelial: Rare Bacteria: Many Patient MR# 1001629; Urine Microscopy results: Epithelial: Rare Bacteria: Many Patient MR# 2034160; Urine Microscopy results: Epithelial: Many Bacteria: Few 3. During an interview with the Technical Consultant (TC-1) on 05/31/2022 at 01:40 PM in the facility conference room, TC-1 was asked for documentation of quantification of the terms "rare, few, moderate, many, 1+, 2+, 3+, 4+" when reporting urine microscopy results for 5 of 5 patients reviewed in May 2022. No documentation was provided. This confirmed the above findings.