Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0678403	**(X3) Date Survey Completed** 06/07/2024
Name of Provider or Supplier Unt Student Health And Wellness Center Lab	**Street Address, City, State** 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 the review of the API Performance Summary, the laboratory's API Proficiency Testing records in 2023, and confirmed in an interview, the laboratory failed to have documentation of "Not graded" analytes for 3 of 3 Hematology events reviewed in 2023. The findings were: 1. Review of API Proficiency Testing Performance Evaluation page revealed "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the laboratory's API records in 2023 revealed revealed the laboratory failed to have documentation of reviewing of all analytes with a grade of "not graded" for 3 of 3 Hematology/Coagulation proficiency testing events. 2023 Hematology/Coagulation 1st event Analyte/Method Immature Cell (DIF)(%) Sample DIF-01 Reported Result: 66 Expected Result: 57-100 Performance: Not Graded Analyte/Method Lymphocyte (DIF)(%) Sample DIF-01 Reported Result: 7 Expected Result: 0-16 Performance: Not Graded Analyte/Method Lymphocyte, reactive (DIF)(%) Sample DIF-01 Reported Result: 20 Expected Result: 0-7 Performance: Not Graded Analyte/Method Monocyte (DIF)(%) Sample DIF-01 Reported Result: 1 Expected Result: 0-8 Performance: Not Graded Analyte/Method Neutrophil, band (DIF)(%) Sample DIF-01 Reported Result: 3 Expected Result: 0-8 Performance: Not

Graded Analyte/Method Neutrophil, segmented (DIF)(%) Sample DIF-01 Reported Result: 3 Expected Result: 0-10 Performance: Not Graded Analyte/Method Platelet estimate (DIF) Sample DIF-01 Reported Result: Decreased Expected Result: Decreased Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-01 Reported Result: Neutrophil, band (stab) Expected Result: Blast Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-02 Reported Result: Metamyelocyte (juvenile) Expected Result: See commentary Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-03 Reported Result: Blast Expected Result: Blast Performance: Not Graded Analyte /Method Blood Cell ID (Educational) Sample ECI-04 Reported Result: Dacryocyte (tear-drop cell) Expected Result: Dacryocyte (tear-drop cell) Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-05 Reported Result: Neutrophil, seg or band Expected Result: See commentary Performance: Not Graded 2023 Hematology/Coagulation 2nd event Analyte/Method Basophil (DIF)(%) Sample DIF-02 Reported Result: 1 Expected Result: 0-1 Performance: Not Graded Analyte/Method Eosinophil (DIF)(%) Sample DIF-02 Reported Result: 5 Expected Result: 0-8 Performance: Not Graded Analyte/Method Immature Cell (DIF)(%) Sample DIF-02 Reported Result: 1 Expected Result: 0-1 Performance: Not Graded Analyte/Method Lymphocyte (DIF)(%) Sample DIF-02 Reported Result: 14 Expected Result: 2-28 Performance: Not Graded Analyte/Method Lymphocyte, reactive (DIF) (%) Sample DIF-02 Reported Result: 4 Expected Result: 0-17 Performance: Not Graded Analyte/Method Monocyte (DIF)(%) Sample DIF-02 Reported Result: 2 Expected Result: 0-14 Performance: Not Graded Analyte/Method Neutrophil, band (DIF)(%) Sample DIF-02 Reported Result: 8 Expected Result: 0-8 Performance: Not Graded Analyte/Method Neutrophil, segmented (DIF)(%) Sample DIF-02 Reported Result: 65 Expected Result: 55-81 Performance: Not Graded Analyte/Method NRBC /100 WBC (DIF)(%) Sample DIF-02 Reported Result: 1 Expected Result: 0-1 Performance: Not Graded Analyte/Method Platelet estimate (DIF) Sample DIF-02 Reported Result: Increased Expected Result: Adequate/Normal Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-06 Reported Result: Lymph, reactive (atyp, variant) Expected Result: Lymph, reactive (atyp, variant) Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-07 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-08 Reported Result: Lymphocyte, normal Expected Result: Red blood cell, normal Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-09 Reported Result: Platelet(s), normal Expected Result: Platelet(s), normal Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-10 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded 2023 Hematology/Coagulation 3rd event Analyte /Method Vaginal Wet Preparation Sample VA-03 Reported Result: No yeast, Trich, or clue cells Expected Result: See Data Summary Performance: Not Graded Analyte /Method Basophil (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 0-1 Performance: Not Graded Analyte/Method Eosinophil (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 0-2 Performance: Not Graded Analyte/Method Immature Cell (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 0-1 Performance: Not Graded Analyte/Method Lymphocyte (DIF)(%) Sample DIF-03 Reported Result: 65 Expected Result: 44-90 Performance: Not Graded Analyte /Method Lymphocyte, reactive (DIF)(%) Sample DIF-03 Reported Result: 6 Expected Result: See Data Summary Performance: Not Graded Analyte/Method Monocyte (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 0-9 Performance: Not Graded Analyte/Method Neutrophil, band (DIF)(%) Sample DIF-03 Reported Result: 10 Expected Result: 0-10 Performance: Not Graded Analyte/Method Neutrophil, seg

	or band (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 12-38 Performance: Not Graded Analyte/Method Neutrophil, segmented (DIF)(%) Sample DIF-03 Reported Result: 15 Expected Result: 8-37 Performance: Not Graded Analyte /Method NRBC/100 WBC (DIF)(%) Sample DIF-03 Reported Result: 0 Expected Result: 0-2 Performance: Not Graded Analyte/Method Unclassified Cell (DIF)(%) Sample DIF-03 Reported Result: 4 Expected Result: 0-11 Performance: Not Graded Analyte/Method Platelet estimate (DIF) Sample DIF-03 Reported Result: Adequate /Normal Expected Result: Decreased Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-11 Reported Result: Smudge cell / Basket cell Expected Result: Smudge cell / Basket cell Performance: Not Graded Analyte /Method Blood Cell ID (Educational) Sample ECI-12 Reported Result: Lymph, reactive (atyp, variant) Expected Result: Lymph, reactive (atyp, variant) Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-13 Reported Result: Neutrophil, band (stab) Expected Result: Neutrophil, band (stab) Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-14 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Analyte/Method Blood Cell ID (Educational) Sample ECI-15 Reported Result: Hairy cell Expected Result: See commentary Performance: Not Graded 3. In an interview on 06/04/2024 at 1:40 pm in a conference room, the technical consultant confirmed the above findings. *********This was a reapeated deficiency from the inspection on 05/31/2022********** Key: API= American Proficiency Institute NRBC=Nucleated Red Blood Cells WBC=White Blood Cells
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the laboratory's verification study, patient reports, annual test volume & proficiency testing programs worksheet, and confirmed in an interview, the laboratory failed to verify the reference ranges for 18 of 18 chemistry analytes performing on Horiba Pentra C400 chemistry analyzer. The findings were: 1. Review of the laboratory's verification study revealed the Horiba Pentra C400 chemistry analyzer (SN: 305C4-1546) was completed the beginning of January 2024. Accuracy and precision was signed off by the laboratory director on 02/14/2024. 2. In an interview on 06/04/2024 at 9:30 am in the lab, the technical consultant confirmed the go-live date for the Horiba Pentra C400 (SN: 305C4-1546) was 01/15/2024. 3. Review of the patient reports for chemistry tests revealed 18 of 18 chemistry analytes performed on Horiba Pentra C400 chemistry analyzer. Albumin Alkaline phosphate ALT/SGPT AST/SGOT Direct bilirubin Total bilirubin Calcium Total cholesterol HDL Creatinine Glucose Total protein Triglycerides Blood urea nitrogen (BUN) Sodium Potassium Chloride CO2 4. Review of the laboratory's verification study for Horiba Pentra C400 chemistry analyzer revealed the laboratory failed to verify the reference ranges for 18 of 18 chemistry analytes performing on Horiba Pentra C400 chemistry analyzer. 5. Review of Annual Test Volume & Proficiency Testing

	Programs Worksheet that the laboratory director signed on 05/31/2024 revealed routine chemistry performed on Pentra C400 was 21746. 5. In an interview on 06/04 /2024 at 1:44 pm, the technical consultant confirmed the above findings. Key: ALT=Alanine transaminase AST=Aspartate transferase HDL=high-density lipoproteins
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the review of the laboratory's verification study, patient reports, annual test volume & proficiency testing programs worksheet, and confirmed in an interview, the laboratory failed to verify the reference ranges for 18 of 18 chemistry analytes performing on Horiba Pentra C400 chemistry analyzer. Refer to D5421.