Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0678403	(X3) Date Survey Completed 03/10/2021
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	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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of laboratory SARS-Co-V-2 patient testing records, review of

	laboratory SARS-Co-V-2 result reporting records, and staff interview, it was revealed that the laboratory failed to report SARS-Co-V-2 negative test results for 37 of 37 days reviewed from 01/11/2021 through 03/09/2021. Findings included: 1. Review of SARS-Co-V-2 patient tests records (Test performed using the Quidel Sofia SARS Antigen test kit and instrumentation) from 01/11/2021 through 03/09/2021 revealed 923 patients tested for SARS-CoV-2. 2. Further review of the SARS-Co-V-2 patient tests results revealed of the 923 patients tested for SARS-Co-V-2, 852 patients tested negative. 3. Review of the laboratory's SARS-Co-V-2 result reporting documentation revealed the laboratory faxed SARS-Co-V-2 positive patient results Monday through Friday from 01/11/2021 through 03/09/2021 to the County Health Department. Further review of the laboratory's SARS-Co-V-2 reporting documentation revealed the laboratory failed to report the 852 negative test results to the County Health Department or to the Department of State Health Services. 4. During an interview on 03/10/2021 at 11:45am in the conference room with the Executive Director of the facility, the Lead Technologist, and the Assistant Coordinator for Health Information, the Executive Director and the Assistant Coordinator for Health Information confirmed that only positive SARS-Co-V-2 results were reported.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, review of Gamma Glutamyl Transferase (GGT) manufacturer's instructions, laboratory policy, laboratory patient specimens, and laboratory patient reports, it was revealed the laboratory failed to follow their own policy and manufacturer's instructions for proper specimen collection and analysis for Gamma Glutamyl Transferase (GGT) testing on the Horiba ABX Pentra 400 chemistry analyzer for 1 of 44 patient specimens. Findings included: 1. During a tour of the laboratory on 03/09/2021 at 09:05am, a Horiba ABX Pentra 400 chemistry analyzer was observed. The following analytes were tested on the Horiba ABX Pentra 400: Albumin (ALB) Alkaline Phosphate (ALP) Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium (Ca) Cholesterol (Chol) Chloride (Cl) Carbon dioxide (CO2) Creatinine (Creat) Direct Bilirubin (DBili) Glucose (Glu) Gamma Glutamyl Transferase (GGT) High Density Lipoprotein (HDL) Potassium (K) Sodium (Na) Total Bilirubin (TBil) Total Protein (TP) Triglycerides (Trig) Uric Acid 2. The laboratory policy titled "ABX Pentra 400" (Signed by the laboratory director on 06/28/2017) stated the following under the "Specimen Collection and Storage" section: "The recommended specimens are serum, plasma, urine, CSF (Cerebrospinal Fluid), whole blood, and homogenous fluids ...The anticoagulant lithium heparin is the preferred anticoagulant of choice for tests that can be analyzed using plasma. Use of the incorrect anticoagulant for a test can yield misleading results." Further review revealed that the GGT analyte was tested as an individual analyte or as part of the laboratory's liver panel that included total protein, albumin, direct bilirubin, ALP, AST, ALT, total bilirubin, and GGT analytes. 3. Review of the manufacturer's instructions for Gamma Glutamyl Transferase (REF

	A11A01630) stated the following: "Specimen--Serum" 4. In an interview on 03/09 /2021 at 02:15pm in the conference room, the Lead Technologist stated that all specimens were drawn in green top lithium heparin collection tubes and that lithium heparin plasma was the only specimen type used for all analytes tested on the Horiba ABX Pentra 400 chemistry analyzer. 5. Observed in the laboratory refrigerator on 09 /10/2021 at 9:00am were 44 stored laboratory specimens which were tested 02/24 /2021 through 03/09/2021. Further observation revealed these specimens for testing on the Horiba ABX Pentra 400 chemistry analyzer were all collected in green top Lithium Heparin collection tubes. Further review of the specimens revealed 1 of 44 specimens were tested for GGT. 6. Review of laboratory patient reports revealed the following 1 of 44 patients tested for GGT: Patient 286803 Date/Time of Collection: 03 /04/2021 10:15am Date/Time of Receipt: 03/04/2021 11:18am GGT result = 103 The laboratory failed to follow manufacturer's instructions for proper specimen collection and analysis for Gamma Glutamyl Transferase (GGT) testing on the Horiba ABX Pentra 400 chemistry analyzer for 1 of 44 patient specimens. 7. In an interview on 03 /10/2021 at 09:10am in the conference room, the Lead Technologist, after review of the manufacturer's instructions for GGT testing, confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter AcT 5diff hematology analyzer laboratory policies, random review of patient records (12/17/2021-3/08/2021), and staff interview, it was revealed the laboratory failed to follow their own policy for 3 of 10 flagged Complete Blood Count (CBC) results. Findings included: 1. The laboratory policy titled, "Trigger Criteria for Manual Differential or Slide Scan on Complete Blood Counts"(signed by the laboratory director on 2/04/2021) stated the following: "Any results from patient samples that are suspected to be abnormal should be analyzed under the microscope for verification ... If a patient meets any of the following criteria the laboratory will perform a manual differential to verify the automated differential results: Instrument Generated Flag- All Flags(suspect, asterisked, review) e.g., Atypical lymphs(ATL), Immature cells(IMM), Debris(DB), Small Lymphs(SL)." Further review of the laboratory policy titled, "Trigger Criteria for Manual Differential or Slide Scan on Complete Blood Counts"(signed by the laboratory director on 2/04/2021), revealed the following: "If a patient sample meets any of the following criteria, the laboratory will perform a slide scan: Instrument Generated Flag- RBC- All flags(suspect, asterisked, review) and abnormal morphology(e.g., MICRO, MACRO, SCH)." 2. A random review of patient complete blood count reports from 12/17/2021 through 3/08/2021 revealed the laboratory failed to follow their own policy for the following 3 of 10 flagged CBC results: a. Patient 214374 Results from Instrument: Test Date 12/16/2020; Test Time 02:00:27 PM Beckman Coulter AcT 5diff Flags: DB(Debris), Diff+ Result on Final Patient Report: No documentation of manual differential performed b. Patient 214374 Results from Instrument: Test Date 12/16/2020; Test Time 02:21:34 PM Beckman Coulter AcT 5diff Flags: DB(Debris), Diff+ Result on Final Patient Report: No documentation of manual differential performed The laboratory was asked to provide documentation of

	manual differentials performed on the patients listed above. No documentation was provided. c. Patient 67456 Results from Instrument: Test Date 12/17/2020; Test Time 10:46:15 AM Beckman Coulter AcT 5diff Flags: MICRO Result on Final Patient Report: No documentation of slide scan performed The laboratory was asked to provide documentation of slide scan performed on the patient listed above. No documentation was provided. 3. During the exit interview with the laboratory representatives on 03/10/2021 at 01:00 PM in the conference room, the Lead Technologist, after review of the data, confirmed the above findings.