

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0678403	(X3) Date Survey Completed 08/27/2026
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 onsite recertification survey was conducted on 08/027/2026, and standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records in 2026, and confirmed in interview, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for two of two PT events in 2026 (Event 1 and 2). Findings included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the laboratory director on 06/25/2018) revealed the following: " ...3. Reporting Results: ...c. Upon completion of testing, results placed in the API binder in the appropriate sections, the Pathologist and techs sign the Attestation Statement sheet." 2. Review of API PT records in 2026, revealed the laboratory director failed to document attestation of routine integration of PT samples into the patient workload for two of two PT events in 2026 (Event 1 and Event 2). 3. In an interview with the technical consultant (TC-1) on 08/27/2026 at 10:25 AM in the facility library, TC-1 confirmed the laboratory director failed to attest to the routine integration of PT samples into the patient workload for two of two PT events in 2026 (Event 1 and 2).
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) 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 policy, American Proficiency Institute (API) Proficiency Testing (PT) records in 2026, and confirmed in interview, the laboratory failed to document evaluation of PT scores not graded by the PT program for one of two events in 2026 (Event 1). Findings included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the laboratory director on 06/25/2018) revealed the following: " ...6. Corrective Action: a. Any unsatisfactory or unacceptable testing event must have corrective action documentation placed in the testing packet." 2. Review of API PT records in 2026, revealed the following: Further review revealed the following ungraded analytes in 2026: Event 1 2026 Analytes: Basophil; Blast; Eosinophil; Immature Cell; Lymphocyte; Metamyelocyte; Monocyte; Neutrophil Grade: Not graded 3. In an interview with the technical consultant (TC-1) on 08/27 /2026 at 10:25 AM in the facility library, TC-1 confirmed the laboratory failed to document evaluation of PT scores not graded by the PT program for one of two events in 2026 (Event 1).

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 surveyor observations, review of manufacturer's instructions, laboratory verification studies, patient volumes and confirmed in interview, the laboratory failed to document reference range verification for four of six analytes performed on the Access 2 Immunoassay Analyzer in 2026. Findings included: 1. During a tour of the facility on 08/27/2026 at 09:35 AM, the surveyor observed one Access 2 Immunoassay Analyzer (Serial Number: C58560J) performing patient testing. In an interview during the tour documented above, the laboratory technical supervisor (TS-2) stated the Access 2 was recently put into use for patient testing in July 2026 for the following analytes: a. Free T4 b. Free T3 c. Ferritin d. Folate 2. Review of manufacturer's instructions, "Access 2 Instructions for Use Triiodothyronine Free" (Reference Number A13422) (FT3) revealed the following: " ...Reporting Results Expected Results 1. Each laboratory must establish its own reference ranges to assure proper representation of specific populations." Review of manufacturer's instructions, "Access 2 Instructions for Use Ferritin" (Reference Number 33020) revealed the following: " ...Reporting Results Expected Results 1. Each laboratory must establish its own reference ranges to assure proper representation of specific populations." Review of manufacturer's instructions, "Access 2 Instructions for Use Folate" (Reference Number A98032) revealed the following: " ...Reporting Results Expected Results 1. Each laboratory must establish its own reference ranges to assure proper representation of specific populations." Review of manufacturer's instructions,

"Access 2 Instructions for Use Free T4" (Reference Number C76421) revealed the following: " ...Reporting Results Expected Results 1. Each laboratory must establish its own reference ranges to assure proper representation of specific populations." 3. Review of laboratory Access 2 verification studies performed in June 2026 revealed the laboratory failed to document reference range verification for the following analytes: a. Free T4 b. Free T3 c. Ferritin d. Folate 4. Review of patient testing volumes since testing began in July 2026 revealed the following patient volumes reported for the above analytes: a. Analyte: Free T4; Patient testing volumes from July 2026-August 27, 2026: 2 b. Analyte Free T3; Patient testing volumes from July 2026-August 27, 2026: 2 c. Analyte Ferritin; Patient testing volumes from July 2026-August 27, 2026: 6 d. Analyte Folate; Patient testing volumes from July 2026-August 27, 2026: 1 5. In an interview with the technical consultant (TC-1) on 08/27/2026 at 11:15 AM in the facility library, TC-1 confirmed the laboratory failed to document reference range verification for four of six analytes performed on the Access 2 Immunoassay Analyzer in 2026.