

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0678403	(X3) Date Survey Completed 03/24/2025
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	Based on a proficiency testing desk review survey performed on March 24, 2025, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and the American Proficiency Institute (API) Performance Summary, the laboratory failed to</p>

	<p>achieve satisfactory performance (80% or greater) for the analyte glucose for two consecutive testing events in 2024 (Event 3) and 2025 (Event 1), resulting in an initial unsuccessful performance. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and the American Proficiency Institute (API) Performance Summary, the laboratory failed to achieve satisfactory performance (80% or greater) for the analyte glucose for two consecutive testing events in 2024 (Event 3) and 2025 (Event 1). Findings include: 1. Review of the CASPER Report 155 Individual Laboratory Profile, the laboratory received the following unsatisfactory performances for the analyte glucose for two consecutive testing events: 2024 3rd event: 40% 2025 1st event: 40% 2. Review of the API Performance Summary, the laboratory received the following unsatisfactory performances for the analyte glucose for two consecutive testing events: Routine Chemistry 2024 3rd Event: 40% 2025 1st Event: 40%</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and the American Proficiency Institute (API) Performance Summary, the laboratory director failed ensure successful participation in an HHS approved proficiency testing program for the analyte glucose for two consecutive testing events in 2024 (Event 3) and 2025 (Event 1). Refer to D6016.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and the American Proficiency Institute (API) Performance Summary, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing</p>

program for the analyte glucose for two consecutive testing events in 2024 (Event 3) and 2025 (Event 1). Refer to D2096.