

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0859151	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Univ Of Tennessee Student Health Center	Street Address, City, State 1800 Volunteer Boulevard, Knoxville, TN	
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 desk review of proficiency testing (PT) records from the Certification and</p>

	<p>Survey Provider Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) 2025 records, the laboratory failed to successfully participate in a proficiency testing program approved by Health and Human Services (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the subspecialty of Bacteriology for Throat Culture. Refer to D2020 and D2028.</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155 report and API proficiency testing 2025 records, the laboratory failed to attain an overall testing event score of at least 80% in the subspecialty of Bacteriology for Throat Culture. 1. A review of the CASPER 0155 report revealed the following results for Bacteriology: 2025 2nd Event: 60% 2025 3rd Event: 40% 2. A review of the laboratory's API Proficiency Testing report, results for the test, Throat Culture, were as follows: 2025 2nd Event: 60% 2025 3rd Event: 40%</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>(e) Failure to achieve an overall testing event score of satisfactory performance for 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 CASPER 0155 report and API proficiency testing 2025 records, the laboratory failed to achieve an overall satisfactory performance (80% or better) in the subspecialty of Bacteriology for Throat Culture for two consecutive testing events. Findings included: 1. A review of the CASPER 0155 report revealed the following results for Bacteriology: 2025 2nd Event: 60% 2025 3rd Event: 40% 2. A review of the laboratory's API Proficiency Testing report, results for the test, Throat Culture, were as follows: 2025 2nd Event: 60% 2025 3rd 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 CASPER 0155 report and American</p>

Proficiency Institute (API) 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of the CASPER 0155 report and American Proficiency Institute (API) proficiency records for 2025, the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program. Refer to D2020 and D2028.