

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2206501	<b>(X3) Date Survey Completed</b>  04/19/2022
<b>Name of Provider or Supplier</b>  Austin Peay State University	<b>Street Address, City, State</b>  524 College St, Ard Bldg Basement, Clarksville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's proficiency testing (PT) records and interview with the technical supervisor, the laboratory failed to test PT samples the same number of times it tests patient samples for 2021 event two (one of three PT events). The findings include: 1. Observation of the laboratory on 04.19.2022 at 8:30 a.m. revealed patient testing being performed for SARS COV-2 using the Applied Biosystems 7500 Fast Dx Real-Time PCR System. 2. Review of the laboratory's PT records revealed the following: 2021 event two PT due date = 07.07.2021 Sample numbers COV-3 and COV-4 tested on 06.21.2021 and again on 06.22.2021 3. Interview with the technical supervisor on 04.19.2022 at 10:45 a.m. confirmed the laboratory tested proficiency testing samples more than once for 2021 event two and does not routinely test patient samples multiple times.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the technical supervisor, the laboratory failed to have a procedure to include all six criteria for</p>

assessing personnel competency in 2021 and 2022. The findings include: 1. Review of the laboratory procedure manual revealed the following six criteria were not included in the competency assessment procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2. Interview on 04.14.2022 at 12:45 p.m. with the technical supervisor confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS) with patient testing performed beginning 01.11.2021 until the date of the survey on 04.19.2022.