

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2301889	(X3) Date Survey Completed 03/16/2026
Name of Provider or Supplier The University Of Tennessee Medical Center	Street Address, City, State 1924 Alcoa Highway, Heart Hospital, 5th Floor, 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
D5209	<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 a review of the submitted Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), laboratory's procedure, personnel records, and staff interview, revealed the laboratory's policy failed to include assessment of the regulatory responsibilities for the general supervisor (GS) as required in Subpart M of the State Operations Manual (SOM) Appendix C, and failed to have documentation of GS competency for 2025 on the survey date (03.16.2026). Findings included: 1. A review of the submitted FORM CMS-209 listed one GS for high complexity testing. 2. A review of the laboratory's Personnel Training and Competency procedure revealed that the policy failed to include competency assessment for the GS for high complexity testing. 3. A review of laboratory personnel records revealed the following: -No documented GS competency assessment for 2025 as listed on FORM CMS-209. 4. An interview with the general supervisor on 03.16.2026 at 10:00 a.m. confirmed the above survey findings.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.</p>

1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on observations of the laboratory, record review, and staff interview, the laboratory failed to include a Quality Control Plan and a Quality Assessment Plan in its Individual Quality Control Plan (IQCP) for the reduced frequency of quality control performance for two blood culture vials used from 12.17.2025 through the survey date of 03.16.2026. Findings: 1. Observation of the laboratory on 03.16.2026 at 10:16 a.m. revealed two BD BACTEC FX40 instruments, serial numbers FFB102 and FFB523, in use for detecting the presence of microorganisms in clinical samples, blood, and blood products. Also observed were BD BACTEC Lytic/10 Anaerobic/F Culture Vials (batch number 5344414, expiration date 09.17.2026) and BD BACTEC Plus Aerobic/F Culture Vials (batch number 5275951, expiration date 07.07.2026) used for inoculation of blood samples. 2. A record review of laboratory documents revealed that the IQCP for blood culture vials failed to include a Quality Control Plan and a Quality Assessment Plan. 3. An interview with the general supervisor on 03.16.2026 at 12:00 p.m. confirmed the above survey findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), laboratory records review, and a staff interview, the laboratory director failed to ensure written delegations of duties for the general supervisor (GS) for high-complexity testing on the survey date (03.16.2026). The findings include: 1. A review of the submitted FORM CMS-209 listed one GS for high complexity testing. 2. A review of laboratory records revealed no written delegations of duties by the laboratory director for the GS. 3. An interview with the general supervisor on 03.16.2026 at 10:00 a.m. confirmed the above survey findings.