

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0710168	<b>(X3) Date Survey Completed</b>  03/14/2024
<b>Name of Provider or Supplier</b>  Trinity Medical Clinical Laboratory	<b>Street Address, City, State</b>  6569 Hwy 84, Ferriday, LA	
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>D6123</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: A follow-up survey was performed at Trinity Medical Clinical Laboratory, CLIA ID #19D0710168, on March 13, 2024 through March 14, 2024. Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with laboratory personnel, the Technical Supervisor failed to ensure semiannual competency assessments for two (2) of four (4) laboratory testing personnel included review of Vitek quality control records. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director also served as the Technical Supervisor. 2. Review of personnel records revealed semiannual competency assessments documented for the following personnel, but the laboratory did not have raw data to support review of quality control on the Vitek analyzer: - Testing Personnel 3 - Testing Personnel 5 3. In interview on March 13, 2024, General Supervisor 2 confirmed the laboratory did not have the raw data to support review of Vitek quality control records for the semiannual competency of the personnel identified above.</p> <p>_____ A Recertification survey was performed at Trinity Medical Center Laboratory, CLIA # 19D0710168, on October 23, 2023 through October 27, 2023.</p>
<b>D6124</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not</p>

limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

A follow-up survey was performed at Trinity Medical Clinical Laboratory, CLIA ID #19D0710168, on March 13, 2024 through March 14, 2024. Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with personnel, the Technical Supervisor failed to ensure semiannual competency assessments for testing personnel included direct observation of performance of Vitek instrument maintenance and function checks for four (4) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director also served as the Technical Supervisor. 2. Review of personnel records revealed semiannual competency assessments documented for the following personnel, but direct observation of Vitek maintenance was not documented: - Testing Personnel 2 - Testing Personnel 3 - Testing Personnel 5 - Testing Personnel 7 3. In interview on March 13, 2024, General Supervisor 2 confirmed the laboratory did not document direct observation of Vitek maintenance for the semiannual competency of the personnel identified above. \_\_\_\_\_ A Recertification survey was performed at Trinity Medical Center Laboratory, CLIA # 19D0710168, on October 23, 2023 through October 27, 2023.

**D6125**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

A follow-up survey was performed at Trinity Medical Clinical Laboratory, CLIA ID #19D0710168, on March 13, 2024 through March 14, 2024. Based on review of personnel records and the laboratory's CMS 209 form as well as interview with personnel, the Technical Supervisor failed to ensure four (4) of five (5) testing personnel were assessed semiannually through testing previously analyzed specimens, internal blind samples, or external proficiency samples for microbiology. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director also served as the Technical Supervisor. 2. Review of personnel records revealed the following: - Blind sample correlation: Must include urine, blood, and upper respiratory. 3. Further review of personnel records revealed the following personnel did not have documentation of blind samples for gram stains and cultures of the specimen types required by the laboratory: - Testing Personnel 1 - gram stain (testing personnel only performs gram stains) - Testing Personnel 3 - urine, blood, and respiratory cultures including gram stain - Testing Personnel 5 - urine, blood, and respiratory cultures including gram stain - Testing Personnel 7 - blood and respiratory cultures including gram stain 4. In interview on March 13, 2024 at 11:20 a.m., General Supervisor 2 confirmed the laboratory did not have documentation of blind samples performed as identified above. \_\_\_\_\_ A Recertification survey was performed at Trinity Medical Center Laboratory, CLIA # 19D0710168, on October 23, 2023 through October 27, 2023.