

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2020658	<b>(X3) Date Survey Completed</b> 05/30/2025
<b>Name of Provider or Supplier</b> Corinthian Reference Lab	<b>Street Address, City, State</b> 6201 Southwest Blvd, Benbrook, TX	
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>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicaid &amp; Medicare Services) 116 form, laboratory policy, laboratory proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology specimen grossing at least twice annually for one of two testing events in 2024. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology specimen grossing procedures. 2. Review of the laboratory policy titled "Grossing" revealed: "PROCEDURE ... A peer-to-peer assessment will be performed every six months and annually every year for all grossing personnel." The policy failed to state accuracy assessments for nonregulated must be performed twice a year. 3. Review of the laboratory's proficiency testing for 2024 revealed PT was performed once in 2024. On 05/30/2025 at 10:20 a.m., the laboratory was asked to provide documentation of a second event in 2024 and none was provided. The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology specimen grossing in 2024. 4. During an interview on 05/30/2025 at 11:19 a.m., the Laboratory Manager, after a review of records confirmed the laboratory failed to verify the accuracy of non-regulated histopathology specimen grossing at least twice annually for one of two testing events in 2024.</p>
<b>D5417</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>

CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure two of two bottles of Zambonis Fixative had not exceeded their expiration dates. Findings included: 1. During a tour of the laboratory on 05/30/2025 at 11:35 a.m., the surveyor observed the following stored in a cabinet: 2 bottles of Zambonis Fixative; Lot # 199848; expiration date: 04/30/2025 2. During an interview on 05/30/2025 at 11:35 a.m., the Laboratory Manager, after a review of the reagents confirmed the above findings.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, personnel records, and confirmed in staff interview, the technical supervisor failed to evaluate and document annual competency assessments for two of five testing persons (TP-1 and Tp-5) responsible for high complexity testing in 2024. Findings included: 1. Review of the laboratory's policy "Employee Competency Evaluations" stated: "PROCEDURE ... 2. Competency Evaluations of all testing personnel will be completed by the Laboratory Director or Technical Supervisor on an annual basis. Competency evaluations for other laboratory personnel may be performed by the Laboratory Director or designated agent but always by an evaluator with higher qualifications than the person being evaluated on at least an annual basis." Review of the laboratory's policy "Technical Supervisor" stated: "Job Duties and Responsibilities ... (b) The technical supervisor is responsible for ... (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-review of quality control records, proficiency testing, assessment of test performance through testing previously analyzed specimens [sic] (1) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless methodology or instrumentation changes, in which case, the individual's performance must be reevaluated." 2. Review of personnel records revealed the technical supervisor failed to evaluate and document annual competency assessment for TP-1 and TP-5 in 2024. 3. During an interview on 05/30/2025 at 10:10 am, the Laboratory Manager confirmed the technical supervisor failed to evaluate and document annual competency assessments for two of five testing persons (TP-1 and TP-5) responsible for high complexity testing in 2024.