Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2333252	07/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Glory Vista Diagnostics	10611 Glory Vista Lane, Cypress, TX	

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	An announced survey of the laboratory was conducted on 07/20/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, specimen transport records and staff interview, the laboratory failed to follow its own policy and document monitoring of transport conditions to ensure specimen integrity for one of one type of specimen transported by the laboratory, stained histopathology slides. Findings included: 1. Review of laboratory's "Slide Transport Policy" [document 493-1241(B)] revealed: "4.2 Slide Packaging and Handling ... Temperature and humidity confirmed during transport." The policy did not define the acceptable temperature and humidity levels during transport required to ensure specimen integrity. 2. Review of laboratory's specimen transport records revealed the laboratory did not have documentation of verifying temperature or humidity during histopathology slides' transport. 3. In an interview on 07/20/2026 at 1720 hours in the laboratory, the Laboratory Director confirmed the findings.
D5403	PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures, quality control records, test volumes and staff interview, the laboratory failed to include negative control slide requirements in their protocols for seven of seven stains performed by the laboratory, the von Kossa, PAS, GMS, Fite, Congo Red, H&E and AFB stains. Findings included: 1. Review of the laboratory's staining protocols for the von Kossa, PAS, GMS, Fite, Congo Red, H&E and AFB stains revealed the protocols required only positive control slide review and did not include the requirements for negative control slides. 2. Review of laboratory's quality control records revealed the laboratory documented stain acceptability only for positive control slides. There was no documentation for negative control slides to ensure no false positive results were erroneously reported due to external factors/interference during staining. 3. Review of laboratory test volumes revealed the laboratory expected an annual test volume of approximately 1000 tests utilizing these stains. 4. In an interview on 07/21/2026 at 1430 hours via telephone, the Laboratory Director confirmed the findings. Key: PAS - Periodic Acid-Schiff GMS - Grocott-Gomori Methenamine Silver H&E - Hematoxylin and Eosin AFB - Acid-Fast Bacillus