Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505003	03/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Labs Inc	9200 Wall Street Attn Karen Pruett, Austin, 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	Complaint Investigation An unannounced complaint investigation was performed on 3 /5/2026 to 3/6/2026. A standard level deficiency was cited.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's 2020 validations studies, patient test results, and interview with the Laboratory Director, the laboratory failed to document performance specifications (precision, accuracy, sensitivity, specificity) two for two analytes (Chlamydia and Gonorrhea(CT/NG) modified FDA approved assays on the Cobas 8800 with patients under the age of fourteen as evidenced by: 1.Review of the manufacturer's instructions of the Cobas 8800 stated, "Cobas CT/NG has not been evaluated in patient younger than 14 years of age." 2.In review of the laboratory's 2020 validation studies: the laboratory did not perform an establishment study for precision, accuracy, sensitivity, and specificity for those patients under the 14 years of age in their patient study for CT/NG. 3.The laboratory performed in total

	98 patients under the age of 14 from December 2025 to February 2026. 4.In interview with the Laboratory Director and Quality Manager on 3/6/2026 at 1640 stated that they had not done studies for patients under the age of 14 for CT/NG.