Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0669013	02/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Elsa Medical Clinic	101 S Broadway, Elsa, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from October 2020 through December 2021, the laboratory failed to provide documentation of reviewing quality control to detect errors over time for 15 of 15 months reviewed. The findings included: 1. Review of the laboratory's quality control records from December 2020 through December 2021 found the laboratory would print end of the month Levy-Jennings reports; the data was not evaluated. Therefore, the laboratory did not have a mechanism in place to detect errors over time. 2. Review of the laboratory's submitted Form CMS-116 approved by the laboratory director on January 7, 2022 listed an

	annual hematology volume of 9804. 3. The findings were confirmed in interview of testing personnel 1 (as listed on Form CMS-209) at 14:30 hours in the office. She agreed that the information was printed but had not been evaluated to determine errors over time. Key: CMS - Centers for Medicaid and Medicare Services