Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2281797	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Citizens Imaging Center	9410 Zac Lentz Pkwy, Victoria, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of patient test records, review of the laboratory's verification studies for the Nova Biomedical Statsensor, and staff interview, the laboratory failed to have documentation of verifying 2 of 2 patient normal ranges as part of the studies. The findings included: 1. A review of patient test records identified the laboratory utilized 2 patient normal ranges to assess whole blood creatinine results. They were: a) Male results 0.72 - 1.25 mg/dl b) Female results 0.57 - 1.11 mg/dl 2. A review of the laboratory's verification studies for the Nova Biomedical Statsensor determined verification of the normal ranges was not included in the studies. 3. The laboratory was asked to provide documentation of verifying the patient normal ranges. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 03/1/2024 at 0930 hours in his office.
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each

	testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed. This STANDARD is not met as evidenced by: Based on review of patient reports from 1/23/2024 to 2/14/2024, and staff interview, the laboratory failed to include the testing facility's name and address on 10 of 10 reports. The findings included: 1. A review of a random sampling of patient reports from 1/23/2024 to 2/14/2024 identified 10 of 10 patient reports which did not contain the testing facility's name and address. They were: Date Specimen ID 1/23 G00130R 1 /29 G00068R 1/30 G00062R 1/31 G00076R 1/31 G00080R 2/05 G00129R 2/07 G00075R 2/08 G00094R 2/09 G00158R 2/14 G00070R 2. The laboratory director confirmed the findings in an interview conducted 03/19/2024 at 0940 hours in his office.