Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0992051	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Citizens Medical Center Pulmonary Function Lab	9406 Zac Lentz Parkway, 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
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.
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 the laboratory verification studies and confirmed in interview, the laboratory failed to document complete verification studies for the blood gas analysis (pH, PCO2, pO2 and THb) on the Siemens Rapid Point 500 analyzer. Findings were: 1. Review of the laboratory verification studies for the Siemens Rapid point 500 analyzer revealed no documentation of the precision, accuracy, linearity, and reference range studies for pH, PCO2, pO2 and THb testing. The laboratory provided the quality control data of the verification studies, but no assessment of the data was available for review. Moreover, the original validation studies (prior to the move of the analyzer) was unavailable for review. 2. An interview with the Respiratory

	supervisor and Cardio manager on 7/31/19 at 1020 hours in the conference room confirmed the above findings. Key: PCO2 - partial pressure of carbon dioxide pO2 - partial pressure of oxygen THb - total hemoglobin
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports and confirmed in interview, the laboratory failed to include the name and address of the laboratory performing the blood gas analysis for 7 of 7 reviewed. Findings were: 1. Random review of the July 2019 final reports for blood gas analysis revealed 7 of 7 patient final reports with no documentation of the laboratory name and address. 2. An interview with the respiratory supervisor and cardio manager on 7/31/19 at 1120 hours in the conference room confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel records and confirmed in interview, the technical consultant failed to document the semiannual competency assessment for 9 of 9 testing personnel. Findings were: 1. Review of the laboratory CMS 209 revealed documentation the laboratory had 9 testing personnel. 2. Review of the 2018 and 2019 personnel records revealed the 2019 competency assessment for TP1, TP2, TP3, TP4, TP5, TP6, TP8, and TP9 were performed by TP7, who doesn't qualify as a technical consultant. Testing person 7 has a high school diploma. 3. Further review of the 2018 and 2019 competency assessments revealed all competencies were performed at the 45D0498702 lab, not this laboratory. 4. An interview with the respiratory supervisor and cardio manager on 7/31/19 at 0925 hours in the conference room confirmed the above findings. They were unaware the technical consultant was the only person who could perform the competency assessments and that they had to maintain separate competencies for each laboratory.