Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999632	10/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Brownsville Pulmonary Center Pa	844 Central Blvd Suite 420, Brownsville, 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 at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of chemistry records available at the time of the survey and interview of facility personnel it was revealed that the laboratory failed to document a complete initial verification study on the OPTIMedical CCA-TS2 300 analyzer prior to testing patient specimens. The findings included: 1. A review of chemistry records revealed no documentation of a reference range verification study prior to testing

	patient samples for the OPTIMedical CCA-TS2 chemistry analyzer put into use in July 2020. The review also revealed no final statistical analysis and approval of the accuracy, precision and reportable range studies. The patient reference ranges in use are: pH 7.350 - 7.450 PCO2 35.0 - 45.0 mmHg PO2 80.0 - 100.0 mmHg 2. The laboratory failed to have a policy for acceptance criteria when performing a verification study on a new analyzer. 3. An interview of the primary testing person on October 20, 2020 at 11:00 hours in the laboratory confirmed the findings. He confirmed that the laboratory used the same reference ranges from the previous analyzer. Key pH - a scale used to specify the acidity or basicity of an aqueous solution PO2 - partial pressure of oxygen PCO2 - partial pressure of carbon dioxide