Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220712	12/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Meritus Pulmonary Consultants	12821 Oak Hill Ave, Hagerstown, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the remote survey documentation received on 09/30/2020 and email correspondence, the laboratory did not ensure that the reportable ranges listed in the procedure consistently matched. Findings: 1. The remote survey documentation received on 09/30/2020 had a page titled "Reportable Ranges" listing the following ranges: pH = 6.30-8.00, pCO2 = 5-250, and pO2 = 0-800. Another document under section 11 titled "Reportable Range of ABL 80 with CO-OX" of the procedure manual lists a different set of reportable ranges: pH = 6.80-7.90, pCO2 = 5-120, and pO2 = 0-730. 2. According to the documents received on 09/30/2020 the laboratory

	director did not ensure that the analyzer and procedure manual had one set of defined reportable ranges for the analytes tested and reported.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the maintenance calibration verification documents and email correspondence, the laboratory did not ensure that the manufacturer's instructions for calibration verification were followed. Findings: 1. The remote survey documents received on 09/30/2020 were reviewed. 2. The calibration records that were sent show that the calibration had been performed on 07/26/18, 02/01/19, 08/08/19 and 07/08/20. 3. According to the records that were sent the calibration was due on 02/02/2020. 4. An email was sent on 10/16/2020 inquiring about the 11 month gap between the last two calibrations. The response that was received on 12/15/2020 stated that "The only explanation could be COVID." 5. According to the documents received on 09/30/2020 and confirmed by the email correspondence received on 12/15/2020 the laboratory's records did not included the required calibration in February 2020 and documentation stating when the laboratory stopped testing due to the COVID-19 pandemic.
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 the final patient reports and email correspondence, the laboratory did not ensure that the final test report listed the name and address listed of the laboratory that is listed on the CLIA certificate. Findings: 1. The additional remote survey documents received on 12/15/2020 were reviewed. 2. Four final reports were sent via email on 12/15/2020 with the following dates 10/05/2020, 10/13/2020, 10/20 /2020, and 10/21/2020. The final reports did not list the name and address of the lab performing the tests. 3. According to the documents received on 12/15/2020 the laboratory did not ensure that the final report included the name and address of the laboratory listed on the CLIA certificate.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: I. Based on review of the "Responsibilities of ABG [arterial blood gas] Personnel" procedure and email correspondance, the laboratory director did not ensure that the "Responsibilities of ABG Personnel" procedure was updated to reflect the current responsibilities. Findings: 1. The "Responsibilities of ABG Personnel" states that 3 of the 4 personnel are responsible for "Meeting with Dr. Alencherry to review and sign proficiency testing, QC [quality control] drifts graphs, and temperature logs. (which is rotated between full time technicians)." Review of the temperature logs that were submitted on 09/30/2020 did not show a rotation of the technicians. 2. The email correspondence received on 12/15/2020 stated that "staffing has changed" and the lead tech "does the majority of the maintenance and care of the machine." 3. According to the documents received on 09/30/2020 and confirmed by the email correspondence received on 12/15/2020, the laboratory director did not update the "Responsibilities of ABG Personnel" procedure to reflect the current responsibilities of the ABG personnel. II. Based on review of the quality assurance (QA) procedure and email correspondence, the laboratory director did not ensure that the forms referred to in Section 8.5 of the QA procedure were being used. Findings: 1. The remote survey documents received on 09/30/2020 were reviewed. 2. According to section 8.5 "Maintenance/Activity and Troubleshooting Documentation" of the "Policy and Procedure Manual" the laboratory is required to document activities, regular maintenance, sensor cassette and solution pack replacement and external quality control validation on the "ABL 80 CO-OX Activity Log." Troubleshooting issues should be documented on the "ABL 80 CO-OX Troubleshooting Log." The section also states "Site coordinator or designee reviews and signs both monthly logs and submits to POCT." 3. On 09/30/2020 the laboratory submitted monthly temperature and maintenance records from December 2018 through February 2019 and November 2019 through March 2020. 4. The records were labeled "Temp Ranges" and included the month, date, time, temperature, initials and comments. Under the comment section the laboratory staff were documenting the maintenance and troubleshooting of the blood gas analyzer. 5. According to the documents received on 09/30/2020 the laboratory director did not ensure that the laboratory staff were using the forms referred to in the "Maintenance/Activity and Troubleshooting Documentation" procedure to document instrument maintenance, sensor cassette and solution pack replacement, external quality control validation, and troubleshooting.