Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220712	03/05/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory did not ensure that all the testing personnel that tested patient samples performed the PT. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." 2. A review of hematology PT attestation worksheets from 2016 and 2017 showed that PT was not performed by 1 of the 3 testing personnel in 6 of 6 events. 3. During an interview on 2 /26/18 at 9:20 AM, a laboratory staff member stated that the testing person worked in another office and tested patient samples infrequently at this laboratory, and confirmed that PT samples were not tested each year by all the staff that perform patient testing to ensure accurate and reliable patient test results.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the laboratory staff, the laboratory did not ensure that an eye wash station was located in the laboratory area where

	testing occurs. Findings: 1. During a tour of the laboratory, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 2/26/18 at 12:15 PM, the laboratory staff confirmed that the laboratory did not have an eye wash station in the room where laboratory testing is performed.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, and interview with the laboratory director (LD), the LD did not ensure the safety of the laboratory staff. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that there was no emergency eye wash station available to laboratory staff. 2. During an interview on 2/26/18 at 12:15 PM, the LD confirmed that there was no emergency eye wash station in the laboratory.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 03/8/2016 for not ensuring that proficiency testing records were reviewed and corrective action taken when necessary. The plan of correction stated that PT records would be reviewed as required. Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory director (LD) failed to ensure that the final results for PT were reviewed and corrective actions taken when necessary. Finding: 1. A review of PT records from 2016 and 2017 showed that in 2 of 6 events, the name of the testing person on the attestation worksheet did not match the name of the person who performed the PT. 2. The attestation worksheet from event 1, 2017 showed the signatures of 2 testing personnel, however the instrument print out and the "Proficiency Testing" log sheet showed that only 1 person had performed the testing; and 3. For event 3, 2017 the "Proficiency Testing" log showed that PT sample 17-3-11 was initialed by one testing person but a different testing person was listed on the instrument print out as having performed testing on that sample. 4. During an interview on 2/26/18 at 12:15 PM, the LD confirmed that the PT records did not accurately reflect which testing person was performing PT.

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 competency documentation and interview with the laboratory staff, the laboratory director acting as technical consultant failed to perform and document the competency review on all testing personnel. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." A review of competency assessments performed from 2016 through 2018 showed that 1 of 3 testing personnel did not have their 6 month competency assessment performed after their initial training on 6/12/17. 2. During the survey on 02 /26/18 at 12:15 PM the laboratory staff confirmed that a 6 month competency assessment was not performed on 1 of 3 testing personnel from 2016 through 2018.