

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220712	(X3) Date Survey Completed 06/11/2026
Name of Provider or Supplier Meritus Pulmonary Consultants	Street Address, City, State 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. A review of the "Laboratory Personnel Report" (CMS-209) showed that the laboratory employed three TP who performed blood gas testing. 2. A review of chemistry PT attestation worksheets from 2024 through 2026 showed that one of three TP performed the PT for six out of six events. 3. During an interview on 06/11/2026 at 12:15 PM, the TC confirmed that PT samples were not tested each year by all the staff who performed patient testing to ensure accurate and reliable patient test results.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and competency assessment record review and interview with the technical consultant (TC), the laboratory failed to establish and follow written policies and procedures for assessing the competency of the testing personnel</p>

(TP) who performed blood gas analysis as defined in subpart M- CFR 493.1413(b)(8) through (9). Findings: 1. Procedure manual review showed that the laboratory did not have a written procedure for how to perform competency assessments on the TP. 2. Record review showed that the laboratory used a form labeled "Performance Evaluation" "Analyzing Arterial Blood Gases" (competency form) to document the competency of TP performing blood gas analysis. 3. During an interview on 06/11/2026 at 11:45 AM, TP #1 stated that the current competency form was written to evaluate competency on the prior blood gas analyzer (ABL-80). The laboratory began testing with a new blood gas analyzer on 02/05/2025 (GEM 5000). 4. A review of the current competency form showed that it did not document all six required procedures that apply to all personnel who perform moderate or high complexity laboratory testing. The form did not include: monitoring the recording and reporting of test results; reviewing intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventive maintenance records; assessing test performance using previously analyzed test specimens, internal blind testing samples, or external PT samples; or assessing problem-solving skills. 5. During an interview on 06/11/2026 at 12:15 PM, the TC confirmed that the laboratory did not establish and follow written policies and procedures to assess the competency of the TP who performed blood gas analysis.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that all chemistry PT results were evaluated and the review documented. Findings: 1. The laboratory performs blood gas analysis on patient specimens. 2. A review of chemistry PT records from five events in 2024 through 2026 showed that in one out of five events ("2025 Chemistry - Core - 3rd Event"), the laboratory director failed to sign the PT results report, documenting that the results had been reviewed and were acceptable. 3. During an interview on 06/11/2026 at 12:15 PM, the TC confirmed that there was no documentation that the PT results had been evaluated and reviewed for the last chemistry event in 2025.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, patient instrument printouts, and electronic medical record (EMR) results and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory's established normal reference range for one out of 10 analytes reported during blood gas analysis was available in the procedure manual and EMR. Findings: 1. The laboratory performs arterial blood gas analysis using the GEM5000 blood gas analyzer (GEM5000). The instrument prints a

"Patient Sample Report" (printout) for each patient tested. The printout lists the results for 10 different measured and/or calculated analytes as well as the "low" and "high" reference (normal) ranges. 2. Results were reviewed for patient #1 tested on 06/10/2026 at 15:21 PM. 3. The normal range listed on the printout for the calculated oxygen saturation (sO₂) was "95.0 to 99.0%." 4. The procedure, "SOP BG004" for the GEM5000 lists the "Arterial Blood Gas Reference Ranges" established by the laboratory. The reference range for sO₂ was blank and did not list any numerical values. 5. A review of patient #1's final report in the EMR showed that the normal range for sO₂ also did not list any numerical values. 6. During an interview on 06/11/2026 at 12:15 PM, the TC confirmed that the laboratory failed to ensure that all of the normal reference ranges for patients' arterial blood gas results were available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.