

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0865208	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Chevy Chase Pulmonary Associates	Street Address, City, State 5530 Wisconsin Avenue #1150, Chevy Chase, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not review the proficiency testing providers evaluation of the laboratory performance. Findings: 1. The laboratory was enrolled in a proficiency testing program for arterial blood gas analysis; 2. the proficiency test provider evaluated the laboratory performance, but the laboratory did not have records showing that these evaluations were reviewed by the laboratory director and staff; and 2. This was confirmed on interview with staff at 12:00 pm on the day of survey.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: A. Based on record review and interview with staff, the chemistry laboratory did not</p>

perform daily electronic control checks as required by the manufacturer each day of patient testing. Findings: 1. The laboratory individual quality control plan requires the lab to perform electronic checks each day of patient testing (SRC); 2. On July 16, 2018 (1 patient tested), July 12, 2018 (1 patient tested) and March 3, 2018 (2 patients tested), the laboratory did not have analyzer printouts to show that the electronic checks were performed; and 3. This was confirmed during interview with staff in the afternoon on day of survey. B. Based on record review and interview with staff, the chemistry laboratory did not perform monthly external (liquid) control checks as required by the manufacturer and the laboratory individualized quality control plan. Findings: 1. The laboratory individual quality control plan requires the lab to perform external (liquid) checks each month (opti-check); 2. On August 21, 2018 (1 patient tested that week), April 17, 2019 (1 patient tested that week) and February 6 and 7, 2019 (patients tested each day), the laboratory did not have analyzer printouts to show that the control checks were performed; 3. The laboratory written procedure for arterial blood gas control testing did not establish a routine practice to ensure quality control testing was performed each month, and did not establish the number of days between quality control testing; and 4. This was confirmed during interview with staff in the afternoon on day of survey.

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
Based on record review and interview with staff, the laboratory director acting as technical consultant did not document that he performed direct observation of the testing person, including dates these observations were made and duties performed as part of the annual competency record. This was confirmed during interview with staff at 12:00 pm on the day of survey.

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with staff, the laboratory director acting as technical consultant did not document that he performed monitoring recording and reporting of test results of the testing person, including dates these observations were made as part of the annual competency record. This was confirmed during interview with staff at 12:00 pm on the day of survey.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records,

proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on record review and interview with staff, the laboratory director acting as technical consultant did not document that he performed review of intermediate test results, quality control records, proficiency testing results and maintenance records of the testing person, including dates these observations were made as part of the annual competency record. This was confirmed during interview with staff at 12:00 pm on the day of survey.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with staff, the laboratory director acting as technical consultant did not document that he performed an assessment of problem solving skills of the testing person, as part of the annual competency record. This was confirmed during interview with staff at 12:00 pm on the day of survey.