

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0175351	<b>(X3) Date Survey Completed</b>  04/05/2018
<b>Name of Provider or Supplier</b>  Pittsburgh Pulmonary & Critical Care Assoc	<b>Street Address, City, State</b>  1200 Brooks Lane Suite 180, Jefferson Hills, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records and interview with Testing Personnel #1 (TP#1), the laboratory failed to monitor and document the condition for storage of the ABL 80 Flex analyzers Quality control material from 2017 to the date of survey. Findings Include: 1. On the date of survey, 04/05/2018, review of temperature records, revealed the laboratory did not document the room temperature of where (items listed below), used on the ABL 80 Flex Blood Gases analyzer, are stored. - 1 of 1 box of Qualicheck 4 + Level #1 Exp: 07/2018 Lot# R0098 - 1 of 1 box of Qualicheck 4 + Level #2 Exp: 12/2018 Lot# R0105 - 1 of 1 box of Qualicheck 4 + Level #3 Exp: 01/2019 Lot# R0091 2. According to the Qualicheck 4 + controls (Levels 1, 2 and 3) package insert, the control ampules are to be is stored at a temperature of 2-25 degrees Celsius. 3. In 2017, 236 patient specimen were tested. 4. TP#1 confirmed the finding above on 04/05/2018 around 10:30 am.</p>