

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105537	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Holy Name Pulmonary Associates Pc	Street Address, City, State 8305a Bergenline Avenue, North Bergen, NJ	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufacture package insert (MPI), QC material, and interview with the Testing Personnel (TP), the laboratory used expired QC material for Arterial Blood Gas tests from 7/12/18 to the date of survey. The findings include: 1. The MPI stated that Critical Care IQM GEM CVP QC expires twelve months once stored at room temperature. a) So the QC material used was expired on 7/12/18. 2. Approximately 4 patients were run and reported from 7/12/18 to 9/11/18. 3. The TP #2 listed on CMS form 209 confirmed on 9/12/18 at 11:00 am via phone call that the laboratory used expired QC material.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a written policy for new QC verification used for Arterial Blood Gas tests performed on the Gem Premier 3000</p>

from 9/4/14 to the date of the survey. The Findings include; 1) This deficiency was cited on the previous survey. 2) The Plan Of Corrections stated "will run QC with new lot number prior to use of CVP vials". 3) The TP # 2 listed on the CMS form 209 confirmed on 9/11/18 at 2:00 PM the laboratory did not establish written policies for new QC lot verification.