

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0538897	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Pulmonary Specialist Grp Of Nevada-Sunset	Street Address, City, State 9280 W Sunset Rd Ste 312, Las Vegas, NV	
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
D0000	This statement of deficiencies was generated as a result of the on-site CLIA recertification survey conducted at your facility on January 10, 2018. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state or local laws.
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 a review of the director approved policy and procedure manual, a review of the laboratory quality assessment documentation for laboratory testing performed in 2016 and 2017 and an interview with the area manager for laboratory services, there was no documentation of an ongoing mechanism to assess quality of the analytic phase of patient testing. Findings include: There was no documentation of evaluation and assessment for the quality of the analytic phase of patient testing. This was confirmed by the area manager of laboratory services on January 10, 2018 at approximately 11:30 am. The laboratory performs approximately 10,500 hematology and chemistry patient laboratory tests annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification,</p>

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a random audit of patient final laboratory test reports from January 6, 2016 to December 12, 2017 and an interview with the area manager for laboratory services, the laboratory failed to ensure that the patient final test report had the name of the laboratory where the test was performed. Findings include: 1. The laboratory failed to have the name of the laboratory where the patient test was performed, Pulmonary Specialist Group of Nevada, on the patient final test report. 2. There were ten of ten patient final test reports that indicated Lung Center of Nevada as the name of the laboratory where the patient tests were performed. This was confirmed by the area manager for laboratory services on January 10, 2018 at approximately 11:30 am. The laboratory performs approximately 10,500 patient laboratory tests annually.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a random audit of patient test results from January 6, 2016 to December 12, 2017, a review of the daily laboratory patient test logs and an interview with the area manager for laboratory services, the laboratory director failed to ensure that the quality assessment program would ensure that laboratory information is accurately transcribed into its information system. Findings include: A random audit of patient test records revealed a patient that had a blood CO-oximetry performed on 12/12/17 with a date of birth of 7/13/1946 on the patient final report and a date of birth of 1/04 /43 recorded in the patient daily log book. This was confirmed by the area manager for laboratory services on January 10, 2018 at approximately 11:00 am. The laboratory performs approximately 10,500 hematology and chemistry tests annually.

D6046

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

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of patient laboratory testing personnel competencies for testing performed in 2016 and 2017 and an interview with the area manager for laboratory services, the technical consultant of the laboratory failed to ensure that laboratory testing personnel maintain their competency in performing test procedures. Findings include: There was no documentation of semiannual competency in the performance of blood gas and CO-oximetry testing for one of five patient laboratory testing personnel. This was confirmed by the area manager for laboratory services on January 10, 2018 at approximately 10:00 am. The laboratory performs approximately 10,500 hematology and chemistry patient laboratory tests annually.