

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0962032	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Pulmonary Specialist Group Of Nevada-Mt View	Street Address, City, State 3150 N Tenaya Way Ste 125, 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 created as a result of an on-site CLIA recertification survey conducted at your facility on March 14, 2019. 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.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results for laboratory testing years 2017 and 2018 and an interview with the laboratory manager, the laboratory testing personnel failed to perform laboratory testing on proficiency testing samples the same number of times that the personnel would test patient samples. Findings include: 1. The laboratory testing personnel failed to test proficiency testing samples the same number of times that patient samples were tested. 2. Patient testing samples which produced abnormal results were repeated for verification while proficiency testing samples that were found to have abnormal test results were not repeated for verification of test results. This was confirmed by the laboratory manager on March 14, 2019 at approximately 10:30 AM. The laboratory performs approximately 8,716 chemistry and hematology patient tests annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure manual and an interview with the laboratory manager, the laboratory personnel failed to follow the policies and procedures written in the manual. Findings include: 1. The laboratory testing personnel failed to follow the "Internal Proficiency Testing" policy that was instituted in June 2006. 2. The policy states that "An internal proficiency testing log will be maintained on all clinic lab personnel. Documentation of the testing of unknowns by each individual will be done on a random basis at least once per month". In addition, it states that "The proficiency testing and review will be accomplished once per month by each individual. The clinic lab supervisor will document the actual result". 3. There was no evidence of the "Internal Proficiency Testing" policy and procedure taking place or documented. This was confirmed by the laboratory manager on March 14, 2019 at approximately 11:00 AM. The laboratory performs approximately 8,716 chemistry and hematology patient tests annually.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, 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 patient audit of laboratory tests performed between 5/05/17 and 1/18/19 and an interview with the laboratory manager, the laboratory failed to have the test report indicate the required information that must be demonstrated on the patient final report. Findings include: 1. The patient final test report failed to indicate the name of the laboratory in which the patient laboratory tests were performed. 2. The patient final test report indicated the name of the laboratory is "CCCN Pulmonary Division". The name of the laboratory in which the test was performed is called "Pulmonary Specialist Group of Nevada-MT View". This was confirmed by the laboratory manager on March 14, 2019 at approximately 11:00 AM. The laboratory performs approximately 8,716 chemistry and hematology patient tests annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel training and competency documents for testing year 2017 and 2018 and an interview with the laboratory manager, the technical consultant failed to perform competency assessment for all laboratory testing personnel at least semiannually during the first year of testing patient samples. Findings include: The technical consultant failed to evaluate two of five laboratory testing personnel semiannually during the first year that the personnel were performing laboratory testing on patient samples. This was confirmed by the laboratory manager on March 14, 2019 at approximately 10:00 AM. The laboratory performs approximately 8,716 chemistry and hematology patient tests annually.