Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0928112	06/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sunview Respiratory And Rehabilitation	12207 N 113th Ave, Youngtown, AZ	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of instrument printouts for patient test results generated from the I-Stat analyzer and interview with the testing personnel, the laboratory failed to retain patient test records, including instrument printouts, for at least 2 years. Findings include: 1. The laboratory performs patient testing on the I-Stat analyzer under the specialty of Chemistry, with an approximate annual test volume of 1,000. 2. No documentation was presented for review during the survey conducted on June 10, 2021 to indicate the laboratory retained patient test records (instrument printouts) from the I-Stat analyzer for testing that occurred prior to January 1, 2021. 3. The testing personnel confirmed that instrument printouts showing patient test results from the I-Stat analyzer for testing that occurred prior to January 1, 2021 were discarded by the laboratory and were not being retained for at least 2 years.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for

	patient testing for one patient record reviewed during the survey. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing and routine chemistry testing on the I-Stat analyzer under the specialty of Chemistry, with an approximate annual test volume of 1,000. 2. No written or electronic request for ABG testing was presented for review for one out of three patient records reviewed during the survey, patient# 3282 tested on 4/16/21 at 09:33 PM. 3. The facility personnel confirmed that the laboratory did not have an electronic or written test requisition for ABG testing that was performed on the patient indicated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for the I-Stat analyzer and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign the test procedure before use. Findings include: 1. The laboratory began testing the CG8+ cartridge on the I-Stat analyzer in January 2020. 2. The CG8+ policy and test procedure presented for review during the survey conducted on June 10, 2021 was not approved, signed and dated by the current laboratory director. The CG8+ policy and test procedure indicated an effective date of 1/22/20. 3. The facility personnel confirmed that the test procedure indicated above was not approved, signed and dated by the current laboratory director before use.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel who performs patient testing on the I-Stat analyzer 2. The facility personnel confirmed that the laboratory failed to provide documentation of initial training for the testing personnel indicated above.
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 lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of eight testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for eight out of eight testing personnel who perform patient testing on the I-Stat analyzer. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for eight testing personnel as indicated above.