Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2167888	04/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Respircare Open Access	2832 E 101st St, Tulsa, OK	

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	The initial survey was performed on 04/16/2021. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure materials had not exceeded their expiration date for 229 of 229 COVID test devices. Findings include: (1) On 04/16/2021 at 10:00 am, the technical consultant stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument: (i) BD Veritor System - qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct nasal swabs. (2) On 04/16/2021 at 10:30 am, the surveyor observed the following expired materials available for use in the laboratory's storage area: (a) 229 BD Veritor SARS-CoV-2 test devices, lot#0317443, expiration date 04/14/2021. (2) The surveyor showed the expired materials to the technical consultant who stated on 04/16/2021 at 10:40 am the expired materials were available for use and stated they should have been discarded once they had expired.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results

	available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the proficiency testing program released proficiency testing results to HHS and the State Agency. Findings include: (1) Prior to the onsite survey (04/16/2021), the surveyor printed the laboratory's proficiency testing scores for review from the CMS Casper database. The scores included on the Casper Report 0096D, did not report for the 2019 and 2020 proficiency testing events. It appeared the laboratory did not participate in proficiency testing; (2) On 04/16/2021 at 10:25 am, the technical consultant stated to the surveyor: (a) The laboratory performed pCO2, pH, and pO2 using the G3+ cartridge with the Abbott iSTAT 1 Analyzer beginning 06/01/2019; (b) The laboratory performed Calcium, Glucose, Hematocrit, Hemoglobin, Sodium, Potassium, pCO2, pH, and pO2 using the CG8+ cartridge with the Abbott iSTAT 1 Analyzer beginning 05/21/2020. (3) The surveyor asked the technical consultant if the laboratory participated in proficiency testing during 2019 and 2020. On 04/16/2021 at 10:55 am, the technical consultant stated that all available proficiency testing events had been performed in 2019, 2020 and 2021; (4) The surveyor then reviewed the 0096D report which did not show scores under the columns for the six testing events with technical consultant; (5) The technical consultant stated on 04/16/2021 at 11:15 am, the laboratory had not authorized release of proficiency testing scores for the events of 2019, 2020, and 2021.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for test timing for a blood gas cartridge for four of four test reports. Findings include: (1) On 04/16/2021 at 10:25 am, the technical consultant stated to the surveyor: (a) The laboratory performed Calcium, Glucose, Hematocrit, Hemoglobin, Sodium, Potassium, pCO2, pH, and pO2 using the CG8+ cartridge with the Abbott iSTAT 1 Analyzer; (2) The surveyor reviewed the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge". For test timing, the instructions stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) The surveyor then reviewed patient testing records on 09/10/2020, 04/09/2021, and 03/22/2021 and identified the following for four of four patient test reports: (a) Patient Report #1 - Although the result time was on 09/10/2020 at 02:21 pm; the time of specimen collection was not documented; (b) Patient Report #2 - Although the result time was on 04/09/2021 at 12:10 pm, the time of specimen collection was not documented; (c) Patient Report #3 - Although the result time was on 03/22/2021 at 03:

	46 pm, the time of specimen collection was not documented; (d) Patient Report #4 - Although the result time was on 03/22/2021 at 07:45 pm, the time of specimen collection was not documented; (5) The surveyor reviewed the findings with the technical consultant. The technical consultant stated on 04/16/2021 at 02:26 pm, the laboratory could not prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with technical consultant the laboratory failed to follow written quality control policies for 2 of 9 months; and failed to ensure data supported the QC (Quality Control) frequency as defined in the QCP (Quality Control Plan) portion of the IQCP (Individualized Quality Control Plan). Findings include: QUALITY CONTROL PLAN (1) On 04/16/2021 at 10:25 am, the technical consultant stated to the surveyor: (a) The laboratory performed Calcium, Glucose, Hematocrit, Hemoglobin, Sodium, Potassium, pCO2, pH, and pO2 using the CG8+ cartridge with the Abbott iSTAT 1 Analyzer; (2) The surveyor reviewed the IQCP that had been developed for each test system. The QCP portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC records for 9 months (May 2020 through January 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. QC testing had not been performed as follows: (a) CG8+ Cartridge (i) Between 06/29/2020 and 08/12/2020 (ii) Between 11/30/2020 and 01/31/2021 (4) The findings were reviewed with the technical consultant who stated on 04/16/2021 at 02:15 pm, the laboratory had not performed quality control testing as required by the QCP. DATA TO SUPPORT THE FREQUENCY OF THE QUALITY CONTROL PLAN (1) On 04/16/2021 at 10:25 am, the technical consultant stated to the surveyor: (a) The laboratory performed Calcium, Glucose, Hematocrit, Hemoglobin, Sodium, Potassium, pCO2, pH, and pO2 using the CG8+ cartridge with the Abbott iSTAT 1 Analyzer; (b) An IQCP had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective on 04/20/2020) and identified the QCP required two levels of external QC materials be performed once each month (i.e., approximately each 30 days); (3) The surveyor then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Two levels of QC had been tested for 10 days (not at least 30 days). (4) The surveyor reviewed the records with the technical consultant and asked if additional documentation was available to support the reduced external QC frequency of monthly. The technical consultant stated QC had not been tested for at least 30 days.

D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the

	laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 1 of 2 competency evaluations performed. Findings include: (1) On 04/16/2021, the surveyor reviewed records for 2 persons performing moderate complexity testing in 2019, 2020 and to date in 2021 (04/16/2021). The records showed the evaluations for 1 of 2 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 11 /30/2019 evaluation had been performed by testing person #1 (this person had earned an Associate Degree). (2) The surveyor reviewed the records with the technical consultant and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The technical consultant stated to the surveyor on 04/16 /2021 at 11:15 am, the above evaluation had been performed by an individual who did not meet the educational qualifications of a technical consultant.