



TSANZ RESPIRATORY FUNCTION LABORATORY ACCREDITATION OVERVIEW OF CHANGES TO THE PROGRAM (JUNE 2021)

Key changes from the 2016 Program Manual to the revised Manual (June 2021) are summarised below.

1. **Updated flow chart of TSANZ Stakeholders (Section 1.4)** to clarify the workflow and relationships between all stakeholders of the program.
2. **More tests were added to the list of names of tests, for example the 6 Minute Walk Test (section 2.4).** This was done so laboratories would not have to select 'Other' and enter the details themselves as often.
3. **Revised the accreditation process overview and timelines (section 3.1).** This was done to make the process clearer, better explain what took part at each stage, and adjusted time frames where it was necessary.
4. **Updated the process for site visits to include potential virtual site visits.** See new sub section 3.7.5.
5. **Updated and clarified the requirements for staff (for example qualifications and experience).** See section 7.2.2.1
6. **Revised Laboratory Data and Reports, Interpretation of Test Results.** See sections 7.2.4 and 7.2.4.4 respectively.
7. **Requirement of a Quality Assurance Program.** To facilitate continual quality improvement, see section 7.2.6.
8. **Updated of facility requirements.** These new updates focus largely on privacy, confidentiality, and safety, please see section 7.2.8.
9. **A new section has been added, requirements for accreditation of Mobile Laboratory Sites.** See section 7.2.8.4.
10. **Revision of Infection Prevention and Control.** See section 7.2.9.
11. **Updated Safety Procedures.** See section 7.2.10.
12. **Laboratory Procedures and Quality Control Measurements updated.** They now include exercise testing in relation to the latest standards, see section 7.3.
13. **Updated the requirements for predicted values.** See section 7.3
14. **Review and update of the References** (Section 8, page 34).
15. **Update of the Summary of Supporting Program Documentation** (Section 9, page 35).

Key Changes to the Application Forms

16. **A single application form has been created called Application for Accreditation of Primary and Branch Laboratories (Form A).** This form combines the Application for Accreditation and Application for a Branch Site (previous Form A and previous Form B respectively). This new form keeps the application process to one form and cuts down on repetition.
17. **The Application for the Accreditation of Additional Tests (Form B) (previously The Application for additional Tests Form C),** has been updated to reflect the changes in format to Form A, but otherwise remains largely unchanged.