



Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 2023

I, Tracey Duffy, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 8 November 2023

Tracey Duffy
First Assistant Secretary
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 2023*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	11 November 2023

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods Information (Laboratory Testing) Specification 2017

1 Section 4

Before “In this specification:”, insert “(1)”.

2 Section 4 (at the end of the definition of *sample*)

Add:

Note: See also subsection (2).

3 Section 4 (after paragraph (a) of the note)

Insert:

(aa) Commonwealth officer;

4 At the end of section 4

Add:

- (2) For the avoidance of doubt, a reference in this instrument to a sample includes a sample (or part of a sample) taken, collected or otherwise obtained:
 - (a) under the Act; or
 - (b) under regulations made under the Act (including the *Therapeutic Goods Regulations 1990*); or
 - (c) by, or at the request or on the instruction of, a Commonwealth officer (including in the exercise of the executive power of the Commonwealth).
- (3) For the avoidance of doubt, a reference in this instrument to a test includes a test, analysis or examination conducted or otherwise carried out:
 - (a) under the Act; or
 - (b) under regulations made under the Act (including the *Therapeutic Goods Regulations 1990*); or
 - (c) by, or at the request or on the instruction of, a Commonwealth officer (including in the exercise of the executive power of the Commonwealth).