



Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022

I, Greg Hunt, Minister for Health and Aged Care, make the following determination.

Dated 7 January 2022

Greg Hunt
Minister for Health and Aged Care

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Part 1—Preliminary

1 Name

This instrument is the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022*.

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	1.00 am (by legal time in the Australian Capital Territory) on 8 January 2022.	1.00 am (A.C.T.) 8 January 2022

Note: This table relates only to the provisions of this instrument as originally made.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 477(1) of the *Biosecurity Act 2015*.

4 Definitions

Note: A number of expressions used in this instrument are defined in the *Biosecurity Act 2015*, including the following:

- (a) declaration listed human disease;
- (b) human biosecurity emergency period;
- (c) officer of Customs.

In this instrument:

ABN has the same meaning as in the *A New Tax System (Australian Business Number) Act 1999*.

COVID-19 human biosecurity emergency period means a human biosecurity emergency period if the declaration listed human disease in relation to the period is human coronavirus with pandemic potential.

Note 1: COVID-19 is the name given by the World Health Organization to the disease.

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Note 2: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the name given by the International Committee on Taxonomy of Viruses to the virus that causes the disease.

COVID-19 rapid antigen test kit means a medical device that:

- (a) is a single use lateral flow or immunochromatographic test kit; and
- (b) is classified as a Class 3 IVD medical device (within the meaning of the *Therapeutic Goods (Medical Devices) Regulations 2002*); and
- (c) is included in the Register (within the meaning of the *Therapeutic Goods Act 1989*); and
- (d) has an intended purpose, accepted in relation to that inclusion, that relates to the detection of the novel coronavirus SARS-CoV-2 that causes COVID-19.

GST Act means the *A New Tax System (Goods and Services Tax) Act 1999*.

law enforcement officer means:

- (a) the Commissioner of the Australian Federal Police; or
 - (b) a Deputy Commissioner of the Australian Federal Police; or
 - (c) a member of the Australian Federal Police; or
 - (d) a special member of the Australian Federal Police;
- (all within the meaning of the *Australian Federal Police Act 1979*).

officer of Customs has the same meaning as in the *Customs Act 1901*.

price gouging: see subsection 5(2).

retail transaction: see subsection 5(3).

Part 2—Price gouging

5 Requirement not to engage in price gouging in relation to COVID-19 rapid antigen test kits

- (1) A person must not engage in price gouging in relation to a COVID-19 rapid antigen test kit.
- (2) A person engages in *price gouging* in relation to a COVID-19 rapid antigen test kit if:
 - (a) the person supplies, or offers to supply, the test kit during the COVID-19 human biosecurity emergency period; and
 - (b) the person purchased the test kit in a retail transaction; and
 - (c) the value of the consideration for which the person supplies, or offers to supply, the test kit is more than 120% of the value of the consideration for which the person purchased the test kit.
- (3) For the purposes of determining whether the person purchased the test kit in a *retail transaction*, it is not relevant whether or not, at the time of purchase, the person intended to supply, or offer to supply, the test kit.
- (4) For the purposes of paragraph (2)(c), disregard so much of the value of the consideration for which the person supplies, or offers to supply, the test kit as is directly attributable to costs reasonably incurred by the person in transporting or delivering the test kit.

6 Enforcement—requirement not to dispose of, or deal with, COVID-19 rapid antigen test kits

- (1) Subject to section 7, a person must not dispose of, or deal with, a COVID-19 rapid antigen test kit if:
 - (a) a law enforcement officer has notified the person, in writing, that:
 - (i) the officer suspects on reasonable grounds that the person has engaged, is engaging or intends to engage in price gouging in relation to the test kit; and
 - (ii) the person is required not to dispose of, or deal with, the test kit; and
 - (iii) the notice will be withdrawn if the person satisfies a law enforcement officer on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the test kit; and
 - (b) the notice has not been withdrawn.
- (2) If a person has been notified as mentioned in paragraph (1)(a) in relation to a COVID-19 rapid antigen test kit, a law enforcement officer must withdraw the notice, in writing, if the officer is satisfied on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the test kit.

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7 Enforcement—requirement to surrender COVID-19 rapid antigen test kits

Requirement to surrender test kits

- (1) A person must surrender a COVID-19 rapid antigen test kit to a law enforcement officer if the officer notifies the person, in writing, that:
 - (a) the officer suspects on reasonable grounds that the person has engaged, is engaging or intends to engage in price gouging in relation to the test kit; and
 - (b) the person is required to surrender the test kit to the officer; and
 - (c) the test kit will be destroyed or given away after 21 days unless the person satisfies a law enforcement officer on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the test kit.

Dealing with surrendered test kits

- (2) Subsections (3) and (4) apply if a person surrenders a COVID-19 rapid antigen test kit under subsection (1).
- (3) A law enforcement officer must return the test kit to the person as soon as practicable if:
 - (a) the law enforcement officer is satisfied on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the test kit; and
 - (b) the test kit has not been destroyed or given away under subsection (4).
- (4) A law enforcement officer must do the following as soon as practicable if, 21 days after the person surrenders the test kit, the officer is not satisfied as mentioned in paragraph (3)(a):
 - (a) if the officer believes on reasonable grounds that:
 - (i) the test kit is defective; or
 - (ii) there is a risk that the test kit is defective and, because of that risk, the test kit should not be used;destroy the test kit;
 - (b) otherwise—give the test kit to the National Medical Stockpile.

Part 3—Export restrictions

8 Prohibition of export of COVID-19 rapid antigen test kits during COVID-19 human biosecurity emergency period

Subject to section 9, a person must not export from Australia a COVID-19 rapid antigen test kit during the COVID-19 human biosecurity emergency period.

9 Export of COVID-19 rapid antigen test kits during COVID-19 human biosecurity emergency period—exceptions

Non-commercial

- (1) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit on a ship or aircraft by a person if:
 - (a) the person is:
 - (i) a passenger on board the ship or aircraft; or
 - (ii) a member of the crew of the ship or aircraft; and
 - (b) the test kit is:
 - (i) accompanied personal or household effects of the person; and
 - (ii) for the personal use of the person.
- (2) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit by a person if:
 - (a) the intended recipient of the test kit is a relative of the person; and
 - (b) the test kit is for the personal use of the relative; and
 - (c) the export is not by post.
- (3) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit by a person if:
 - (a) the intended recipient of the test kit is an employee of the person; and
 - (b) the test kit is for the personal use of the employee; and
 - (c) the export is not by post.
- (4) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit by a person if:
 - (a) the person is a humanitarian organisation or agency; and
 - (b) the export is not for commercial purposes; and
 - (c) the export is not by post.

Commercial

- (5) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit by a person if:
 - (a) the person manufactured the test kit; and
 - (b) the export is not by post.

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- (6) Section 8 does not apply to the export of a COVID-19 rapid antigen test kit by a person if:
 - (a) the person exports the test kit in the ordinary course of the person's business; and
 - (b) the person is registered under the GST Act and has an ABN; and
 - (c) the export is not by post.

10 Requirement to surrender COVID-19 rapid antigen test kits to an officer of Customs

- (1) This section applies if:
 - (a) a person attempts to export a COVID-19 rapid antigen test kit during the COVID-19 human biosecurity emergency period; and
 - (b) both the following apply:
 - (i) the test kit is in the possession of an officer of Customs;
 - (ii) the export of the test kit is prohibited under section 8.
- (2) The person must surrender the test kit to an officer of Customs if the officer notifies the person, in writing, that the person is required to surrender the test kit to the officer.
- (3) If the person surrenders the test kit under subsection (2), an officer of Customs must do the following as soon as practicable:
 - (a) if the officer believes on reasonable grounds that:
 - (i) the test kit is defective; or
 - (ii) there is a risk that the test kit is defective and, because of that risk, the test kit should not be used;destroy the test kit;
 - (b) otherwise—give the test kit to the National Medical Stockpile.