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INFECTIOUS DISEASES ACT 1976

INFECTIOUS DISEASES (ANTIGEN RAPID TEST PROVIDERS) (AMENDMENT) REGULATIONS 2022

In exercise of the powers conferred by section 73 of the Infectious Diseases Act 1976, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Infectious Diseases (Antigen Rapid Test Providers) (Amendment) Regulations 2022 and come into operation on 21 January 2022.

Amendment of regulation 2

2. Regulation 2 of the Infectious Diseases (Antigen Rapid Test Providers) Regulations 2021 (G.N. No. S 267/2021) (called in these Regulations the principal Regulations) is amended —

(*a*) by inserting, immediately after the definition of "relevant testing activity" in paragraph (1), the following definition:

> "‘"remote communication", in relation to any supervision of a self-administered test, means communication by means of audio and visual electronic technology, where the supervisor and supervised subject can simultaneously communicate by sight and sound with each other throughout the period of supervision;
>
> *Illustration*
>
> Real-time electronic communication such as video conferencing, tele-conferencing or live chat.";

(*b*) by inserting, immediately after the definition of "self-administered test" in paragraph (1), the following definition:

> "'"self-administered test supervisor" means the individual who supervises a supervised subject performing a self-administered test;";

(*c*) by inserting, immediately after the definition of "specified training provider" in paragraph (1), the following definition:

> "'"supervised subject" means the individual who performs a self-administered test under the supervision of a self-administered test supervisor;"; and

(*d*) by inserting, immediately after paragraph (1), the following paragraph:

> "(1A) A reference in these Regulations to an individual supervising another individual performing a self-administered test is a reference to either —
>
> (*a*) the self-administered test supervisor supervising the supervised subject performing the self-administered test in the presence of the self-administered test supervisor at all times during the self-administered test (called in these Regulations an in-person supervision of a self-administered test); or
>
> (*b*) the self-administered test supervisor supervising the supervised subject performing the self-administered test using remote communication (called in these Regulations a remote supervision of a self-administered test).".

Amendment of regulation 4

3. Regulation 4(2) of the principal Regulations is amended by inserting, immediately after the words "the performing of any regulated activity", the words "not consisting of any remote supervision of a self-administered test".

Amendment of regulation 5

4. Regulation 5 of the principal Regulations is amended by inserting, immediately after paragraph (5), the following paragraph:

"(6) To avoid doubt, no application is required under this regulation for premises to be specified in an approval where the approval relates to regulated activity that consists only of remote supervision of self-administered tests.".

Amendment of regulation 6

5. Regulation 6 of the principal Regulations is amended by inserting, immediately after paragraph (3), the following paragraph:

"(4) To avoid doubt, no premises are approved or treated as approved under this regulation where the approval in question relates to regulated activity that consists only of remote supervision of self-administered tests.".

Amendment of regulation 12

6. Regulation 12 of the principal Regulations is amended —

(*a*) by deleting paragraph (1A) and substituting the following paragraphs:

"(1A) Where an approved test provider provides any service which involves in-person supervision of a self-administered test, the duty of the approved test provider is to take measures to ensure that the self-administered test is performed by the supervised subject only when the supervised subject is in the presence of a self-administered test supervisor who is a qualified self-administered test supervisor mentioned in regulation 10(3).

(2) Where an approved test provider provides any service which involves remote supervision of a self-administered test, it is the duty of the approved test provider to take measures to ensure compliance with all the following:

(*a*) a self-administered test supervisor is, at all times during the self-administered test for a supervised subject, located in a room or an enclosed place which is designed or constructed such that the following information cannot be seen or heard by anyone who is not involved (directly or indirectly) with remote supervision of self-administered tests:

(i) the identity of the supervised subject performing the self-administered test;

(ii) the results of the self-administered test;

(iii) any other medical information pertaining to the supervised subject in connection with the self-administered test;

(*b*) a self-administered test supervisor ascertains and records accurately all of the following in order for the approved test provider to satisfy regulation 14:

(i) the particulars of identity of every supervised subject the self-administered test supervisor has performed a remote supervision of a self-administered test;

(ii) the date and time every such self-administered test started and ended;

(iii) the results of every self-administered test supervised but not if sub-paragraph (*d*) was not or cannot be complied with in respect of any such test;

(*c*) a self-administered test supervisor must, immediately before the start of a self-administered test by a supervised subject —

(i) require the supervised subject to show the self-administered test supervisor that the packaging of the test product to be used by the supervised subject for the self-administered test is undamaged or otherwise satisfy the self-administered test supervisor that the test product is new and has not been earlier opened; and

(ii) be satisfied that the supervised subject will be performing the self-administered test using a stable and flat surface on which the test product and all its components may be placed throughout the test;

(*d*) a self-administered test supervisor has and maintains an unobstructed line of sight of —

(i) the test product used by the supervised subject for the self-administered test and all its components, from the start to the end of a self-administered test by a supervised subject;

(ii) the face of the supervised subject, from the start of the supervised subject undergoing the relevant sampling activity to the end of the relevant testing activity;

(iii) the supervised subject when performing the relevant testing activity; and

(iv) the results of the self-administered test in order to ascertain those results for the relevant assessment activity.

(3) It is the duty of every approved test provider to ensure that any test product that is used in the performance of any regulated activity provided, or caused or allowed to be provided, by the approved test provider in the course of business, is used in a manner that is in conformity with the directions of the manufacturer of the test product.”; and

(*b*) by deleting the words “or (1A)” in paragraph (4) and substituting the words “, (1A), (2) or (3)”.

Amendment of regulation 14

7. Regulation 14(1) of the principal Regulations is amended by inserting, immediately after the words “the approved test” in sub-paragraph (*d*), the words “unless regulation 12(2)(*d*) was not or cannot be complied with in respect of that test”.

Deletion and substitution of Schedule

8. The Schedule to the principal Regulations is deleted and the following Schedule substituted therefor:

"THE SCHEDULE

Regulations 2 and 12(1)

APPROVED TEST PRODUCTS AND METHOD OF SAMPLING

	First column	*Second column*
	Test product	*Method of removing respiratory specimen*
1.	BD Veritor™ System for Rapid Detection of SARS-CoV-2.	Anterior nasal, Nasopharyngeal
2.	Standard Q COVID-19 Ag Test	Anterior nasal, Nasopharyngeal
3.	Roche SARS-CoV-2 Rapid Antigen Test Nasal (previously known as Roche SARS-CoV-2 Rapid Antigen Test)	Anterior nasal, Nasopharyngeal
4.	Panbio™ COVID-19 Ag Rapid Test Device (Nasal) (previously known as Panbio™ COVID-19 Ag Rapid Test Device)	Anterior nasal, Nasopharyngeal
5.	BD Kit for Rapid Detection for SARS-CoV-2	Anterior nasal
6.	Roche SARS-CoV-2 Antigen Self-Test Nasal	Anterior nasal
7.	BD Veritor At-Home COVID-19 Test	Anterior nasal
8.	QuickVue At-Home OTC COVID-19 Test	Anterior nasal
9.	Standard Q COVID-19 Ag Home Test	Anterior nasal
10.	Panbio™ COVID-19 Antigen Self-test	Anterior nasal
11.	Flowflex SARS-CoV-2 Antigen Rapid Test	Anterior nasal
12.	AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	Anterior nasal

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[G.N. Nos. S 397/2021; S 591/2021; S 683/2021; S 767/2021; S 1043/2021]

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