

Infectious Diseases (Antigen Rapid Test Providers) Regulations 2021

Table of Contents

Enacting Formula

Part 1 PRELIMINARY

1 Citation and commencement

2 Definitions

3 Saving for Government, etc.

Part 2 APPROVED TEST PROVIDERS

4 Only approved test providers may provide regulated activity

5 Application to be test provider

6 Applications treated as approved

7 Grounds for refusal

8 Validity period of test provider approval

9 Conditions of approval for premises not subject to HCSA or PHMCA licence

Part 3 OPERATING REQUIREMENTS

10 Only trained personnel may perform regulated activity

11 Qualified person to act as supervisor

12 Requirements for how regulated activity is performed

13 (Deleted)

14 Submission of test results to Director

15 Informing test subject of results

16 Safety systems

17 Use of reagents and other materials

Part 4 REGULATORY ACTION

18 Suspending or revoking approvals

19 Proceedings for regulatory action

THE SCHEDULE Approved test products and method of sampling

No. S 267

**INFECTIOUS DISEASES ACT
(CHAPTER 137)**

**INFECTIOUS DISEASES
(ANTIGEN RAPID TEST PROVIDERS)
REGULATIONS 2021**

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

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Infectious Diseases (Antigen Rapid Test Providers)

Regulations 2021 and come into operation on 24 April 2021.

Definitions

2.—(1) In these Regulations, unless the context otherwise requires —

“approval” means an approval under these Regulations to provide in the course of business at any premises in Singapore a service for hire or reward involving the performing of any regulated activity, but excludes an approval when it is suspended;

[S 591/2021 wef 10/08/2021]

“approved test” means an antigen rapid test performed in Singapore in relation to an individual using any of the test products specified in the Schedule, the purpose of which is to test for the presence of SARS-CoV-2 in that individual;

[S 591/2021 wef 10/08/2021]

“approved test provider” means a person who has an approval;

“Class A test provider” means an approved test provider holding any HCSA licence or PHMCA licence;

[S 1043/2021 wef 03/01/2022]

“HCSA licence” means a licence issued under the Healthcare Services Act 2020 and in force;

[S 1043/2021 wef 03/01/2022]

“PHMCA licence” means a licence which is issued under the Private Hospitals and Medical Clinics Act (Cap. 248) and in force;

“prescribed notice” means the relevant notice set out at <https://go.gov.sg/artmemo>;

“qualified nurse” means a registered nurse or an enrolled nurse within the meaning of the Nurses and Midwives Act (Cap. 209), who holds a valid practising certificate under that Act;

“qualified person” means an individual who —

- (a) is a legally qualified medical practitioner;
- (b) is a qualified nurse;
- (c) has, after obtaining any of the following qualifications, acquired at least 3 continuous years of practical experience in clinical laboratory work in Singapore:
 - (i) a degree in Biomedical Science;
 - (ii) a degree or diploma in Medical Laboratory Science; or

- (d) has undergone training conducted by a specified training provider, in each of the following:
 - (i) to perform every type of regulated activity;
 - (ii) to supervise the performing of every type of regulated activity;

[S 591/2021 wef 10/08/2021]

“qualified self-administered test supervisor” means an individual who —

- (a) is a qualified person; or
- (b) meets —
 - (i) any requirement mentioned in regulation 10(1)(a), (b) or (c); and
 - (ii) any requirement mentioned in regulation 10(2)(a), (b), (c) or (d);

[S 591/2021 wef 10/08/2021]

“regulated activity” means any of the following types of activity performed in Singapore:

- (a) a relevant sampling activity;
- (b) a relevant testing activity;
- (c) a relevant assessment activity;
- (d) supervising the performing by another individual of a self-administered test;

[S 591/2021 wef 10/08/2021]

[S 591/2021 wef 10/08/2021]

“relevant assessment activity” means ascertaining the results of an approved test on a respiratory specimen from an individual and recording the results, even if uncertain or invalid;

“relevant sampling activity” means removing a respiratory specimen from the lining of the oral or nasal passage of an individual for the purpose of a relevant testing activity;

“relevant testing activity” means subjecting the respiratory specimen from an individual to an approved test for the purpose of testing the presence of SARS-CoV-2 in that individual;

“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.

[S 38/2022 wef 21/01/2022]

“respiratory specimen” includes human biological tissue, saliva or mucus;

“responsible executive”, in relation to an applicant for approval, means —

- (a) where the applicant is a body corporate (including a limited liability partnership) —
 - (i) an individual for the time being holding the office of chairperson, director, partner, chief executive officer, manager or company secretary (as the case may be) of the body corporate or any position analogous to any of those offices; or
 - (ii) for a corporation whose affairs are managed by its members, any of those members as if the member were a director of the corporation;
- (b) where the applicant is a partnership (including a limited partnership), a partner of the partnership;
- (c) where the applicant is a sole proprietor, the sole proprietor; or
- (d) where the applicant is an unincorporated association (other than a partnership), an individual for the time being holding the office of president, secretary or member (as the case may be) of the committee of the unincorporated association, or any position analogous to any of those offices,

and includes any person carrying out the duties of any office referred to in paragraph (a), (b), (c) or (d) if the office is vacant;

“self-administered test” means all of the following:

- (a) a relevant sampling activity performed by an individual on himself or herself for the purpose of a relevant testing activity described in