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INFECTIOUS DISEASES ACT (CHAPTER 137)

INFECTIOUS DISEASES (ANTIGEN RAPID TEST PROVIDERS) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

Regulation

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 involving the carrying on of any regulated activity for hire or reward, but excludes an approval when it is suspended;

"approved test" means an antigen rapid test carried out 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;

"approved test provider" means a person who has an approval;

"Class A test provider" means an approved test provider holding any PHMCA licence;

"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 carrying out of every type of regulated activity;

"regulated activity" means any of the following types of activity carried on in Singapore:

(*a*) a relevant sampling activity;

(*b*) a relevant testing activity;

(*c*) a relevant assessment activity;

"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;

"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;

"specified training provider" means the HMI Institute of Health Sciences Pte. Ltd.;

"working day" means any day other than a Saturday, Sunday or public holiday.

(2) Unless expressly provided otherwise in these Regulations, any word or expression in these Regulations that is defined in the COVID-19 (Temporary Measures) (Control Order) Regulations 2020 (G.N. No. S 254/2020) has the meaning given to it by those Regulations.

Saving for Government, etc.

3. These Regulations do not apply to prevent or restrict the Government or any public body doing or omitting to do anything in the performance of any function, the exercise of any power or the discharge of any duty of the Government or public body (as the case may be) under law.

PART 2

APPROVED TEST PROVIDERS

Only approved test providers may provide regulated activity

4.—(1) A person commits an offence if the person —

(*a*) intentionally provides, or intentionally causes or allows to be provided, in the course of business at any premises in Singapore; or

(*b*) intentionally holds out, or intentionally causes or allows to be held out, as providing in the course of business at any premises in Singapore,

a service involving the carrying on of any regulated activity for hire or reward when the person is not approved and not treated as approved under these Regulations by the Director to provide that service and knowing that the person is not so approved or treated as approved.

(2) A person commits an offence if the person —

(*a*) intentionally provides, or intentionally causes or allows to be provided, in the course of business at any premises in Singapore; or

(*b*) intentionally holds out, or intentionally causes or allows to be held out, as providing in the course of business at any premises in Singapore,

a service involving the carrying on of any regulated activity for hire or reward when those premises are not specified and not treated as specified under regulation 6(1) or (3) in that person's approval and knowing that those premises are not so specified or treated as specified.

(3) A person who is guilty of an offence under paragraph (1) or (2) shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Application to be test provider

5.—(1) An application —

(*a*) for approval under these Regulations as a test provider; or

(*b*) for premises to be specified in an approval under these Regulations,

must be made to the Director in accordance with this regulation.

(2) An application under paragraph (1) for approval or for additional premises to be specified in an approval must —

(*a*) be in the form and manner the Director specifies;

(*b*) state each premises at which the applicant intends to provide a service involving the carrying on of the regulated activity to which the application relates;

(*c*) contain a description of the service involving the carrying on of the regulated activity to which the application relates and how the regulated activity will be carried on in each of the premises stated under sub-paragraph (*b*);

(*d*) state each approved test to be used in providing the service and the fees to be charged by the applicant for each test;

(*e*) describe the administrative procedures for maintaining records of the regulated activity in the application to be carried out by the applicant;

(*f*) state whether the applicant is also using those premises as a private hospital, medical clinic or clinical laboratory under the authority and in accordance with the terms and conditions of a PHMCA licence;

(*g*) state whether the applicant is an occupier of the premises stated under sub-paragraph (*b*);

(*h*) in relation to each premises that are stated under sub-paragraph (*b*) and are not the subject of a PHMCA licence —

(i) be accompanied by a risk assessment conducted and endorsed by a qualified person employed or engaged by the applicant, in relation to the safety and health risks posed to any individual who may be affected by the carrying on of the regulated activity in the application, such as but not limited to the crowd management of individuals seeking to undergo or carry out approved tests and the handling of potentially biohazardous material; and

(ii) specify the processes, policies and protocols planned so as to eliminate any foreseeable risk to any such individual;

(*i*) contain an address in Singapore at which notices and other documents under these Regulations for the applicant may be served;

(*j*) be accompanied by any information that the Director requires to decide on the particular application; and

(*k*) be accompanied by a non-refundable fee of $385.

(3) Upon receiving an application under paragraph (1), the Director may carry out, or arrange to be carried out, such investigations and inquiries in relation to the application as the Director considers necessary for a proper consideration of the application, which may include an inspection of either or both the following:

(*a*) the premises stated under paragraph (2)(*b*) as where the applicant intends to provide a service involving the carrying on of any regulated activity to be authorised by the approval;

(*b*) any vehicle, equipment or other thing which the applicant intends to use to provide a service involving the carrying on of the regulated activity to be authorised by the approval.

(4) The Director may refuse an application under paragraph (1) —

(*a*) that is incomplete or not made in accordance with this regulation; or

(*b*) where an inspection mentioned in paragraph (3) in relation to the application is refused.

(5) The Director may, in any particular case, waive in whole or part the payment of the application fee specified in paragraph (2)(*k*).

Applications treated as approved

6.—(1) In the case of a person's application for approval or for additional premises to be specified in an approval, the person is, upon the Director receiving the application, treated as approved under these Regulations to provide in the course of business a service involving the carrying on of the regulated activity at the premises

specified in the application or those additional premises are treated as specified in the person's approval (as the case may be) if —

(*a*) the person holds a PHMCA licence;

(*b*) those premises are the subject of the PHMCA licence; and

(*c*) the person states in the person's application under regulation 5(2)(*b*), those premises as where the person intends to provide a service involving the carrying on of the regulated activity to which the application relates.

(2) An application —

(*a*) for approval, other than an application which may be treated as approved under paragraph (1); or

(*b*) for additional premises to be specified in an approval, being premises not subject to a PHMCA licence,

must be made at least 5 working days before the date the person intends to start providing in the course of business, at the premises stated in the application, a service involving the carrying on of the regulated activity to which the application relates.

(3) In the case of a person's application mentioned in paragraph (2), the person is treated as approved under these Regulations to provide in the course of business a service involving the carrying on of the regulated activity at the premises specified in the application or those additional premises are treated as specified in the person's approval (as the case may be) on the 5th working day after the application is received by the Director unless the Director —

(*a*) earlier approves the application; or

(*b*) earlier refuses the application under regulation 7.

Grounds for refusal

7.—(1) For the purpose of determining whether or not a person should be approved or refused approval, or refused specifying any additional premises in an approval, the Director must have regard, and give such weight as the Director considers appropriate, to all of the following matters:

(*a*) the adequacy of the premises, vehicle, equipment or other thing proposed to be used in providing the service involving the carrying on of the regulated activity in the application;

(*b*) the adequacy of the risk assessment and processes, policies and protocols mentioned in regulation 5(2)(*h*);

(*c*) whether the applicant and, where necessary, whether every responsible executive of the applicant is a suitable person to be involved in providing the service involving the carrying on of the regulated activity in the application;

(*d*) whether the applicant has an approval specifying any other premises not mentioned in the application;

(*e*) the demand for the service in the application;

(*f*) whether the applicant holds a PHMCA licence in respect of any premises;

(*g*) the qualifications and training of the individuals the applicant employs or contracts or intends to employ or contract to carry out the regulated activity involved in the service;

(*h*) the applicant's ability to provide the service in a manner that conforms to the requirements of these Regulations and is clinically and ethically appropriate;

(*i*) whether approving the applicant advances the purpose of preventing, protecting against, delaying or otherwise controlling the incidence or transmission of COVID-19 in Singapore.

(2) For the purpose of determining whether or not a person or a responsible executive of the person is a suitable person to be involved in providing the service involving the carrying on of a regulated activity in the application, the Director must have regard, and give such weight as the Director considers appropriate, to all of the following matters:

(*a*) the person's or individual's relevant knowledge, competency and experience in matters connected with the regulated activity in the application;

(*b*) whether the applicant does or does not have (or is likely or unlikely to have) the financial capacity and ability to provide the service involving the carrying on of the regulated activity in the application according to the provisions of these Regulations.

(3) To avoid doubt, the Director is not confined to consideration of the matters specified in paragraph (1) or (2) and may take into account such other matters and evidence as may be relevant.

Validity period of test provider approval

8.—(1) Every approval is valid for 2 years unless one of the following first occurs:

(*a*) for a Class A test provider only, the test provider ceases to hold any PHMCA licence;

(*b*) the approval is revoked under Part 4;

(*c*) a notice to stop given in accordance with paragraph (2) takes effect.

(2) An approved test provider who intends to wholly stop providing, in the course of business, a service involving the carrying on of any regulated activity for hire or reward, must give a notice to stop containing the date of stoppage to the Director, at least 5 working days before ceasing to provide the service; and that notice to stop takes effect on —

(*a*) the 5th working day after the Director receives that notice; or

(*b*) the date of stoppage stated, if that is later.

Conditions of approval for non-PHMCA licence premises

9. The Director may, when approving an application in regulation 6(2) before the 5th working day after the application is received, impose conditions —

(*a*) fixing the place within those premises that are the subject of the application within which the regulated activity authorised by the approval may be carried out; and

(*b*) relating to measures to be taken by the approved test provider to mitigate or eliminate risks identified in the risk assessment mentioned in regulation 7(1)(*b*).

PART 3

OPERATING REQUIREMENTS

Only trained personnel may carry out regulated activity

10.—(1) An approved test provider must ensure that any individual employed or engaged by the approved test provider to perform any relevant sampling activity or any relevant testing activity for an approved test —

(*a*) is a legally qualified medical practitioner;

(*b*) is a qualified nurse; or

(*c*) has undergone training to perform the relevant sampling activity or relevant testing activity for the approved test, conducted by a specified training provider or any person mentioned in sub-paragraph (*a*) or (*b*).

(2) An approved test provider must ensure that any individual employed or engaged by the approved test provider to perform a relevant assessment activity for an approved test —

(*a*) is a legally qualified medical practitioner;

(*b*) is a qualified nurse;

(*c*) has obtained any of the following qualifications and has, after obtaining his or her 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 to perform the relevant assessment activity for the approved test, conducted by a specified training provider or any person mentioned in sub-paragraph (*a*), (*b*) or (*c*).

Qualified person to act as supervisor

11.—(1) The qualified person who endorses the risk assessment mentioned in regulation 5(2)(*h*)(i) for any premises must supervise the carrying on of the regulated activity at those premises.

(2) Where for any reason the qualified person mentioned in regulation 5(2)(*h*)(i) or a qualified person appointed under this paragraph ceases to be employed or engaged by the approved test provider, the approved test provider must not carry on any regulated activity before the approved test provider appoints another qualified person to replace the firstmentioned qualified person.

Requirements for how regulated activity is carried on

12.—(1) It is the duty of an approved test provider to take such measures to ensure that any individual employed or engaged by the approved test provider to perform any relevant sampling activity removes a respiratory specimen from an individual to be tested using a test product specified in the first column of the Schedule in accordance with the method specified opposite the test product in the second column of that Schedule.

(2) Subject to regulation 13, where the result of an approved test carried out by an approved test provider for an individual is uncertain or invalid (called in this regulation the first result), the approved test provider must —

(*a*) where sufficient respiratory specimen was removed to perform the relevant testing activity again — carry out the relevant testing activity immediately after the first result is ascertained; or

(*b*) in any other case —

(i) without delay and in no case more than 2 hours after the first result is available, request the individual to

undergo another approved test, within 24 hours after the first result is available; and

(ii) where the individual consents to undergoing another approved test, carry out another relevant sampling activity in respect of the individual for the purposes of carrying out another relevant testing activity, within 24 hours after the first result is available.

(3) Where an individual mentioned in paragraph (2) does not consent to undergoing another approved test within 24 hours after the first result is available, the approved test provider must notify the Director immediately upon the expiry of those 24 hours.

(4) An approved test provider commits an offence if the approved test provider intentionally or negligently contravenes any duty imposed on the approved test provider under paragraph (1), and shall be liable on conviction of the offence to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 3 months or to both.

Approved test not allowed in certain circumstances

13.—(1) An approved test provider must not intentionally carry on, or intentionally cause or allow to be carried on, a regulated activity in respect of an individual whom the approved test provider knows or has reason to suspect —

(*a*) has at any time —

(i) undergone an approved test or a polymerase chain reaction test in respect of which the last test result is positive for SARS-CoV-2;

(ii) undergone 2 or more approved tests in respect of which the test result is uncertain or invalid for 2 consecutive tests; or

(iii) undergone an approved test carried out by another approved test provider, in respect of which the test result is uncertain or invalid; and

(*b*) has not, at any time after sub-paragraph (*a*)(i), (ii) or (iii) has occurred —

(i) undergone a polymerase chain reaction test in respect of which the last test result is negative for SARS-CoV-2; or

(ii) recovered from a COVID-19 infection and been certified as having so recovered by a legally qualified medical practitioner in Singapore approved by and in the form specified by the Director.

(2) An approved test provider who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 3 months or to both.

Submission of test results to Director

14.—(1) Where an approved test provider carries on a relevant assessment activity, the approved test provider must, no later than 30 minutes after completing the relevant assessment activity, submit the following information to the Director:

(*a*) the name of the individual, nationality and other identifying particulars required by the Director;

(*b*) the date and time that the relevant sampling activity was carried out;

(*c*) the type of approved test applied to the respiratory specimen;

(*d*) the results of the approved test.

(2) The information specified in paragraph (1) must be submitted to the Director through any of the following websites:

Website name	*URL*
Antigen Rapid Test FormSG	https://form.gov.sg/#!/5f8dbd6f540c7c001193b26c
Patient Risk Profile Portal	https://php.healthhub.sg/gp
Swab Registration System	https://swab.hpb.gov.sg.

(3) An approved test provider who is subject to a requirement under paragraph (1) to submit any information to the Director commits an offence if the approved test provider intentionally or negligently submits the information not within the time delimited under that paragraph, and shall be liable on conviction of the offence to a fine not exceeding $3,000.

(4) An approved test provider who is subject to a requirement under paragraph (1) to submit any information to the Director commits an offence if the approved test provider —

(*a*) intentionally or negligently contravenes the requirement under paragraph (1); or

(*b*) intentionally alters, suppresses or destroys any information which the approved test provider is required under paragraph (1) to give,

and shall be liable on conviction of the offence to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 3 months or to both.

Informing test subject of results

15.—(1) An approved test provider providing a service involving the carrying on of a regulated activity must ensure that the individual from whom a respiratory specimen is taken for an approved test to be applied in the course of that service is given, without delay and in no case more than 2 hours after the approved test result is available, the test result.

(2) Where the test result of an approved test carried out on an individual by an approved test provider shows the presence of SARS-CoV-2 in that individual, the approved test provider must, without delay and in no case more than 24 hours after the approved test result is available, issue the prescribed notice to the individual.

(3) Where the test result of an approved test carried out on an individual by an approved test provider is uncertain or invalid and the approved test provider knows or has reason to suspect that the individual had undergone another approved test earlier in respect of which the test result is also uncertain or invalid, the approved test

provider must, without delay and in no case more than 24 hours after the approved test result is available, issue the prescribed notice to the individual.

(4) Where the approved test provider, for any reason, fails to or is unable to issue the prescribed notice to the individual under paragraph (2) or (3), the approved test provider must notify the Director immediately upon the expiry of 24 hours after the approved test result is available.

(5) In this regulation, a reference to an individual includes a reference to —

(*a*) where the individual is a minor, the individual's parent or guardian; or

(*b*) where the individual is under the care of another person, the person who has such care.

Safety systems

16. An approved test provider must establish and maintain a safety system consisting of the following:

(*a*) safety policy and objectives:

(i) the approved test provider's commitment to safety;

(ii) the responsibilities of trained personnel employed or engaged by the approved test provider, and their safety accountability;

(iii) the documentation of the safety system;

(*b*) safety risk assessment:

(i) the identification of hazards;

(ii) the safety risk assessment and mitigation;

(*c*) safety assurance:

(i) the measuring and monitoring of safety performance;

(ii) the continuous improvement of the safety system;

(*d*) safety promotion:

(i) the training and education regarding safety management;

(ii) the communication on safety.

Use of reagents and other materials

17.—(1) An approved test provider must ensure that reagents (including quality control materials) that are used in the course of providing a service involving approved tests are —

(*a*) registered or provisionally approved by the Health Sciences Authority under the Health Products Act (Cap. 122D);

(*b*) stored and used under the conditions specified by the manufacturer;

(*c*) handled in a manner that minimises deterioration or exposure to the environment;

(*d*) not used beyond the shelf life or expiry date, whichever is earlier; and

(*e*) labelled with the date of opening and shelf life once opened for use.

(2) For each reagent that is used, the approved test provider must ensure that the following information is recorded and retained for a period of 2 years after the date it is first opened for use:

(*a*) the lot number;

(*b*) the expiry date;

(*c*) the personnel who prepared the reagent.

PART 4

REGULATORY ACTION

Suspending or revoking approvals

18. Subject to regulation 19, if the Director is satisfied that —

(*a*) any approved test provider is contravening or not complying with, or has contravened or failed to comply with any of the conditions of approval;

(*b*) an approved test provider is providing the service involving the carrying on of a regulated activity authorised by its approval —

(i) in an unsafe manner;

(ii) in contravention of the requirements in regulation 10, 11, 12(2), 15, 16 or 17; or

(iii) in a way that does not advance or significantly hinders the purpose of preventing, protecting against, delaying or otherwise controlling the incidence or transmission of COVID-19 in Singapore;

(*c*) an approved test provider is convicted of any offence under these Regulations or the Act committed during the term of the approval as an approved test provider;

(*d*) an approval had been obtained by fraud or misrepresentation; or

(*e*) the public interest of Singapore requires,

the Director may (without any compensation) suspend, for a period not exceeding 2 months, or revoke the approval as an approved test provider.

Proceedings for regulatory action

19.—(1) Before exercising any powers under regulation 18, the Director must give written notice to the approved test provider concerned —

(*a*) stating that the Director intends to take regulatory action against the approved test provider;

(*b*) specifying the type of action in regulation 18 that the Director proposes to take, and each instance of contravention or non-compliance that is the subject of the action; and

(*c*) specifying the time (being not less than 5 working days after the date of service of notice on the approved test provider) within which written representations may be made to the Director with respect to the proposed action.

(2) The Director may, after considering any written representation under paragraph (1)(*c*), decide to take such regulatory action mentioned in regulation 18 as the Director considers appropriate.

(3) Where the Director has made any decision under paragraph (2) against any approved test provider, the Director must serve on the approved test provider concerned a notice of the Director's decision.

(4) A decision to revoke any approval of an approved test provider which is specified in the notice given under paragraph (3) takes effect from the date on which that notice is given, or on such other date as may be specified in the notice.

THE SCHEDULE

Regulations 2(1) 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	Anterior nasal, Nasopharyngeal
4.	Panbio™ COVID-19 Ag Rapid Test Device	Anterior nasal, Nasopharyngeal

THE SCHEDULE — *continued*

First column	*Second column*
Test product	*Method of removing respiratory specimen*
5. Quidel Sofia SARS Antigen FIA Kit	Anterior nasal

[S 397/2021 wef 24/06/2021]

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