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No. S 267

INFECTIOUS DISEASES ACT (CHAPTER 137)

INFECTIOUS DISEASES (ANTIGEN RAPID TEST PROVIDERS) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

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 paragraph (*b*);

(*b*) a relevant testing activity performed by an individual on the respiratory specimen removed from himself or herself under paragraph (*a*);

(*c*) a relevant assessment activity performed by an individual involving a respiratory specimen removed from himself or herself under paragraph (*a*) following a relevant testing activity performed by that same individual as described in paragraph (*b*);

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

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

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

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

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

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

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

(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).

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

(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 for hire or reward involving the performing of any regulated activity 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.

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

(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 for hire or reward involving the performing of any regulated activity not consisting of any remote supervision of a self-administered test 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.

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

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

(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 performing of the regulated activity to which the application relates;

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

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

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

(*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 performed by the applicant;

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

(*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 an HCSA licence or a PHMCA licence, as the case may be;

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

(*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 an HCSA licence or 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 performing of the regulated activity in the application, such as but not limited to the crowd management of individuals seeking to undergo or perform approved tests and the handling of potentially biohazardous material; and

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

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

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

(*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 perform, or arrange to be performed, 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 performing of any regulated activity to be authorised by the approval;

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

(*b*) any vehicle, equipment or other thing which the applicant intends to use to provide a service involving the

performing of the regulated activity to be authorised by the approval.

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

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

(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*).

(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.

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

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 performing 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 an HCSA licence or a PHMCA licence;

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

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

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

(*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 performing of the regulated activity to which the application relates.

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

(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 an HCSA licence or a PHMCA licence,

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

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 performing of the regulated activity to which the application relates.

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

(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 performing 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.

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

(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.

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

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 performing of the regulated activity in the application;

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

(*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 performing of the regulated activity in the application;

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

(*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 an HCSA licence or a PHMCA licence in respect of any premises;

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

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

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

(*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 performing 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 performing of the regulated activity in the application according to the provisions of these Regulations.

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

(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 HCSA licence or PHMCA licence;

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

(*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 performing 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.

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

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

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 performed; and

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

(*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*).

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

PART 3

OPERATING REQUIREMENTS

Only trained personnel may perform 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*).

(3) An approved test provider must ensure that any individual employed or engaged by the approved test provider to supervise another individual performing any self-administered test is a qualified self-administered test supervisor.

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

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

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 performing of the regulated activity at those premises.

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

(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 perform, or cause or allow to be performed, any regulated activity before the approved test provider appoints another qualified person to replace the firstmentioned qualified person.

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

Requirements for how regulated activity is performed

12.—(1) An approved test provider must take such measures to ensure that —

(*a*) any relevant sampling activity removing a respiratory specimen for testing using a test product specified in the first column of the Schedule; or

(*b*) any relevant sampling activity performed by an individual on himself or herself for the purpose of removing a respiratory specimen for testing using a test product specified in the first column of the Schedule,

is performed in accordance with the method specified opposite the test product in the second column of that Schedule.

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

(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).

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

(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.

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

(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.

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

(2) [*Deleted by S 767/2021 wef 11/10/2021*]

(3) [*Deleted by S 767/2021 wef 11/10/2021*]

(3A) [*Deleted by S 767/2021 wef 11/10/2021*]

(3B) [*Deleted by S 767/2021 wef 11/10/2021*]

(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), (1A), (2) or (3), 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.

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

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

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

13. [*Deleted by S 767/2021 wef 11/10/2021*]

Submission of test results to Director

14.—(1) Where an approved test provider performs a relevant assessment activity, the approved test provider must, no later than 30 minutes after completing the relevant assessment activity and in the manner the Director specifies in accordance with paragraph (2), 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 performed;

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

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

(*d*) the results of the approved test unless regulation 12(2)(*d*) was not or cannot be complied with in respect of that test.

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

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

(2) The Director must specify the manner of submitting the information for the purposes of paragraph (1) in a notice to approved test providers and publish (or cause to be published) the notice in such a way the Director considers will bring the notice to the attention of every approved test provider.

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

(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 performing of a regulated activity must ensure that the individual from whom a respiratory specimen is removed 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.

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

(2) Where the test result of an approved test performed 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.

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

(3) [*Deleted by S 767/2021 wef 11/10/2021*]

(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), the approved test provider must notify the Director immediately upon the expiry of 24 hours after the approved test result is available.

[S 767/2021 wef 11/10/2021]

(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 performing of a regulated activity authorised by its approval —

(i) in an unsafe manner;

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

[S 767/2021 wef 11/10/2021]

(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;

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

(*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 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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Ministry of Health,
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