NOTIFICATION OF THE FOOD AND DRUG ADMINISTRATION RE: SPECIFICATION OF STANDARDS AND EVALUATION OF TEST KITS AND REAGENTS RELATED TO DIAGNOSIS OF SARS-CoV-2 (VIRUS CAUSING COVID-19) INFECTION, B.E. 2564 (2021)*

Whereas it is expedient to revise the Notification of the Food and Drug Administration Re: Specification of Standards and Evaluation of Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection, B.E. 2563 (2020) dated the 20th day of April B.E. 2563 (2020);

By virtue of the provisions in Number 19 and Number 20 of the Schedule on Medical Device Standards with Which Manufacturers and Importers Must Comply annexed to the Notification of the Ministry of Public Health Re: Medical Device Standards with Which Manufacturers and Importers Must Comply, B.E. 2563 (2020) dated the 27th day of April B.E. 2563 (2020) and the provision in Number 1 of the Lists of Medical Devices annexed to the Notification of the Ministry of Public Health Re: Medical Devices Which Require Technological Assessments, B.E. 2563 (2020) dated the 27th day of April B.E. 2563 (2020), the Secretary-General of the Food and Drug Administration hereby issues the Notification as follows.

Clause 1. The Notification of the Food and Drug Administration Re: Specification of Standards and Evaluation of Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection, B.E. 2563 (2020) dated the 20th day of April B.E. 2563 (2020) shall be repealed.

Clause 2. Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection must conform to the following standards:

(1) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through the real time RT-PCR method must have the sensitivity, specificity and other characteristics that conform to the MED 1 - 2564 annexed to this Notification.

(2) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time

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RT-PCR method, such as RT-LAMP or CRISPR, must have the sensitivity, specificity and other characteristics that conform to the MED 2 - 2564 annexed to this Notification.

(3) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by a method other than (1) and (2) must have the sensitivity, specificity and other characteristics that conform to the MED 3 - 2564 annexed to this Notification.

Clause 3. Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection shall be evaluated as follows.

(1) The sensitivity, specificity and other characteristics of the test kits and reagents that test for genetic materials through real time RT-PCR method shall be evaluated in accordance with the criteria specified in clause 2 (1).

(2) The sensitivity, specificity and other characteristics of the test kits and reagents that test for genetic materials through a method other than the real time RT-PCR method, such as RT-LAMP or CRISPR, shall be evaluated in accordance with the criteria specified in clause 2 (2).

(3) The sensitivity, specificity and other characteristics of the test kits and reagents that test for antibodies or antigens shall be evaluated in accordance with the criteria specified in clause 2 (3).

This Notification shall come into force immediately.

Announced on the 11th day of January B.E. 2564 (2021)
Paisarn Dunkum
Secretary-General of the Food and Drug Administration

Standards and Evaluation of Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Genetic Materials Through the Real Time RT-PCR Method

1. Scope

This prescription applies to test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through the real time RT-PCR method.

2. Definitions

(1) "Analytical sensitivity" means the limit of detection in accurately detecting the lowest amount of the analyte.

(2) "Specificity" means the ability of a test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection to show a negative result when tested on a specimen which does not contain the analyte.

(3) "Real time RT-PCR" means a reverse transcription polymerase chain reaction to create a copy of a chain of DNA by using an RNA genetic material as a reactant.

3. Characteristics: A test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection submitted for evaluation must—

(1) contain all components as specified by the manufacturer or product owner;

(2) be in a proper condition.

4. Standard Quality

(1) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through the real time RT-PCR method must have standard qualities which conform to the testing or analysis criteria specified in the Schedule 1.

(2) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through the real time RT-PCR method, which are specified as capable of testing for specific analytes, must meet the testing or analysis criteria for all such specified analytes.

Schedule 1 Testing or Analysis Criteria for Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Genetic Materials Through the Real Time RT-PCR Method

No.	Prescription	Evaluation Criteria
1	Analytical sensitivity	Not more than 1,000 copies/ml
2	Method specificity: primers/probes specific to SARS-CoV-2 (virus causing COVID-19)	Upon testing, there must be no cross-reactivity rate with SARS-CoV, MERS-CoV and other strains of human corona viruses, e.g., NL-63, OC-43, 229-E and HKU-1.

Standards and Evaluation of Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Genetic Materials Through a Method Other than the Real Time RT-PCR Method, Such as RT-LAMP or CRISPR

1. Scope

This prescription applies to test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time RT-PCR method, such as RT-LAMP or CRISPR.

2. Definitions

(1) "Analytical sensitivity" means the limit of detection in accurately detecting the lowest amount of the analyte.

(2) "Specificity" means the ability of a test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time RT-PCR method, such as RT-LAMP or CRISPR, to show a negative result when tested on a specimen which does not contain the analyte.

(3) "Real time RT-PCR" means a reverse transcription polymerase chain reaction to create a copy of a chain of DNA by using an RNA genetic material as a reactant.

(4) "RT-LAMP" means a reverse transcription chain reaction in combination with an isothermal amplification of genetic materials from a stem-loop.

(5) "CRISPR" means the combination of the amplification of genetic materials with recombinase polymerase enzyme and the application of CRISPR-Cas (Clustered Regularly Interspaced Short Palindromic Repeats-Cas) to detect an infection of a virus.

3. Characteristics: A test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time RT-PCR method, such as RT-LAMP or CRISPR, which are submitted for evaluation must—

(1) contain all components as specified by the manufacturer or product owner;

(2) be in a proper condition.

4. Standard Quality

(1) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time RT-PCR method, such as RT-LAMP or CRISPR, must have standard qualities which conform to the testing or analysis criteria specified in the Schedule 2.

(2) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for genetic materials through a method other than the real time

RT-PCR method, such as RT-LAMP or CRISPR, which are specified as capable of testing for specific analytes, must meet the testing or analysis criteria for all such specified analytes.

Schedule 2 Testing or Analysis Criteria for Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Genetic Materials Through a Method Other than the Real Time RT-PCR Method, Such as RT-LAMP or CRISPR

No.	Prescription	Evaluation Criteria
1	Analytical sensitivity	Not more than 4,000 copies/ml
2	Method specificity: primers/probes specific to SARS-CoV-2 (virus causing COVID-19)	Upon testing, there must be no cross-reactivity rate with SARS-CoV, MERS-CoV and other strains of human corona viruses, e.g., NL-63, OC-43, 229-E and HKU-1.

Standards and Evaluation of Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Antibodies or Antigens

1. Scope

This prescription applies to test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens.

2. Definitions

(1) "Diagnostic sensitivity" means the ability of a test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens to show a positive result when a specimen to which such test kit and reagent refer gives a positive result.

(2) "Diagnostic specificity" means the ability of a test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens to show a negative result when a specimen to which such test kit and reagent refer gives a negative result.

(3) "Non-specificity" means the possibility that a test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens will give a positive result on a specimen that has a possibility of giving a false positive result.

3. Characteristics: A test kit and a reagent related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens, which are submitted for evaluation must—

(1) contain all components as specified by the manufacturer or product owner;

(2) be in a proper condition.

4. Standard Quality

(1) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens must have standard qualities which conform to the testing or analysis criteria specified in the Schedule 3 or Schedule 4, as the case may be.

(2) Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection by testing for antibodies or antigens, which are specified as capable of testing for specific analytes, must meet the testing or analysis criteria for all such specified analytes.

Schedule 3 Testing or Analysis Criteria for Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Antibodies

No.	Prescription	Evaluation Criteria
1	Diagnostic sensitivity	≥ 85 %, n ≥ 50
2	Diagnostic specificity	≥ 98 %, n ≥ 100
3	Non-specificity	≤ 10 %, n ≥ 20

Schedule 4 Testing or Analysis Criteria for Test Kits and Reagents Related to Diagnosis of SARS-CoV-2 (Virus Causing COVID-19) Infection by Testing for Antigens

No.	Prescription	Evaluation Criteria
1	Diagnostic sensitivity	≥ 90 %, n ≥ 50
2	Diagnostic specificity	≥ 98 %, n ≥ 100
3	Non-specificity	≤ 10 %, n ≥ 20
4	Limit of Detection (LoD) (if any)	

*Remark n means number of specimens