



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



123 MAR 2021

FDA MEMORANDUM
No. 2021-009

TO: ALL CONCERNED STAKEHOLDERS AND PARTIES

SUBJECT: Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection

I. RATIONALE

On 12 March 2020, Food and Drug Administration (FDA) Memorandum No. 2020-006 was approved allowing for the issuance of Special Certification for imported in-vitro diagnostic (IVD) kits used for diagnosis and screening of Coronavirus Disease 2019 (COVID-19).

Consequently, FDA Memorandum No. 2020-011 and FDA Memorandum No. 2020-022 were issued requiring mandatory performance testing of COVID-19 antibody and antigen test kits with FDA issued Special Certification by the Research Institute for Tropical Medicine (RITM), respectively, as part of the post-marketing surveillance of COVID-19 In Vitro Diagnostics (IVDs). Relative to this, RITM issued Guidelines on the Evaluation of In Vitro Diagnostic Medical Devices and Other Related Laboratory Diagnostic Supplies for COVID-19 which took effect on 13 July 2020 guiding the manufacturers, importers and distributors on the requirements for the performance evaluation of their COVID-19 test kits.

To ensure the safety, quality and performance of all COVID-19 test kits available in the market, it is imperative to set standard parameters for these IVD products.

The World Health Organization (WHO) Interim Guidance entitled “Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays” has set the $\geq 80\%$ sensitivity and $\geq 97\%$ specificity for SARS-CoV-2 antigen-detecting rapid diagnostic tests (Ag-RDTs). Subsequently, Department of Health (DOH) Department Memorandum No. 2020-0439 entitled “Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, Reintegration Strategies for COVID-19” states the acceptable performance of $>90\%$ sensitivity and $>95\%$ specificity for antibody test kits may be used.



Review conducted by the Center for Device Regulation Radiation Health and Research (CDRRHR) from the different National Regulatory Agencies yields an average of $\geq 95\%$ sensitivity and $\geq 99\%$ specificity of RT-PCR based test kits

II. OBJECTIVE

This Memorandum aims to set the minimum performance requirement for COVID-19 test kits. In addition, it aims to provide specific guidelines on the re-evaluation of product performance of COVID-19 test kits issued with Special Certification by FDA.

III. GUIDELINES

A. Minimum Performance Requirements

In the absence of other available standard performance requirements set for other types of COVID-19 test kits for screening of SARS-CoV-2 infection and for the purpose of ensuring the quality of test kits available in the country, the following minimum performance requirements shall be implemented:

Type of COVID-19 Test Kits for Screening of SARS-CoV-2 Infection	Minimum Performance Requirements	Reference
a. RT-PCR test kits	$\geq 95\%$ sensitivity and $\geq 99\%$ specificity	Existing document used by National Regulatory Agencies which prescribe value for used sensitivity and specificity.
b. COVID-19 antibody test kits	$> 90\%$ sensitivity and $> 95\%$ specificity	Department Memorandum No. 2020-0439 entitled "Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, Reintegration Strategies for COVID-19"
c. COVID-19 antigen test kits	$\geq 80\%$ sensitivity and $\geq 97\%$ specificity	WHO Interim Guidance entitled "Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays"

The minimum performance requirements shall be revised accordingly when an internationally acceptable reference standard for each type of COVID-19 test kits has been established.

B. Performance Validation as a Requirement for Market Approval

The product profile indicating the specificity and sensitivity of the COVID-19 test kit shall be an additional requirement prior to the issuance of a Special Certification under FDA Memorandum 2020-006.

Compliance to the above-specified minimum performance requirements based on the performance validation by RITM shall be required prior to the issuance of

Special Certification for all COVID-19 test kits. Failure of the product to comply shall be ground for disapproval of the application for Special Certification for the product.

C. Validity

All issued Special Certification under FDA Memorandum No. 2020-006 shall be valid for a period of six (6) months from date of this guideline unless otherwise revoked earlier. Thereafter, affected Market Authorization Holders (MAH) may apply for re-issuance of the Special Certification following the requirements of this Memorandum.

All special certificates issued upon compliance of the requirements of this Memorandum shall be granted one (1) year validity and may be renewed accordingly until such time that the regulatory guidance for in-vitro diagnostic devices shall be in effect.

D. Re-evaluation of Product Performance

All COVID-19 test kits that are already certified and with pending application for Special Certification with FDA prior to the effectivity of this Memorandum shall comply with the above-specified minimum performance requirements based on the performance validation by RITM.

Upon receipt of the Notice from the FDA regarding the failed performance of the COVID-19 test kits and to stop the distribution or sale of the said products, the MAH may seek re-evaluation with RITM within twenty (20) working days from receipt of said Notice. FDA shall be notified of the re-evaluation within said period.

The result of the re-evaluation of the product performance by RITM shall be final and shall be basis of the Notice to allow distribution or sale, product recall or revocation of the Special Certification as may be applicable.

E. Revocation of Certification and Product Recall

All IVDs which failed the performance validation shall be subjected to sanctions and penalties such as but not limited to revocation of certification as prescribed under Republic Act 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations.

Furthermore, all existing COVID-19 test kits which failed to meet the minimum quality and performance requirement shall be subjected to immediate recall in accordance with FDA Circular No. 2016-012 entitled "Guidelines on Product Recall". The concerned MAH shall ensure that the delisted COVID-19 test kit is no longer available in the market seven (7) days after the issuance of an FDA Advisory.

IV. EFFECTIVITY

This Memorandum shall take effect immediately and shall remain valid unless otherwise revoked, repealed, or rescinded.


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