

Republic of the Philippines Department of Health

OFFICE OF THE SECRETARY

January 28, 2022

DEPARTMENT CIRCULARNo. 2022 1 2021 - 0323 - 8

TO:

ALL UNDERSECRETARIES; ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, CENTERS FOR HEALTH DEVELOPMENT AND **SERVICES**; **EXECUTIVE** DIRECTORS OF SPECIALTY HOSPITALS, AND NATIONAL NUTRITION COUNCIL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA, AND INSTITUTES; PRESIDENT THE **PHILIPPINE** HEALTH INSURANCE CORPORATION: DIRECTORS OF PHILIPPINE NATIONAL AIDS COUNCIL AND TREATMENT REHABILITATION CENTERS; AND OTHERS CONCERNED

SUBJECT: Further Amendment to Department Circular No. 2021-0323 entitled "Price Cap for COVID-19 Rapid Antigen Testing"

The Department Circular No. 2021-0323 entitled "Price Cap for COVID-19 Rapid Antigen Testing" and Department Circular No. 2021-0323-A, also known as "Amendment to Department Circular No. 2021-0323 entitled "Price Cap for COVID-19 Rapid Antigen Testing" are hereby amended to reflect the following changes:

I. Price Cap for SARS-CoV-2 Antigen Rapid Diagnostic Test Kit

Cost Component	Price (in Philippine Peso)
SARS-CoV-2 Antigen Rapid Diagnostic Test Kit equivalent to one (1) test, which is inclusive of the materials and accessories necessary for the procedure (appropriate swab, test kit cartridge, buffer or equivalent, tube or equivalent for mixing of buffer with sample, dropper, or equivalent sample delivery instrument)	350.00

The price cap shall apply to the retail of SARS-CoV-2 Antigen Rapid Diagnostic Test (RDT) Kit (also known as "COVID-19 antigen RDT kits"). This **does not include** COVID-19 Antigen RDTs marketed or labeled as self-administered test kits which can be bought over-the-counter (i.e., without the need for a doctor's prescription) and can be performed by non-healthcare professionals or lay users in homes, non-hospital, or non-laboratory settings.

Based on Administrative Order No. 2021-0043, the antigen rapid diagnostic test kits shall meet the following requirements:

- 1. FDA special certification or FDA registered with a minimum sensitivity of 80% and specificity of 97%, in conformity with HTAC specifications
- 2. To ensure accuracy and reliability of antigen RDT results, the sensitivity and specificity of antigen RDT shall be validated by any of the following institutions:
 - A. RITM the list of RITM evaluated antigen RDT kits can be accessed in this link https://bit.ly/ritmkitevalulation
 - B. WHO Emergency Use Listing (EUL) for In Vitro Diagnostic (IVDs) Detecting SARS-COV-2- the list of IVDs with WHO EUL can be accessed through this link https://bitly/WHOEULIVDs
 - C. WHO FIND- the list of WHO FIND evaluated antigen RDT kits can be accessed through this link https://www.finddx.org/sarscov2-eval-antigen
 - D. Other reputable international laboratories; and local laboratories authorized by RITM
- 3. Therefore, antigen rapid diagnostic test kits that do not meet the above mentioned qualifications are not recommended for public use.

II. Price Cap for COVID-19 Antigen Testing Service

Applying the mandated price cap for antigen rapid diagnostic test kits and the updated operational cost for conducting the above mentioned service, the new price cap for Antigen Rapid Diagnostic Testing Service shall be:

Cost Components	Price (in Philippine Peso)
SARS-CoV-2 Antigen Rapid Diagnostic Test Kit	350.00
Operational Cost (Other Related Laboratory Supplies and Overheads)	250.00
10% Allowable Mark-up	60.00
FINAL COST (PRICE CAP)	660.00

Antigen rapid diagnostic test kits subsidized or donated by the DOH and other government agencies to DOH licensed public and private health facilities and clinical laboratories shall be provided at zero cost to individuals. Only items directly procured by DOH-licensed health facilities and clinical laboratories and not provided by DOH can be charged (i.e., Personal Protective Equipment (PPEs), gloves, disinfectants, etc.). Moreover, DOH licensed health facilities and clinical laboratories may have prices lower than the prescribed price cap for antigen rapid diagnostic testing, provided that quality of services is maintained.

II. W. Price Cap for Self-Administered SARS-CoV-2 Antigen Rapid Diagnostic Test Kit

In anticipation of the use of self-administered test kits, a price cap shall be set for self-administered antigen rapid diagnostic test kits, subject to regular review by the Technical Working Group.

Cost Component	Price (in Philippine Peso)
SARS-CoV-2 Antigen Rapid Diagnostic Test Kit equivalent to one (1) test, which is inclusive of the materials and accessories necessary for the procedure (appropriate swab, test kit cartridge, buffer or equivalent, tube or equivalent for mixing of buffer with sample, dropper, or equivalent sample delivery instrument, manual or leaflet containing instructions on the use of the self-administered test kit)	350.00

IV. Date of Effectivity

The updated price caps for antigen rapid diagnostic test kits and testing services are effective starting February 20, 2022.

V. Reporting of Laboratory Complaints

All DOH-licensed health facilities and clinical laboratories providing antigen RDT service, manufacturers, suppliers, distributors, and retailers selling antigen rapid diagnostic test kits shall **strictly comply** with the mandated price cap. Complaints on laboratories, hospitals, and other facilities that charge prices exceeding the price cap shall be reported and submitted to the Health Facilities and Services Regulatory Bureau (HFSRB). To file a report, concerned persons may contact the HFSRB at hfsrb@doh.gov.ph.

VI. Posting and Dissemination of Price Cap

The price caps shall be published on the DOH website and social media platforms and disseminated widely for the information of the public.

All other provisions of DC No. 2021-0323 and DC No. 2021-0323-A not affected by this Order shall be retained and remain in effect.

This Order shall take effect immediately and shall remain in effect until lifted.

FRANCISCO T. DUQUE III, MD, MSc Secretary of Health