



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

January 26, 2022

**DEPARTMENT MEMORANDUM**

No. 2022- 0033

**FOR :** ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS AND CENTERS FOR HEALTH DEVELOPMENT (CHD); MINISTER OF HEALTH- BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (MOH- BARMM); CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; DOH ATTACHED AGENCIES AND INSTITUTIONS AND ALL OTHERS CONCERNED

**SUBJECT :** Guidelines on the Use of Self-Administered Antigen Testing for COVID-19

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**I. INTRODUCTION**

Department of Health (DOH) - Administrative Order (AO) No. 2021-0043 or "*Omnibus Guidelines on the Minimum Public Health Standards for the Safe Reopening of Institutions*", DM 2020-0468 "*Supplemental Guidelines on the Use of Rapid Antigen Test Kits*", DM 2021-0496 "*Authority for Centers for Health Development (CHDs) and the BARMM-Ministry of Health to procure SARS-COV-2 Antigen Rapid Diagnostic Test Kits (Ag-RDTs)*", Department Circular (DC) No. 2022-0002 "*Advisory on COVID-19 Protocols for Quarantine and Isolation*", DM 2022-0013 "*Updated Guidelines on Quarantine, Isolation, Testing for COVID-19 Response and Case Management for the Omicron Variant*", and their corresponding amendments have laid down the policy directions for the appropriate use of rapid antigen test kits for the diagnosis of COVID-19.

The presence of a highly transmissible COVID-19 variant, Omicron, highlights the need for adaptive changes to ensure continued availability of health and essential services. Because mass vaccination has significantly reduced the individual's chances of getting severe disease and dying, our policies and guidelines on testing, quarantine and isolation are being updated to reflect the current state of information and achieve a favorable risk-benefit ratio. The DOH recognizes the urgency to augment COVID-19 testing by authorizing the use of self-administered antigen test kits to facilitate early case detection, clinical management, and outbreak response activities within local communities.

Hence, guidelines on the appropriate procurement, distribution, use of self-administered antigen test kit and reporting of results shall be issued to reduce the testing gap given the recent increase in cases.

## II. IMPLEMENTING GUIDELINES

- A. Implementation of the Prevention, Detection, Isolation, Treatment Reintegration and Vaccination (PDITR+) strategies shall remain to be the cornerstone of response to prevent further transmission and shall be a shared responsibility of the National Government Agencies (NGAs), Local Government Units (LGUs), private sector, and the general public.
- B. All symptomatic individuals, suspect, probable, or confirmed cases (as defined in AO 2021-0043) detected through DOH-recognized testing modalities shall immediately isolate and instruct their respective close contacts to quarantine, consistent with the amended quarantine and isolation period requirements. DM 2022-0013 highlights the “quarantine or isolation first” approach as the appropriate action after establishing exposure and identification of symptoms.
- C. All public and private DOH-licensed health facilities, CHDs, BARMM - Ministry of Health, NGAs, LGUs, and other private entities may procure, distribute, or dispense self-administered antigen test kits without need for a valid prescription to any individual for the diagnosis of COVID-19, in accordance with the requirements set forth in this issuance.

### 1. Selection and Procurement

- a. In any setting, only self-administered antigen test kits approved by the Philippine Food and Drug Administration (FDA) and validated by the Research Institute for Tropical Medicine (RITM) may be used. The list of FDA-approved test kits shall be made available to the public through this site: [bit.ly/ListofFDAApprovedTestKits](https://bit.ly/ListofFDAApprovedTestKits).
- b. In the event that self-administered antigen test kits are to be procured using DOH funds or to be covered by the Philippine Health Insurance Corporation (PHIC) in their benefit packages, these shall be within the bounds of HTAC recommendations.

### 2. Guidelines For Suppliers, Manufacturers, and Healthcare Providers

- a. Manufacturers, suppliers, and distributors shall develop references for appropriate use for the general public that shall include:
  - i. Instructions for Use that are readable, user-friendly, and simplified to provide adequate guidance to the lay public on the test kit’s proper administration, interpretation of results, and disposal
  - ii. A step-by-step video guide specific to the antigen kit for easy reference of the public, and references and links submitted to the DOH for public posting.
  - iii. Filipino-language translation of the reference materials in plain language format, and preferably with other additional regional dialect translations if available

- b. Concerned NGAs, LGUs, Health Care Provider Network (HCPNs), and health facilities providing the self-administered antigen test kits shall offer facility- or online-based orientation and references which may be in the form of demonstration, instructional videos, leaflets, and other formats which shall highlight:
  - i. The difference of the self-administered and healthcare worker-administered test kits
  - ii. Instructions for use, interpretation and reporting of results
  - iii. Disposal of the used kits to individuals availing the product
  - iv. Contact list or hotlines for those that will require further assistance in conducting the test, or linkage with a laboratory for confirmatory testing, and in reporting their test results.

#### **D. Appropriate Use and Interpretation of Results**

1. All users of self-administered antigen kits shall strictly follow the test kit manufacturer's Instructions for Use to optimize diagnostic yield and accuracy of results.
2. The appropriate use of self-administered antigen test kits and recommended time of testing shall be based on the COVID-19 exposure and symptoms of the individual. Further guidance on antigen testing is provided in DM 2020-0468, DM 2022-0013, and other relevant supplemental policies.
3. RT-PCR is still the preferred diagnostic method for COVID-19, consistent with previously issued guidelines. Self-administered antigen testing shall be recommended **only for symptomatic individuals within 7 days from onset of symptoms**, especially if capacity for timely RT-PCR results is limited or not available.
4. Self-administered antigen test kits shall **NOT** be recommended for (1) asymptomatic close contacts and (2) screening of asymptomatic individuals. For other cases not stated above, self-administered antigen testing shall be optional, including for community level actions wherein case management of probable and confirmed cases remain the same.
5. A positive antigen test among symptomatic individuals, and suspect or probable COVID-19 cases and their close contacts (as defined in Administrative Order No. 2021-0043 "*Omnibus Guidelines on the Minimum Public Health Standards for the Safe Reopening of Institutions*") shall be interpreted and managed as a confirmed COVID-19 case. The provision is clarified to include cases detected using FDA-registered self-administered antigen test kits.
  - a. All symptomatic individuals, suspect, probable, or confirmed cases detected through DOH-recognized testing modalities shall immediately isolate and instruct their respective close contacts to quarantine, consistent with the amended quarantine and isolation period requirements.

- b. Asymptomatic close contacts or individuals with a high index of suspicion for COVID-19 who test negative with self-administered antigen test are recommended to immediately quarantine, conduct symptom monitoring, and consult with a healthcare provider.

#### **E. Reporting of Results**

1. All individuals with a positive self-antigen test shall report to their Barangay Health Emergency Response Team (BHERT) or healthcare provider. Healthcare providers shall report cases by filling out a COVID-19 Case Investigation Form (CIF) within 24 hours of detection. Healthcare providers shall submit the accomplished CIF to their Local Epidemiology and Surveillance Unit, who shall submit it to the appropriate reporting platform. The COVID-19 CIF and guidelines in filling out the form are provided in [tinyurl.com/CIF-FORM-VER9](https://tinyurl.com/CIF-FORM-VER9) and DM 2020-0436, respectively.
2. LGUs and telemedicine providers accredited by the DOH shall put in place their own reporting system to facilitate the necessary local COVID-19 response upon detection of a positive case through self-testing.
3. Reporting of results of self-administered antigen test is mandatory, consistent with the relevant provisions of Republic Act (RA) No. 11332 or the Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act, RA 10173 or the Data Privacy Act of 2012, and Section V.H. of AO 2021-0043.

#### **F. Monitoring and Community Surveillance**

1. LGUs shall monitor the use of self-administered antigen test kits and immediately report to the DOH, through the CHDs, all circumstances of indiscriminate use of antigen tests.
2. All stakeholders are highly enjoined to be vigilant of unauthorized, counterfeit, and substandard test kits in the market. To report any sale, distribution, advertisement, and use of uncertified test kit, the online reporting platform eReport can be accessed at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport).

### **III. ROLES AND RESPONSIBILITIES**

#### **A. The DOH - Public Health Services Team (PHST) shall:**

1. Oversee, monitor, and evaluate the implementation of the provisions on the use of self-administered antigen test kits.
2. Formulate, update, and provide policy direction on the use of self-administered antigen test kits., and evaluate the implementation on the use of self-administered antigen test kits.
3. Develop and maintain an online self-reporting system for individuals to report their respective test results.
4. Supervise the Regional Epidemiology and Surveillance Units in their monitoring of compliance of Disease Reporting Units (DRUs) to data

submission and quality requirements in relation to reporting of rapid antigen testing.

5. Provide feedback to the Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF-EID), National Task Force (NTF) Against COVID-19, and other relevant bodies and agencies regarding self-administered antigen test statistics, as necessary.
6. Develop the appropriate information and education campaign for the proper use and disposal of self-administered antigen test kits.

**B. DOH- Centers for Health Development (CHDs) shall:**

- a. Provide technical assistance, guidance, and capacity-building of LGUs relative to updating of localized guidelines and submission of data on self-administered antigen testing.
- b. Monitor compliance of DRUs to data submission and quality requirements in relation to reporting of self-administered antigen testing.

**C. Food and Drug Administration (FDA) shall:**

- a. Ensure the quality of self-administered antigen test kits in the market.
- b. Monitor compliance of manufacturers, importers, distributors, and retailers.
- c. Continuously update the DOH, and the general public, of the FDA-approved self-administered antigen test kits.

**D. Research Institute for Tropical Medicine (RITM) shall:**

- a. Validate the performance of self-administered antigen test kits prior to issuance of Special Certification by the FDA.
- b. Continuously update the FDA, DOH, and other concerned stakeholders of the RITM-validated self-administered antigen test kits.

**E. Manufacturers, Distributors, and Suppliers shall:**

- a. Ensure that their self-administered antigen test kits are FDA-approved and validated by the RITM.
- b. Develop and issue references such as Instructions for Use for guidance of the general public on the test kit's proper administration, interpretation of results and disposal.
- c. Submit reports of suspected counterfeit, uncertified, and substandard test kits to the FDA.

**F. Disease Reporting Units (health facilities, clinics, telemedicine providers) shall:**

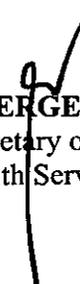
- a. Provide patient counseling and information on proper use of self-administered antigen tests, including next steps to take once a self-test turns positive.
- b. Report all cases testing positive to the nearest Local Health Office and Epidemiology and Surveillance Unit for inclusion in the case counts.
- c. Conduct preliminary triage and refer all cases to the Barangay Health Emergency Response Team for management and monitoring.

**G. X. Local Government Units (LGUs) shall:**

1. Support the conduct of health promotion and health education activities in relation to self-administered antigen testing in facilities and communities.
2. Ensure compliance in relation to the procurement, distribution, use and reporting of self-administered antigen test results within their jurisdiction.
3. Ensure the use of a standard platform for reporting of results of all self-administered antigen testing within their jurisdiction.
4. Ensure unhampered access to reporting lines and immediate provision of necessary response.
5. Ensure submission of received reports within their jurisdiction to the DOH.

For information and strict compliance.

By Authority of the Secretary of Health:

  
**MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO II**  
Undersecretary of Health  
Public Health Service Team

## Annex A

### Guidelines on the Disposal and Management of Waste from Self-Administered Antigen Test Kits

1. All wastes generated from the use of self-administered antigen test kits, such as, but not limited to, swab, kit, gloves, and body fluids, should be considered as **infectious waste**, unless otherwise specified in the respective instructions for use.
2. Infectious waste must be separated from other wastes and have a dedicated area or space during handling and collection. Any waste combined with waste generated from testing kits should also be considered as infectious waste.
3. All infectious waste should be packaged in sealed bags or containers that are leak resistant, impervious to moisture, and durable enough to prevent tearing from normal conditions of handling and/or transportation, such as vibration or changes in temperature, humidity, or atmospheric pressure.
4. All infectious waste bags or containers shall be labeled properly with the warning signage “CAUTION: INFECTIOUS WASTES”.
5. All infectious wastes should be stored indoors in a well-ventilated area and not around areas used for food preparation or consumption.
6. In case of spills, there should be immediate decontamination. Spills must be treated thoroughly using an appropriate disinfectant, preferably using 1,000 ppm or 0.1% sodium hypochlorite for a minimum contact time of 5 minutes.
7. All infectious wastes shall be collected and removed at regular intervals. Storage times should not exceed the following periods:
  - a. 48 hours during cool season
  - b. 24 hours during hot season
8. Transport of infectious wastes must conform to the rules and regulations mandated by the Environmental Management Bureau - Department of Environment and Natural Resources.
9. All applicable requirements related to health care waste management such as those provided in the DOH Health Care Waste Management Manual ([bit.ly/HCWMMManual4thed](http://bit.ly/HCWMMManual4thed)) and DM 2020-0170 “Interim Guidelines on the Management of Health Care Waste in Health Facilities, Community Quarantine Units, and Temporary Treatment and Monitoring Facilities with Cases of Coronavirus Disease 2019 (COVID-19)”, and their respective updates, shall continue to apply.