



28 MAY 2020


**FDA ADVISORY**  
No. **2020-1012**

**TO: ALL CONCERNED HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT: Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit "Femometer Covid-19 IgG/IgM Rapid Test Cassette"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the uncertified Covid-19 test kit:

**Catalogue – Femometer Rapid Test Kit**



**FAST:** Instant results in 10-20 minutes with an intuitive visual interpretation. No other professional equipment needed.

**ACCURATE:** Clinical trials have been conducted by hospitals and professional laboratories, proving the accuracy of the test and is over 99.42% (IgG) and 93.41% (IgM).

**SAFE:** Compared to Nucleic Acid Testing which requires sampling at a hospital, Femometer uses colloidal gold method to detect antibodies IgG and IgM to detect whether a person is infected. The whole process can be done at home.


**PRODUCT USE**

The COVID-19 IgG/IgM Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood Serum/Plasma. It provides an aid in the diagnosis of infection with Novel coronavirus.

PACKAGE		STORAGE / STABILITY	
One box (1 tests) contains:		<ul style="list-style-type: none"> <li>Store as packaged in the sealed pouch at the temperature of 4°C-30°C or 40°F-86°F</li> <li>Once the pouch is opened, the test should be used within one test. Prolonged exposure to hot and humid environment will cause product deterioration</li> <li>The LOT and expiration date is printed on the labeling</li> </ul>	
1 Test Strips	1 Desiccants		
1 Dropper	1 Diluents		
1 Needles	1 User Manual		
1 Alcohol Pads			


**TEST PROCEDURE**

- Allow the test, specimen and/or controls to reach room temperature (15°C-30°C (59°F-86°F)) prior to testing.
- Remove the test cassette from the sealed pouch and use as soon as possible.
- Hold the dropper vertically and transfer 1 drop of specimen (approximately 10%) to the specimen well(S) of the test device, then add 2 drops of buffer (approximately 70%) and start the timer. See the illustration below.
- Wait for the colored line(s) to appear. Interpret the results in 15 minutes. Do not read the results after 20 minutes.



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**PACKAGE DETAILS**

PACKAGING PER BOX	CONTENT:
- 40 Test Kits per Box	One box (1 tests) contains:
<b>BOXES PER CARTON</b>	
- 20 Boxes per Carton	1 Test Strips 1 Desiccants 1 Diluents 1 Needles 1 Dropper 1 Alcohol Pads 1 User Manual

**MEASUREMENTS AND DIMENSIONS**

**Product Name:** Femometer COVID-19 IgG/IgM Rapid Test Cassette  
**Model:** WB/S/P  
**Size:** 123\*60\*20mm, weight: 20g  
**Operation Temperature:** 15-30 °C  
**Storage Temperature:** 4-30 °C

**MATERIALS AND CERTIFICATION**

The test is made of high-quality ABS and PP materials. All the materials have gone through tests under various extreme environments. The test strip is approved by CE under directive 98/79/EC Annex III

Figure 1. Uncertified Femometer Covid-19 IgG/IgM Rapid Test Cassette



The FDA verified through post-marketing surveillance that the abovementioned medical device is not certified and/or no FDA Special Certification has been issued as of 15 May 2020. Pursuant to the Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this uncertified medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, FDA Circular No. 2016-016 entitled “Prohibition of Online Selling of FDA Certified Covid-19 Antibody Test Kits” prohibits online selling and commercial use of such products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at [cdrrhr-prsdd@fda.gov.ph](mailto:cdrrhr-prsdd@fda.gov.ph), or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered/uncertified medical device, the online reporting facility, **eReport** can be accessed at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport).

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

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