



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. ~~2020-1105~~

17 JUN 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device in Foreign Characters "Human Chorionic Gonadotropin (HCG) Test Strip (Colloidal Gold Method)"

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the unregistered medical device:

本公司通过 ISO 13485 认证 本产品通过 CE 认证

早早孕快速检测试纸 (板型)

人绒毛膜促性腺激素 (HCG) 检测试纸 (胶体金法)
Human chorionic gonadotropin (HCG) test strip (Colloidal gold method)

内配尿杯 更科学更准确

24 小时检测
1 分钟显示

板型 单人份/盒

本产品仅用于一次性体外诊断用

方便 快捷 准确

专业只为中国女性

其他内容详见说明书

检测方法

1. 撕开铝箔袋，取出检测试纸。
2. 将尿液收集在干净干燥的尿杯中，手持试纸手柄端，将Max线或箭头标识的一端浸入尿液中，注意不要使尿液超过箭头所指的横线，保持10-20秒后取出平放。如果配有吸管，可用吸管从尿杯中吸取少量尿液，将2-5滴尿液缓慢滴至测试板孔中。
3. 1-5分钟观察结果。10分钟后读取的结果无效。

检验结果的解释

1. 阳性：在试纸条白色显示区上端和下端同时呈现两条红色线（控制线C和反应线T），提示怀孕。
2. 阴性：只在试纸条白色显示区上端呈现一条红色线（控制线C），而显示区下端无红线，提示未怀孕。
3. 无效：5分钟在试纸条白色显示区上端无控制线C出现，提示试验失败或试纸无效。

注意事项

- (1) 本产品仅用于一次性体外诊断用。
- (2) 请在有效期内使用，当确定使用时再将包装打开。
- (3) 子宫肿瘤、葡萄胎或更年期病人，因尿液中HCG含量较高，可能出现阳性结果。

储存条件及有效期

本产品应储存于4-30℃、避光、干燥处，有效期为36个月。
产品打开包装后，应在1小时内使用。

包装规格：单人份/盒（板型）

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Figure 1. Unregistered Human Chorionic Gonadotropin (HCG) Test Strip (Colloidal Gold Method)



The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued. 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 unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

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

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

Dissemination of this advisory to all concerned is hereby requested.


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Director General

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