Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

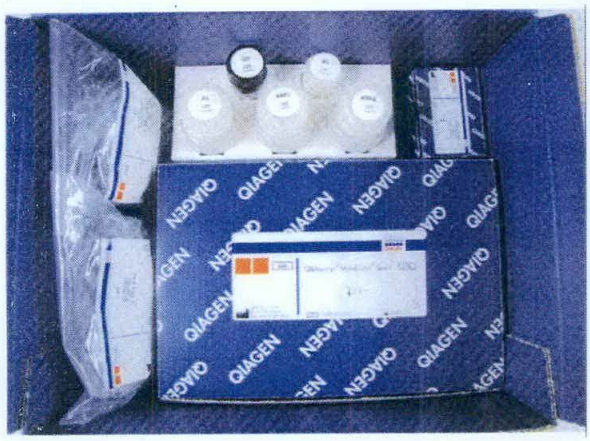
14 AUG 2017

FDA ADVISORY
No. 2017-251

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of QIAamp DSP Virus Kit CE**

All concerned healthcare professionals are hereby advised by the Food and Drug Administration (FDA) regarding the recall of QIAamp DSP Virus Kit CE (see photos of the product below) distributed by Getz Bros. Phils., Inc. The QIAamp DSP Virus Kit is a generic system that uses silica-membrane technology (QIAamp technology) for isolation and purification of viral nucleic acids from human plasma or serum for in vitro diagnostic purposes.



Figures 1 and 2: Photos of QIAamp Virus Kit CE

The following LOT numbers distributed after 2 September 2016 are affected by the recall:

- **154025928, 154027751, 154029053, 154029743 and 154029744**

All other batches of the product produced before and after this issue are not affected.

The above-stated medical device products are being voluntary recalled by Getz Bros. Phils., Inc. An investigation revealed that the root cause of the issue was a deviation from the correct storage conditions which led to reduced stability and decreased performance.

The performance of the eluates obtained with the QIAamp DSP Virus Kit with LOT numbers mentioned above in downstream applications could be reduced which may lead to the following consequences:

1. In downstream applications, with controls processed through sample preparation, may lead to an increased number of invalid results
2. In quantitative downstream applications, without controls processed through sample preparation, lower quantification and false negative cannot be ruled out.
3. In qualitative downstream applications, without controls processed through sample preparation, false negative results cannot be ruled out.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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