Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 AUG 2017

FDA ADVISORY
No. 2017-248

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: VOLUNTARY RECALL OF IPSOGEN BCR-ABL1 Mbcr IS-MMR Kit and IPSOGEN BCR-ABL1 Mbcr RGQ RT-PCR Kit

All are hereby advised by the Food and Drug Administration (FDA) about the lots of the following Research Use Only (RUO) Ipsogen Kits distributed by Getz Bros. Philippines Inc. 5th floor Ortigas Bldg. Ortigas Ave Pasig City, Philippines:

Research Use Only (RUO) Kit name	Kit Ref	Kit Lot	IS-MMR Calibrator MAT	IS-MMR Calibrator LOT	Erroneous NCN Assigned IS-Cal Value for the IS-MMR Calibrator	Corrected NCN Assigned IS-Cal Value for the IS-MMR Calibrator
Ipsogen BCR-ABL1 MBCR IS-MMR Kit	670713	95701390	1071927	95701327	0.081	0.124
		95701403				
		95701513				
		95701655				
		95701524				
		95700448		95700957	0.094	0.143
		95700450				
		95700997				
		95701174				
		95701664		95701806	0.092	0.140
		95701896				
		95701897				
		95701974				
Ipsogen BCR-ABL1 Mbcr RGQ RT-PCR Kit	670913	95701191	1062899	95701222	0.1238	0.1848
		95701413				
		95701532				
		95700425		95700842	0.1385	0.2057

The cited product are being voluntarily recalled by Getz Bros. Philippines Inc. because of the report issued by its main manufacturer in other country. According to the report, there is a labelling error in the IS-Cal Value used in the calculation for the conversion of the

qualitative results to the international standard on certain lots. This error has led to significant change in the molecular response reporting for IS-MMR and RT-PCR kits. For the ipsogen BCR-ABL1 Mbcr IS-MMR kit, the magnitude of error may induce a change from "inconclusive result" to "MMR" status or "no MMR" status to "inconclusive result." For ipsogen BCR-ABL1 Mbcr RGQ RT-PCR Kit the magnitude of error may induce a change from "MR4" to "MR4.5"; "MMR" to "MR4"; and "no MMR" to "MMR." Thus, erroneous data might be obtained from these affected lots.

All consumers are advised not to purchase or use the affected product lots. Distributors, retailers, hospitals that have any lot of the stated medical device product are instructed to discontinue further distribution, sale and use.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, R.Ph
Director General

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