

Urgent Field Safety Notice

Commercial name of the affected product:

RightSign HIV 1.2.O Rapid Test Cassette (CE2265)

RightSign HCV Rapid Test Cassette (CE2265)

RightSign HBsAg Rapid Test Cassette (CE2265)

FSCA-identifier: 20160616

Type of action: Recall (the return of a MEDICAL DEVICE to the supplier)

Date: June 20, 2016 (original June 16, 2016)

Attention: Shanghai International Holding Corp. GmbH (Europe), EU customer

Details on affected devices:

Catalog	Name	Brand	Lot No.
IHBSG-C31	HBsAg Rapid Test Cassette (Serum/Plasma) (CE2265)	Rightsign	HBSG14060001 HBSG14100001 HBSG15040001 HBSG15040002 HBSG15050005 HBSG15060003 HBSG15080001 HBSG15120003 HBSG16030001 HBSG16050014
IHCV-C31	HCV Rapid Test Cassette (Serum/Plasma) (CE2265)	Rightsign	HCV14060001 HCV14100001 HCV15050007 HCV15050008 HCV15090007 HCV15110001 HCV15110002 HCV16030007
IHIV-C42	HIV 1.2.0 Rapid Test Cassette (Whole Blood/Serum/Plasma) (CE2265)	Rightsign	HIV14060001 HIV14060002 HIV14100001 HIV14100002 HIV15080003 HIV15110001 HIV16020005 HIV16050008

Description of the problem:

We received a warning letter from ANSM France for HIV, HCV and HBV rapid tests manufactured by Hangzhou Biotest Biotech Co. Ltd. The warning letter mentioned some nonconformity. We haven't received false result complaint from European market. However, to avoid any potential risk, we decide to recall the valid batches from European market.

Advise on action to be taken by the user:

Considering the potential risk of the products on test result, we notice our distributors don't sell these products. Also, The retained products (unsold and unused) should be quarantined and disposed.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed to all those who need to be aware in your organization or to any organization where the potentially affected devices have been transferred. (if appropriate)

Please transfer this notice to other organizations on which this action has an impact. (if appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact information for manufacturer:

Mr. Tom Chen
Quality Director
Hangzhou Biotest Biotech Co., Ltd
Address: #17, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P.R. China, 311121
Tel: +86 571 8863 0078
Cell: +86 139 5715 6277
Email: tom.chen@biotests.com.cn

Contact information for European Authorized Representative:

Mr. Jin Liang
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726
E-mail: shholding@hotmail.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature

杭州博拓生物科技股份有限公司
Tom Chen
HANGZHOU BIOTEST BIOTECH CO. LTD