



INSTITUTE OF ISOTOPES CO., LTD.

H-1121 Budapest, Konkoly-Thege Miklós út 29-33.

✉ H-1535 Budapest, P.O.B. 851 Hungary

Phone: +36 1 3910802

Fax: +36 1 3922575

www.izotop.hu

izotop@izotop.hu



Budapest, 9 September 2026

CHANGE NOTIFICATION FOR PRODUCT LABELLING

Dear Customer,

We would like to inform you about an upcoming change concerning the labelling of selected components within our IVD product range.

What is changing?

The labels of certain product components will be updated to include the standard toxicity hazard pictogram (skull and crossbones hazard icon) in accordance with regulatory classification guidelines.



This labelling update specifically affects the following components:

- Lyophilized components containing sodium azide (NaN_3).
- Concentrated wash buffer reagents containing sodium azide (NaN_3).

Please note that once the lyophilized components are reconstituted according to the instructions for use, or when the concentrated wash buffer is diluted to its final working concentration, the concentration of sodium azide (NaN_3) drops below the regulatory threshold for hazard labelling. Therefore, the reconstituted or diluted working solutions do not carry hazardous classification.

Why are we making this change?

This change is being implemented to maintain full compliance with applicable safety regulations and hazard communication standards for concentrated and raw component materials.

What does this mean for you?

This update reflects a modification in component and product labelling only. There is no change to the formulation, manufacturing process, storage conditions, quality, or performance of the products. The handling and safety profile of the reconstituted or diluted working solutions used in your assays remain unchanged.

List of affected products

Below is the summary of the affected products and their specific components that will feature the updated hazard labelling:

Catalog Number	Product Name	Affected Component(s)	Packaging / Form
RK-5CT	hGH [I-125] IRMA KIT	Standard (S1-S6) Control (C) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-11CT1	T4 [I-125] RIA KIT	Control (C)	Lyophilized
RK-20PA	Anti-IA2 [I-125] RIA KIT	Tracer Protein-A	Lyophilized Lyophilized
RK-38CT	hCEA [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer
RK-40PA	Anti-GAD65 [I-125] RIA KIT	Tracer Protein-A	Lyophilized Lyophilized
RK-50PA	IAA [I-125] RIA KIT	Protein-A	Lyophilized
RK-51CT	hTG [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer
RK-83CT	hCalcitonin [I-125] IRMA KIT	Standard (S0-S5) Control (CI, CII) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-84CT	hC-peptide [I-125] IRMA KIT	Standard (S1-S5) Control (C) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-86CT	SHBG [I-125] IRMA KIT	Control (C) WBU20CT	Lyophilized Concentrated wash buffer
RK-125CT	CA125 [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer
RK-153CT	CA 15-3 [I-125] IRMA KIT	WBU40CT	Concentrated wash buffer
RK-211CT	CYFRA 21.1 [I-125] IRMA KIT	Standard (S0-S5) Control (CI, CII) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-240CT	CORTISOL [I-125] RIA KIT	Control (C)	Lyophilized
RK-400CT	INSULIN [I-125] IRMA KIT	Standard (S0-S5) Control (C) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-460CT	PROGESTERONE [I-125] RIA KIT	WBU20CT	Concentrated wash buffer
RK-620CT	DHEA-SO4 [I-125] RIA KIT	Control (C)	Lyophilized
RK-724CT	CA 72-4 [I-125] IRMA KIT	WBU40CT	Concentrated wash buffer
RK-750CT	hLH [I-125] IRMA KIT	Control (C) WBU20CT	Lyophilized Concentrated wash buffer
RK-760CT	βhCG [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer
RK-780CT	hPRL [I-125] IRMA KIT	Standard (S1-S6) Control (C) WBU20CT	Lyophilized Lyophilized Concentrated wash buffer
RK-790CT	hFSH [I-125] IRMA KIT	Control (C) WBU20CT	Lyophilized Concentrated wash buffer
RK-800CT	AFP [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer
RK-900CT	Ferritin [I-125] IRMA KIT	WBU20CT	Concentrated wash buffer

When will this take effect?

The updated component, product labels and IFUs with the toxicity hazard pictogram will be introduced gradually starting from the **second half of October 2026 onwards**. During the transition period, you may receive inventory with either previous or updated labelling depending on batch numbers and lot rotation.

Thank you for your understanding and continued trust in our products. If you have any questions or require further assistance, please do not hesitate to contact our Sales team at sales@izotop.hu.

Best regards,



Institute of Isotopes Co., Ltd.

Erzsébet, Szemenyei PhD.

Director of R&D and Quality Management

