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SUBJECT **bioelisa anti-HBs**
Change notification



This is to inform that it has been introduced a change in the validation criteria of the Biokit product:

bioelisa anti-HBs code: 3000-1101

The High Positive Calibrator (HPC) upper absorbance limit for assay validation has been changed from 1.800 to 2.100 absorbance units.

The previous criterion has been demonstrated to be too restricted and occasionally produced unnecessary invalid runs.

Biokit has fully documented that this change does not affect the performance of the kit. As a CE marked product of Class IIA, the change has been approved by the notified body Underwriters Laboratories.

G-1805 is the first batch having the change. There is a visible external white label in the kit cartoon box. For next following two batches, a yellow note will be included in the inside.

Biokit recommends to modify the validation criteria in the semi automated Elisa readers and fully automated Elisa processors such as best 2000 or biomaster jr, running the assay.

Enclosed there is the English version of the updated package insert and a copy of the external label of notice.

Biokit apologizes for the inconveniences that this change may cause.

CHANGE NOTIFICATION

The High Positive Calibrator (HPC) upper absorbance limit for assay validation has been changed. Please, read carefully the Quality Control chapter of package insert.

Biokit apologises for the inconvenience that it may cause.

NOTIFICACIÓN DE CAMBIO

El límite máximo de absorbancia del Calibrador Positivo Alto (CPA) para la validación del ensayo se ha cambiado. Por favor, lea con atención el apartado de Control de Calidad del manual de usuario.

Biokit lamenta los inconvenientes causados.

NOTIFICAÇÃO DE MUDANÇA

O limite máximo de absorbância do Calibrador Positivo Alto (CPA) para validar o ensaio foi mudado. Por favor, leia com atenção o capítulo de Controle de Qualidade da bula do produto.

Biokit lamenta os inconvenientes causados.