

ADVISORY NOTICE

04_2024_Change in stability/storage information – Hb Vario HbA1c Control Set

Dear customer,

We hereby inform you that for Hb Vario HbA1c Control Set, catalogue number REG00041, the following change in the stability/storage section has been implemented in the instruction of use (IFU) from batch number 2402177 (Expiry 07/2025).

The change applies to all batches which have been already released to the market.

The change of stability information in the IFU consists of the change:

From:

STABILITY / STORAGE

Stored unopened between 2 and 8 °C this product is stable until the expiration date. After reconstitution, the material is stable for 7 days between 2 and 8 °C. In case of usage of the controls in lysate mode, fresh lysate samples should be prepared daily for optimal performance.

To:

STABILITY / STORAGE

Stored unopened between 2 and 8 °C this product is stable until the expiration date. After reconstitution, the material is stable for 3 days at 2–8 °C and 3 weeks at -20 °C when stored as whole blood aliquots (100 µl aliquots for the whole blood mode or 25 uL aliquots for the lysate mode). Avoid multiple freeze-thaw cycles. In case of usage of the controls in the lysate mode, fresh lysate samples should be prepared daily from the whole blood aliquot for optimal performance.

Please follow the new instructions given for the stability/storage section of the IFU.

In case you have any additional questions, please do not hesitate to contact us.

Best regards,

Erba Lachema s.r.o.

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