

RECALL NOTICE
M30 Apoptosense® ELISA, 10011-008
2020-10-20

Product(s): M30 Apoptosense® ELISA, Cat No. 10011, Lot No. 10011-008

Reason for action: Possible contamination of Standard F and Control High vials

Implementation: Kits of the concerned product should be destroyed.
Destruction should be confirmed to VLVbio according to below.
Destruction should be performed and confirmed to VLVbio as soon as possible, no later than 2020-10-26.

Dear Sir or Madam,

With this letter we would like to inform you that we on the 19th of October received information about possible contamination in vials containing Standard F in the product **M30 Apoptosense® ELISA, Cat. No. 10011, Lot No. 10011-008**. An internal investigation confirms that vials containing Standard F and Control High of a part of the concerned lot shows visible signs of contamination.

The product lot is therefore recalled, and any remaining kits of the lot that have been distributed should be destroyed as soon as possible, not later than 2020-10-26.

Please forward this information to all end users that have received kits from lot 10011-008 and confirm the amount of destroyed and/or used kits to VLVbio per email.

A risk assessment have been performed by VLVbio that shows a low risk that the affected product would give incorrect results if used for analysis, as long as the standard curve and internal controls shows normal results as compared to the values given in the certificate of analysis. The recall is performed as a precautionary measure.

In case of questions or concerns regarding analytical results obtained from using the concerned product lot, please contact: support@vlvbio.com.

Please forward this recall notice to everyone that may be affected within your organisation.

For any further questions, please contact our Marketing Department:

Email: marketing@vlvbio.com

Phone: +46 8 122 053 00

Sincerely,



Ulrika Bernhardt
Quality Assurance Manager,
VLVbio AB