



VLVbio

PEVIVA® Product Line Overview

The dead cells still count!

VLVbio
www.vlvbio.com



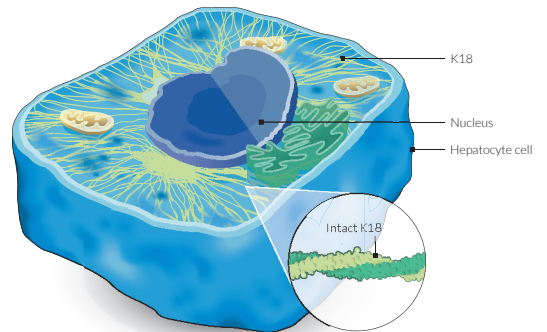
Product Line

The PEVIVA® Product Line was invented by VLVbio, a Swedish biotechnology company devoted to the manufacture, R&D and sales of unique biomarker assays intended for:

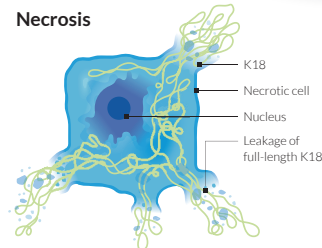
- **Non-invasive diagnosis as well as treatment follow-up of certain types of liver diseases.**
- **Preclinical research in drug development.**
- **Rapid and non-invasive monitoring of anti-cancer drug efficacy.**

VLVbio has, since the establishment of the company, the exclusive rights to the M30® antibody. The M30® is a unique apoptosis marker used in the M30 Apoptosense® ELISA and the M30 CytoDeath™ ELISA, which measures the amount of caspase cleaved keratin 18 leaked from epithelial cells. VLVbio also offers the M65® ELISA, M65 EpiDeath® and M65 EpiRat™ ELISA. These three assays are based on two anti-keratin 18 mouse monoclonal antibodies (M5 and M6) measuring total cell death (apoptosis and necrosis) by quantifying cleaved and intact keratin 18.

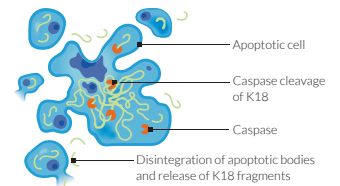
Hepatocyte cell death



Necrosis



Apoptosis



Only intact CK18

Caspase-cleaved CK18

M30[®] products

M30 Apoptosense[®] ELISA (prod. No. 10011)

The M30 Apoptosense[®] ELISA measures the amount of caspase cleaved keratin 18 in human serum and cell culture supernatants, as well as cell spheroids and xenograft models, reflecting the amount of apoptosis. The assay is based on the unique M30[®] antibody, which recognizes a neo-epitope of keratin 18 formed after caspase cleavage. The assay can be combined with the M65[®] ELISA for the analysis of cell death mode, necrosis or apoptosis.

The M30 Apoptosense[®] ELISA is CE marked as a medical device for in vitro diagnostic use. All reagents are provided in a convenient ready-to-use format.



Clinical IVD application for the M30 Apoptosense[®] ELISA:

- As an aid in diagnosing Non-Alcoholic Steatohepatitis (NASH) in Non-alcoholic fatty liver disease (NAFLD) suspect patients.
- As a screening tool for pediatric patients at risk for developing NASH.
- As an intervention follow-up to check for treatment effect in NASH patients.
- As an aid in diagnosing Alcoholic Steatohepatitis (ASH) in Alcoholic Liver Disease (ALD) suspect patients.
- As a prognostic tool and treatment response prediction in ASH patients.

Research application for the M30 Apoptosense[®] ELISA:

- **Hepatology:** Measures level of hepatocyte apoptosis in different liver diseases such as NAFLD, ALD, Hepatitis C Virus (HCV) and more.
- **Oncology:** Measures chemotherapy-induced apoptosis in epithelial carcinoma.
- **Toxicology:** Suitable when evaluating different pharmaceutical agents' impact on hepatocyte and/or renocyte apoptosis such as drug-induced liver injury (DILI), toxicant-associated fatty liver disease (TAFLD).

Features of the M30 Apoptosense[®] ELISA:

- The kit includes 96 determinations: 7 standards, 2 controls and 39 test samples in duplicate.
- The measuring range is 0–1 000 U/L (working range 75–1 000 U/L), with a sensitivity of 20 U/L.
- Assay procedure takes approximately 5 hours.
- Sample type: human serum. Multiple freeze-thaw cycles of samples are well tolerated.
- Reagent storage: +2–8 °C.
- Can be split up for use at several occasions.

M30 CytoDeath™ ELISA (prod. No. 10900)

The M30 CytoDeath™ ELISA offers a unique possibility to measure apoptotic 2D cell cultures, multicellular spheroids and organ culture systems. The M30 CytoDeath™ ELISA is a product developed for cell culture applications, with a dynamic range and sensitivity suitable for in vitro work, making it a useful drug screening tool.

Similar to the M30 Apoptosense® ELISA, the M30 CytoDeath™ ELISA is based on the M30® antibody, detecting the caspase cleaved keratin 18. All reagents are provided in a convenient ready-to-use format.



Suitable for measurement of apoptosis in cell cultures

Research application for the M30 CytoDeath™ ELISA:

- **Oncology:** Measures chemotherapy-induced apoptosis in epithelial carcinoma in cell cultures and spheroids.
- **Toxicology:** Suitable for in vitro characterization of apoptosis inducing drugs, including establishment of time course kinetics and dose-response relationships.

Features of the M30 CytoDeath™ ELISA:

- The kit includes 96 determinations: 4 standards and 44 test samples in duplicate.
- The measuring range is 0 – 3 000 U/L (working range 250 – 3 000 U/L), with a sensitivity of 60 U/L.
- Assay procedure takes about 5 hours.
- Sample type: human cell cultures from epithelial cells.
- Reagent storage: +2 – 8 °C.
- Can be split up for use at several occasions.



M65[®] products

M65[®] ELISA (prod. No. 10020)

The M65[®] ELISA measures soluble keratin 18 released from dying epithelial cells. It can be used to assess overall cell death due to apoptosis and necrosis. The M65[®] ELISA is intended for human serum and is CE marked as a medical device for in vitro diagnostic use.

The M65[®] ELISA is primarily intended to be used together with the M30 Apoptosense[®] ELISA. The combination of the M30 Apoptosense[®] ELISA and the M65[®] ELISA allows for the determination of the relative contribution of apoptosis or necrosis to the total amount of cell death. All reagents are provided in a convenient ready-to-use format.



Clinical IVD application for the M65[®] ELISA:

- As an aid in diagnosing NASH in NAFLD suspect patients.
- As an intervention follow-up to check for treatment effect in NASH patients.
- As an aid in diagnosing ASH in ALD suspect patients.
- As a prognostic tool and treatment response prediction in ASH patients.

Research application for the M65[®] ELISA:

- **Hepatology:** Measures the level of total hepatocyte cell death in liver diseases such as NAFLD, ALD, HCV and more.
- **Oncology:** Measures chemotherapy-induced cell death in epithelial carcinoma.
- **Toxicology:** Suitable for evaluation of cell death mode of hepatocytes and/or renocytes due to pharmaceutical agents' impact.

Features of the M65[®] ELISA:

- The kit includes 96 determinations: 7 standards, 2 controls and 39 test samples in duplicate.
- The measuring range is 0 – 2 000 U/L (working range 125 – 2 000 U/L), with a sensitivity of 25 U/L.
- Assay procedure takes approximately 3 hours.
- Sample type: human serum. Multiple freeze-thaw cycles of samples are well tolerated.
- Reagent storage: +2 – 8 °C.
- Can be split up for use at several occasions.

M65 EpiDeath® ELISA (prod. No. 10040)

The M65 EpiDeath® ELISA measures the concentration of soluble keratin 18 in human serum and cell culture supernatants. The keratin 18 levels reflect the amount of total cell death, due to apoptosis and necrosis.

The M65 EpiDeath® ELISA represents the next generation of keratin 18 positive biomarkers. The assay is CE marked as a medical device for in vitro diagnostic use. All reagents are provided in a convenient ready-to-use format.



Diagnostic and prognostic NIT for DILI

Clinical IVD application for the M65 EpiDeath® ELISA:

- As an aid in early detection or diagnosis of DILI in DILI suspect patients.
- As a prognostic tool in DILI patients.
- As an aid in diagnosing ASH in ALD suspect patients.
- As a prognostic tool and treatment response prediction in ASH patients.

Research application for the M65 EpiDeath® ELISA:

- **Hepatology:** Measures the level of total hepatocyte cell death from liver damage due to a disease or viral infection.
- **Toxicology:** Suitable for evaluating different chemical or pharmaceutical agents' impact on hepatocyte and/or renocyte cell death due to e.g. DILI, TAFLD and more.

Features of the M65 EpiDeath® ELISA:

- The kit includes 96 determinations: 8 standards, 2 controls and 38 test samples in duplicate.
- The measuring range is 0 – 5 000 U/L (working range 67 – 5 000 U/L), with a sensitivity of 25 U/L.
- Assay procedure takes approximately 5 hours.
- Sample type: human serum. Multiple freeze-thaw cycles of samples are well tolerated.
- Reagent storage: +2 – 8 °C.
- Can be split up for use at several occasions.

M65 EpiRat™ ELISA (prod. No. 10060)

The M65 EpiRat® ELISA measures the concentration of soluble keratin 18 in rat serum. The keratin 18 levels reflect the amount of total cell death, due to apoptosis and necrosis in rat epithelial cells.

M65 EpiRat® ELISA is developed for the use to measure liver damage in pre clinical studies for safety and efficacy which makes it useful as a drug screening tool. All reagents are provided in a convenient ready-to-use format.



Research application for the M65 EpiRat™ ELISA:

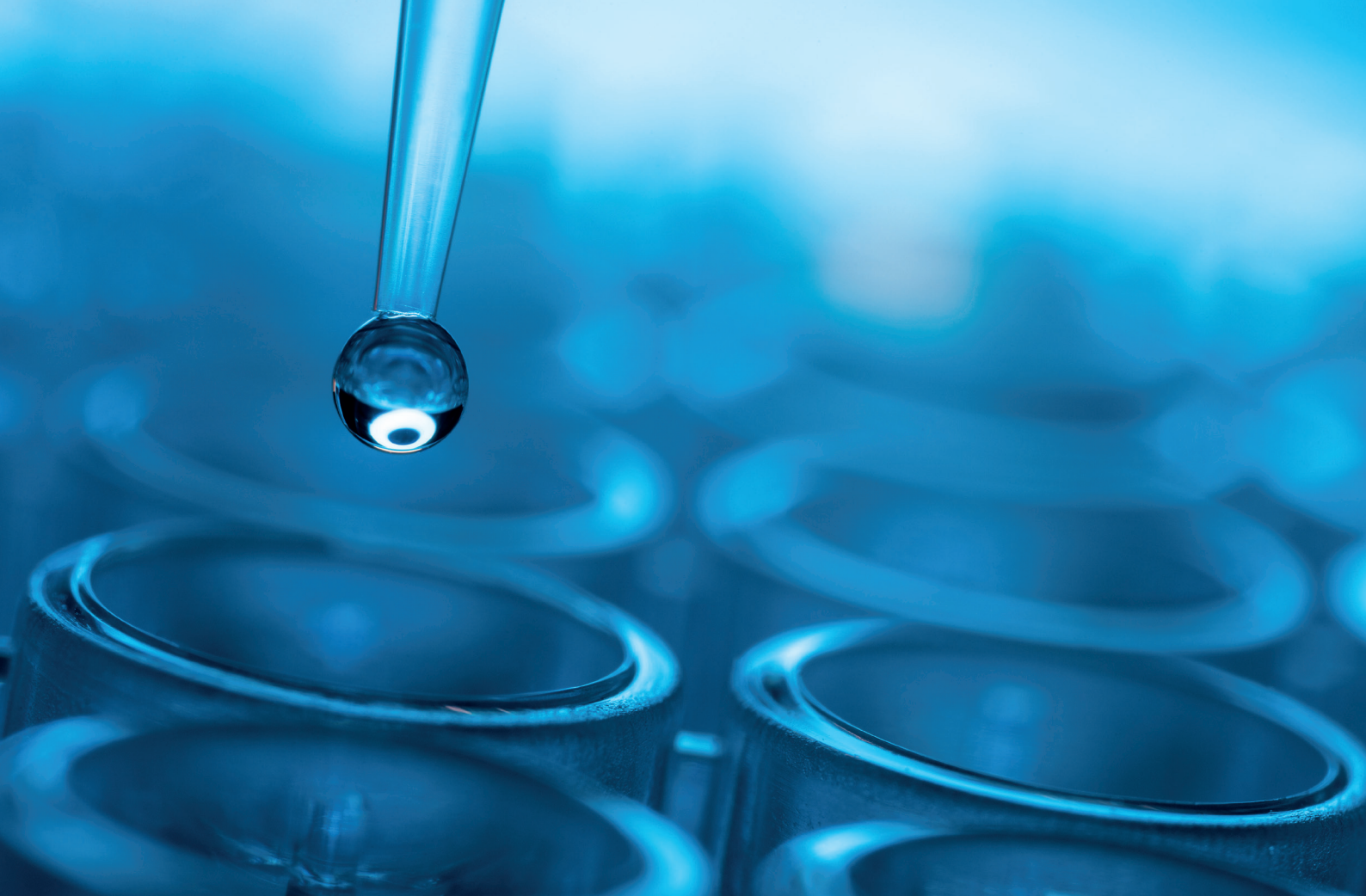
- **Pre-clinical studies:** to analyse the effect of drugs on treatment effect and disease progression. Perfectly suited for translational research studies for new compounds in oncology and hepatology, e.g. NASH and DILI.
- **Toxicology:** allows for the quantification of the amount of cell death in hepatocytes to assess liver toxicity.

Features of the M65 EpiRat™ ELISA:

- The kit includes 96 determinations: 5 standards and 43 test samples in duplicate.
- The measuring range is 0 – 2 000 U/L (working range 98 – 2 000 U/L), with a sensitivity of 50 U/L.
- Assay procedure takes about 5 hours.
- Sample type: rat serum and plasma (heparin, citrate, EDTA) samples.
- Reagent storage: +2 – 8 °C.
- Can be split up for use at several occasions.

The PEVIVA® Product Line can be used with blood samples, samples from cell cultures and spheroids or on xenografts to measure apoptosis, total cell death and the ratio between apoptosis and necrosis.

Products	Apoptosis	Total Cell Death	Cell Cultures	Spheroids	Xenografts	Blood/Plasma Samples	Animal Blood Samples	CE IVD
M30 Apoptosense® ELISA	✓	-	✓	✓	✓	✓	-	✓
M30 CytoDeath™ ELISA	✓	-	✓	✓	-	-	-	-
M65® ELISA	-	✓	✓	✓	✓	✓	-	✓
M65 EpiDeath® ELISA	-	✓	✓	✓	✓	✓	-	✓
M65 EpiRat™ ELISA	-	✓	-	-	-	-	✓	-



VLVbio™ Product Line

ELISA Products	Prod. No
M30 Apoptosense® ELISA	10011
M30 CytoDeath™ ELISA	10900
M65® ELISA	10020
M65 EpiDeath® ELISA	10040
M65 EpiRat™ ELISA	10060



How to order

VLVbio is collaborating with distributors all over the world to provide fast, reliable and convenient service for you. Please visit www.vlvbio.com or email order@vlvbio.com to find your local distributor.