

M30 Apoptosense® ELISA

Apoptosis Biomarker Assay

Catalog Prod. No. 10011

In USA, Canada and Japan: For research and laboratory use only. Not for human or diagnostic use.

General Information

Analyte:	<p>Soluble human intermediate filament protein fragments of keratin 18 (K18) [ccK18 (caspase-cleaved Cytokeratin-18)] that contain the M30 neo-epitope (K18Asp396-NE).</p> <p>The M30 neo-epitope (K18Asp396-NE), is a sensitive and integrative indicator specific for epithelial cell death involving caspase-3, -7 or -9 activation.</p>
Intended Use:	Quantitative measurement of the apoptotic cell death biomarker K18Asp396-NE ("M30 antigen" or caspase-cleaved (Cyto)keratin 18, ccK18) released from apoptotic epithelial cells / tissues (e.g. hepatocytes).
Samples:	<p>Human serum or plasma (EDTA, Citrate, Heparin plasma), containing K18Asp396-NE (M30)-reactive material released from apoptotic K18 positive human cells. Multiple freeze-thaw cycles of samples are well tolerated.</p> <p>NOTE! The same type of material i.e. serum or plasma collected by one method should be used for a specific project.</p>
Interfering Substances:	The assay is not sensitive to highly elevated hemoglobin levels (< 100 mg/dL), highly elevated triglyceride levels (< 1 250 mg/dL) or highly elevated bilirubin levels (< 12.5 mg/dL) allowing the analysis of even grossly haemolyzed, hyperlipidemic or icteric blood samples.
Sample Volume:	2 × 25 µL (duplicate samples).
Sample Stability:	Fresh samples are stable for up two days at 2–8 °C, for at least 9 months at -20 °C; and for at least two years when stored at -80 °C.
Number of Tests:	96 determinations: 7 Standards, 2 Controls and 39 samples in duplicates.
Reagent Storage:	2–8 °C. Do not freeze!
Assay Time:	270 min (approx.).
References:	<ul style="list-style-type: none"> ■ Bantel H. et al.; (2004) <i>Detection of apoptotic caspase activation in sera from patients with chronic HCV infection is associated with fibrotic liver injury.</i> Hepatology 40: 1078 – 1087 ■ Wieckowska A. et al.; (2006) <i>In vivo assessment of liver cell apoptosis as a novel biomarker of disease severity in nonalcoholic fatty liver disease.</i> Hepatology. 44:27-33 ■ Yagmur E. et al.; (2007) <i>Elevated apoptosis-associated cytokeratin 18 fragments (CK18Asp386) in serum of patients with chronic liver diseases indicate hepatic and biliary inflammation.</i> Clin Biochem. 40:651-5 ■ Feldstein A. E. et al.; (2009) <i>Cytokeratin-18 fragment levels as noninvasive biomarkers for nonalcoholic steatohepatitis: A multicenter validation study.</i> Hepatology 50:1072 – 8 ■ Anty R. et al.; (2010) <i>A new composite model including metabolic syndrome, ALT and ccK18 for the diagnosis of non-alcoholic steatohepatitis in morbidly obese patients.</i> Aliment Pharmacol Ther. 32:1315-22 ■ Fitzpatrick E. et al.; (2010) <i>Serum levels of CK18 M30 and leptin are useful predictors of steatohepatitis and fibrosis in paediatric NAFLD.</i> J Pediatr Gastroenterol Nutr. 51:500-6 ■ Joka E. et al.; (2012) <i>Prospective Biopsy-Controlled Evaluation of Cell Death Biomarkers for Prediction of Liver Fibrosis and Nonalcoholic Steatohepatitis.</i> Hepatology 40:651-655 ■ Feldstein A. E.; et al.; (2013) <i>Serum Cytokeratin-18 Fragment Levels Are Useful Biomarkers for Nonalcoholic Steatohepatitis in Children</i> Am J Gastroenterol. 108:1526-31 ■ Jain A. K. et al.; (2013) <i>Serum keratin fragment 18 (CK18) levels significantly predict changes in liver histology in children and adolescents with nonalcoholic fatty liver disease (NAFLD): Results from the TONIC trial</i> AASLD Presentation and Abstract #114 (2013) ■ Bantel H. et al.; (2014) <i>Robust detection of liver steatosis and staging of NAFLD by an improved ELISA for serum cytokeratin-18 fragments.</i> Am J Gastroenterol. 109:140-1

Performance Characteristics

Calibration:	The units measured by the M30 Apoptosense® ELISA are defined against a synthetic peptide containing the M30 and M5 monoclonal antibody epitopes. 1 U/L = 1.24 pM.
Working Range:	75 – 1 000 U/L
Detection Limit:	20 U/L, Standard A (0 U/L) + 2 S.D.
Reference Range:	Recommended reference values for application in chronic liver diseases (CLD): <150 U/L: healthy 150-200 U/L: slightly elevated > 200 U/L: elevated
Reproducibility:	Intra-Assay (WA) Precision: CV < 10 % for values > 100 U/L. Inter-Assay (BA) Precision: CV < 10 % for values > 100 U/L.
Hook Effect:	No high dose “hook effect” occurs before 50 000 U/L which is well above concentrations of K18Asp396-NE (M30)-reactive material observed in human blood samples.

Reagents

Coated Microstrips:	One Microplate, 96 dry wells (12 strips × 8 wells). The wells are coated with mouse monoclonal anti-K18 antibody M5.
HRP Conjugate:	Concentrate. One vial containing mouse monoclonal M30 antibody (anti-K18Asp396-NE) conjugated to horseradish peroxidase (HRP).
Conjugate Dilution Buffer:	One vial containing phosphate buffer with protein stabilizers.
Standards A – G:	The values of the Standards A – G are 0, 75, 150, 250, 500, 750 and 1 000 U/L, respectively.
Control Low and High:	Two vials containing M30-reactive recombinant standard material.
TMB Substrate:	One vial containing TMB (3,3',5,5'-Tetramethylbenzidine) Solution.
Stop Solution:	One vial containing 1.0 M sulfuric acid.
Wash Tablet:	One tablet for preparation of Wash Solution.

PEVIVA Products from VLVbio

M30 Apoptosense® ELISA Prod. no. 10011	M65® ELISA Prod. no. 10020	M5 Keratin 18 Prod. no. 10600	M30 CytoDEATH™ Unconjugated Prod. No. 10700 Biotin Prod. No. 10750 Fluorescein Prod. No. 10800 Orange Prod. No. 10850
M30 CytoDeath™ ELISA Prod. no. 10900	M65 EpiDeath® ELISA Prod. no. 10040	M6 Keratin 18 Prod. no. 10650	

For further information, please visit www.peviva.com - order online at www.shop.peviva.com

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