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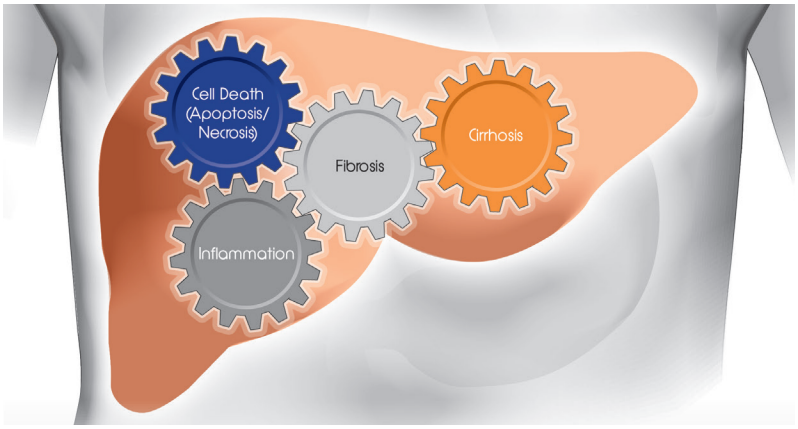
Biomarker Assays for NASH Clinical Trials



Cytokeratin 18 (CK18 and ccK18): Non-invasive biomarkers for assessing hepatocyte apoptosis and necrosis

Biomarker	Utility in NASH Clinical Trials	Available Assays	Catalog #
Total CK18 (M65®)	Biomarker for hepatocyte cell death (apoptosis and necrosis)	M65® ELISA	P10020
		M65® EpiDeath® ELISA	P10040
Caspase-cleaved CK18 (ccK18/M30®)	Biomarker for hepatocyte apoptosis	M30® Apoptosense® ELISA	P10011

- CK18 and ccK18 have been used as secondary endpoints in over 60 NAFLD/NASH clinical trials to **assess efficacy of new therapeutics**
- **Mechanistic biomarkers:** Hepatocyte apoptosis and necrosis are underlying mechanisms involved in the pathogenesis of NAFLD. Changes in CK18 and ccK18 may reflect changes in disease activity in study subjects in response to drug therapy
- More **specific for liver** than ALT & AST
- **Sensitive:** Depending on mechanism of action of the drug, changes can be observed within weeks, or even hours
- **Non-invasive:** Changes in serum CK18 and ccK18 have been shown to correlate with changes in liver histology (ballooning, inflammation, and fibrosis)
- CK18 can be used as a **prescreening tool** to **reduce screen failure rates** by helping to identify study subjects with a NAS ≥ 4

*Research use only in the U.S. and Canada. Not for diagnostic procedures.

Additional NASH Biomarker ELISAs Available from Diapharma:

Biomarker	Utility in NASH Clinical Trials	Available Assays	Catalog #
Adiponectin	Adipokine; regulator of hepatic glucose and lipid metabolism - promotes insulin sensitivity; low plasma levels are associated with NASH	TECO® High Sensitive Adiponectin	TE1014
		ImmunoDiagnostics Adiponectin	31010
		ImmunoDiagnostics Rapid Adiponectin	31012
Collagen IV	Component of the ECM; biomarker for hepatic fibrosis	Diapharma Serum Collagen IV	DPGACTE-001
FABP4	Plays a crucial role in insulin resistance and type 2 diabetes; circulating levels correlate with liver inflammation and fibrosis	ImmunoDiagnostics Fatty-Acid Binding Protein 4	31030
FGF-19	Regulator of hepatic bile acid synthesis & glucose homeostasis	ImmunoDiagnostics FGF-19	31200
FGF-21	Regulator of hepatic glucose and lipid metabolism	ImmunoDiagnostics FGF-21	31180
Fibronectin	Component of the ECM; biomarker for hepatic fibrosis	Technozym® Fibronectin	TC12030
hsCRP	Biomarker for inflammation	ImmunoDiagnostics hsCRP	31220
		ImmunoDiagnostics Rapid hsCRP	31121
Hyaluronic Acid (HA)	Component of the ECM; biomarker for hepatic fibrosis	TECO® Hyaluronic Acid (HA) PLUS	TE1018-2
Insulin	Promotes the absorption of glucose; insulin resistance has been linked to NASH	ImmunoDiagnostics Insulin	31380
Intact Proinsulin	Precursor of insulin; potential pro-atherogenic effect by increasing PAI-1 synthesis and blocking fibrinolysis	TECO® Intact Proinsulin	TE1011
L-FABP	Key player in hepatic lipid metabolism	Diapharma L-FABP (FABP1)	DPGLFABP
Leptin	Promotes fibrosis by activating hepatic stellate cells; serum levels correlate with hepatic steatosis	TECO® Leptin ELISA	TE1016
Lipocalin-2/NGAL	Biomarker for hepatic inflammation	NGAL	DPG-NGAL
		NGAL	DPG-2NGAL
		ImmunoDiagnostics Lipocalin-2	31050
Mac-2 BP	Biomarker for hepatic fibrosis	Mac-2 Binding Protein	DPG27362
Noggin	Antagonist of bone morphogenetic proteins (BMPs); levels have been shown to be decreased in subjects with NAFLD	FluoBolt™ Noggin	FIA-1701
Osteopontin	Involved in activation of hepatic stellate cells; biomarker for hepatic fibrosis	Osteopontin	DPG27158
		Osteopontin N-half	DPG27258
PAI-1	Promotes hepatic fibrogenesis by inhibiting metabolism of extracellular matrix proteins; potential link between NAFLD and cardiovascular disease	Technozym® PAI-1 Antigen	TC12075
		Technozym® PAI-1 Actibind®	TC16075
		ImmunoDiagnostics PAI-1 (Antigen)	31070
sCD163	Macrophage activation marker	IQ Macro163™	IQP-383

Questions about any product in our lineup?
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