

Drug-Induced Phospholipidosis GLP/non-GLP Assessments: Sample Requirements

Drug induced phospholipidosis (DIPL) is a phospholipid storage disorder characterized by an excessive accumulation of multi-lamellar bodies (myeloid bodies) in cells and tissues. The patented biomarker di-docosahexaenoyl (22:6)-BMP (di-22:6-BMP) is a lysosomal phospholipid that is increased in the tissues of animals and humans with DIPL. Nextcea uses validated high sensitivity LC-MS/MS methods to measure the absolute concentrations of di-22:6-BMP in plasma/serum, urine, and tissue samples.

Non-clinical Samples

Sample Type	Collection	Sample	Storage/Shipping of
		Volumes/Weight	Specimens
Serum/Plasma	Plasma: Choice of	~ 300 µL	 Store in -80°C freezer.
	anticoagulant such as sodium		 Ship frozen on dry ice
	heparin or lithium heparin		
Urine	Non-clinical: Overnight urine	~ 300 µL	• Store in -80°C freezer.
	collection in cooling cage pan		 Ship frozen on dry ice
Tissues (lung,	Snap-frozen	~ 300 mg	• Store in -80°C freezer.
liver, kidney, heart			 Ship frozen on dry ice
etc.)			

Clinical Samples

Sample Type	Collection	Sample Volumes	Storage/Shipping of
			Specimens
Serum/Plasma	Plasma: Choice of	~ 300 µL	• Store in -80°C freezer.
	anticoagulant such as sodium		 Ship frozen on dry ice
	heparin or lithium heparin		
Urine	Preferred mid-stream urine	~ 1 mL	• Store in -80°C freezer.
	sample.		 Ship frozen on dry ice

* Serum, plasma, and urine samples may be stored up to 1 year at -80 °C before use.

Hsieh F., Tengstrand E. Detecting Phospholipidosis and Diagnosing Lysosomal Storage Disorders. US Patent 8,313,949, Japanese Patent 5,702,363, and European Patent EP2419742.

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Tengstrand E., Miwa G., and Hsieh F. Bis(monoacylglycerol)phosphate as a non-invasive biomarker to monitor the onset and time-course of phospholipidosis with drug induced toxicities. Expert Opinion in Drug Metabolism and Toxicology 2010; 6(5):555-570.

Tengstrand-Baronas E., Lee J.W., Alden C., and Hsieh F. Biomarkers to monitor drug-induced phospholipidosis. Toxicology and Applied Pharmacology 2007;218:72-78.

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