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**

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

**Clinical Samples**

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

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


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.

