

CLINICAL PATHOLOGY PANELS IN PRECLINICAL STUDIES

Clinical pathology panels are widely used in healthcare to diagnose disease, monitor positive and negative effects of a therapeutic regimen, check health status and risks etc. A panel typically includes a group of analytes or endpoints that collectively provide information on a specific physiological state. For example, a typical kidney panel would include albumin, creatinine, blood urea nitrogen, and measurement of the glomerular filtration rate to assess waster removal and assess kidney health¹. Another widely used panel is a lipid panel that includes total cholesterol, HDL, LDL and triglycerides. The sample types are very diverse and range from biofluids such as serum, urine, saliva, plasma, cerebrospinal fluid and whole blood as well as tissues from biopsy and fine needle aspirates². Several standard panels are used daily in health centers and clinics across the world and are also used in preclinical pharmacology, ADME and toxicology studies. While standard panels are useful, there is strong interest to use custom panels to generate the most informative data on disease development and therapeutic response. For example, a standard lipid panel includes different cholesterol forms and triglycerides. However, apolipoprotein B100 is not included in a typical lipid panel but has been shown to be more specific and predictive to assess cardiac risk compared to LDL alone³. Similarly, apolipoprotein A is a more informative marker than HDL but is not included in a typical panel. However, it is important to note that lipoproteins can be assessed as a secondary panel for patients if needed.

Small and large animals are the models of choice for preclinical studies including mice, rats and nonhuman primates (NHPs) and clinical pathology panels are used to assess the animal health, identify informative markers and monitor disease development and therapeutic response. One of the key aspects of preclinical studies is small sample volumes which can be as low as 10 microliters. Several analyzers are available that can be optimized for small sample volumes but it is important to note that the low sample volumes can introduce variability in the results, so sample processing needs to be performed precisely and carefully. Another important aspect is flexibility in preclinical studies compared to clinical panels. Typically, clinical panels are fixed and not customizable as the workflow from sample collection to processing and analysis are highly regulated. However, non-GLP preclinical studies are open to modification and customization so the analyte panel can be modified depending on the results from other experiments. This flexibility is critical to ensure that the panels are optimized for the study objectives.

The use of clinical pathology panels in preclinical in vivo studies generates data that uses similar processes, instrumentation and data analysis as clinical testing. Due to the translational value of the panels, informative markers identified in preclinical studies can be used to monitor disease progression, therapeutic response and toxicity can be used during clinical trials.

References:

1. <https://stanfordlab.com/content/stanfordlab/en/clinical-pathology/clinical-chemistry.html>
2. <https://www.cpllabs.com/clinicians/general-specimen-types/>
3. <https://my.clevelandclinic.org/health/diagnostics/24992-apolipoprotein-b-test>