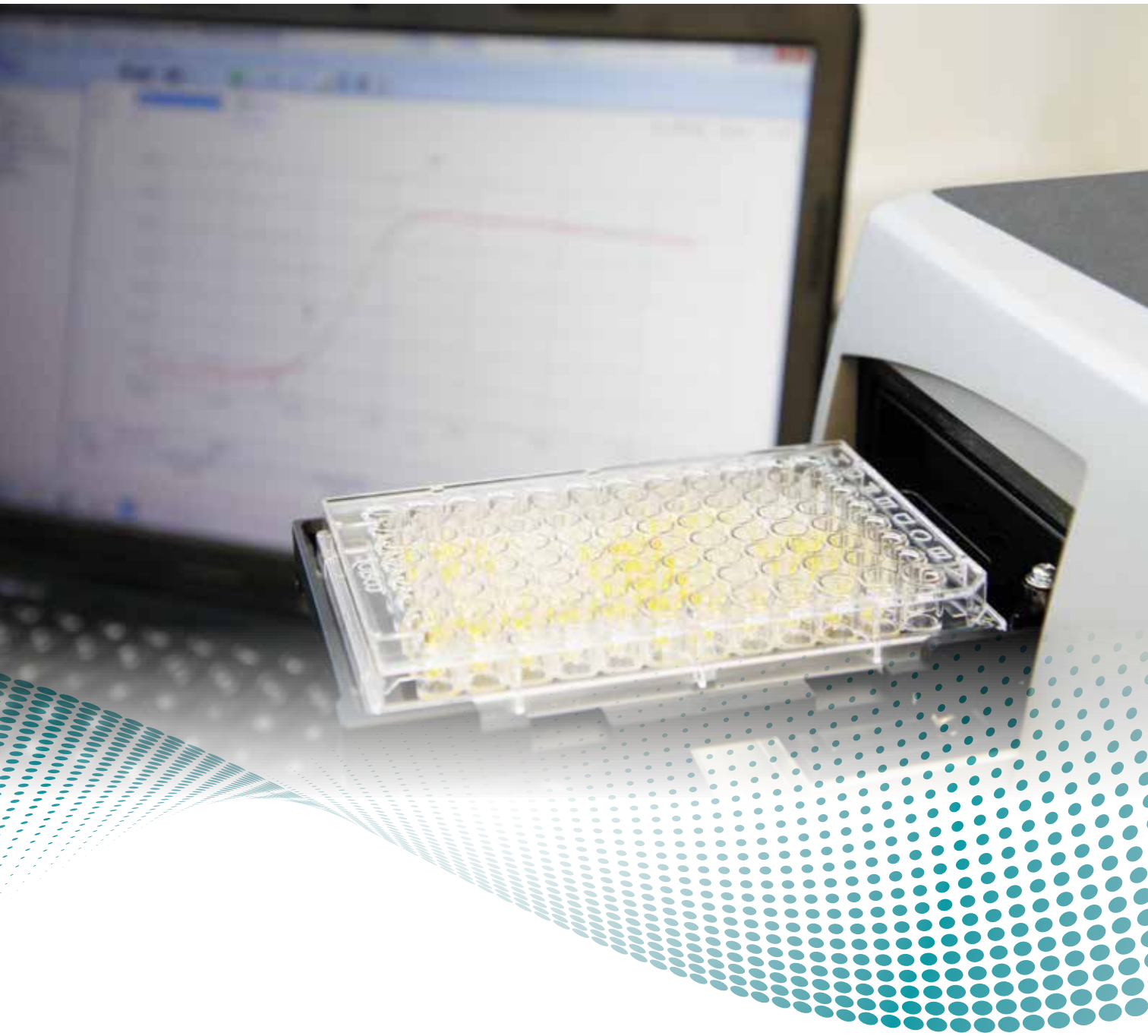
microcoat



Endotoxin and Pyrogen Testing Service

Use the power of diversity

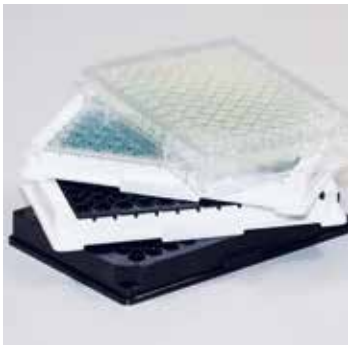
Endotoxin and Pyrogen Testing Service

New analytical methods for pyrogen detection have become available in addition to the classical Limulus Amebocyte Lysate-based assays. These provide considerable advantages especially for difficult-to-test samples. We at Microcoat have established the entire set of commercially available assays, enabling us to identify the true nature of a contamination in a given sample. This helps to avoid false positive and false negative results and provides improved strategies in process optimization and troubleshooting (OOS analysis).

Have the choice among all available tests

- Kinetic Chromogenic LAL Assay
  Standard method based on the Limulus Amebocyte Lysate enzyme cascade. May lead to false positives triggered by the Factor G pathway.
- Recombinant Factor C Assay (EndoZyme®)
  Fluorescent assay based on recombinant Factor C from horseshoe crab but excluding the activation pathway via Factor G.
- EndoLISA®
  ELISA-like fluorescent microplate assay employing a phage-derived LPS capture protein and recombinant horseshoe crab Factor C, suitable for complex samples.
- Monocyte Activation Test (MAT)
  IL-1ß ELISA detecting Toll-like receptor mediated stimulation of human blood monocytes in response to various pyrogens.
- ß-Glucan Assay
  Chromogenic assay based on Limulus Amebocyte Lysate, specific for ß-glucans.





Routine endotoxin and pyrogen testing and method validation

For routine testing (in-process controls, release testing), we use standardized protocols according to the Pharmacopoeia guidelines. When employing alternative methods, we offer method validation according to regulatory requirements.

Project-based service for method development and troubleshooting

Based on our long-lasting experience in endotoxin testing and method development, we offer support in the implementation of alternative tests and sample preparation methods for targets which fail detection with classical LAL testing, e.g.

- Samples containing high concentrations of interfering substances
- Formulations exhibiting endotoxin masking
- Ingredients non-specifically activating the Limulus cascade
- Raw materials missing the required sensitivity
- Solids or medical devices that do not match with classical test routines

Please contact endotoxinservice@microcoat.de for further information.