



BIOANALYTICAL SERVICES

With over 20 years of experience and operating out of two GLP compliant laboratories, SGS Life Science Services is Europe's largest bioanalytical facility (125 staff). Pharma and biotech companies of all sizes have chosen us as their preferred bioanalytical partner. SGS has the **expertise** to both **develop assays from scratch** (including immunoassays) and to **support large scale routine sample analyses**, from pre-clinical and clinical studies.

SERVICES

SGS Life Sciences can assist you with the analysis of :

- In vitro models (cell-based bioassays)
- ADME
- Pre-clinical development
- Early to late phase clinical trials
- Biomarkers
- Immunogenicity testing and analysis of biological products
- Marketed drugs (interactions, reformulations, etc.)

CONTINUOUS FOCUS ON DEVELOPMENT

A dedicated group evaluates assay requests from a strategic and scientific point of view. Methods proprietary to SGS or the sponsor are developed with focus on high-throughput technology (TurboFlow extraction, Multiprobe robots). SGS offers more than **600 validated methods that are ready for use** with very short lead time. Validation criteria follow guidelines from FDA (May 2001) and the Crystal City Conference (May 2006).

All validations are tailored to specific program requirements.

BIOMARKERS

SGS has also actively pursued the assay development & validation of innovative biomarkers, with the support of our clinical teams. SGS has coupled RIA with HPLC to secure further selectivity in biomarker analysis and have developed LC-MS/MS methodologies to measure steroidal and hormonal substances in the low picogram range. Multiplexing on the luminex platform (Biorad Bioplex 200) is also a focus of SGS.

Biomarker development for various therapeutic areas includes:

- Cardiovascular
- Diabetes
- Inflammation
- CNS

LARGE CAPACITIES FOR ON-TIME DELIVERY

RAPID TURN-AROUND BIOANALYSIS FOR ASCENDING DOSE STUDIES, AND HIGH-VOLUME ANALYTICAL THROUGHPUT FOR LARGE SCALE CLINICAL STUDIES

In order to support the bioanalysis of various classes of compounds, SGS offers a large range of techniques and methods. In addition, our exceptional sample processing and analytical capabilities, combined with our scientific expertise, enable us to provide rapid high-volume bioanalysis:

- Mass spectrometry: 24 LC-MS/MS, 5 GC-MS
- Immunoanalysis: RIA, ELISA measurements for routine analysis of a variety of molecules including therapeutic proteins
- Classical HPLC: 5 HPLC systems equipped with UV, fluorescence and electrochemical detectors
- UPLC technology: one instrument, equipped with a PDA detector
- Automated sample preparation using robotics (Multiprobe) or turbulent flow technology (Cohesive)
- Large sample storage capacity combined with excellent sample tracking (400 000 sample storage and equivalent backup))

INNOVATIVE TECHNOLOGIES

- Customized immunoassay development and validation for New Biological Entities
- Experience in immunogenicity testing, using plate-based and cell-based assays
- Flow cytometry capabilities operating in a GLP environment

WITH THE RIGHT QUALITY

- Two GLP compliant bioanalytical sites since 1990/91
- Each site is periodically inspected by the relevant local agency
- Audited by FDA
- 21 CFR Part 11 compliance program
- Independant QA group responsible for project and facility audits and GLP training

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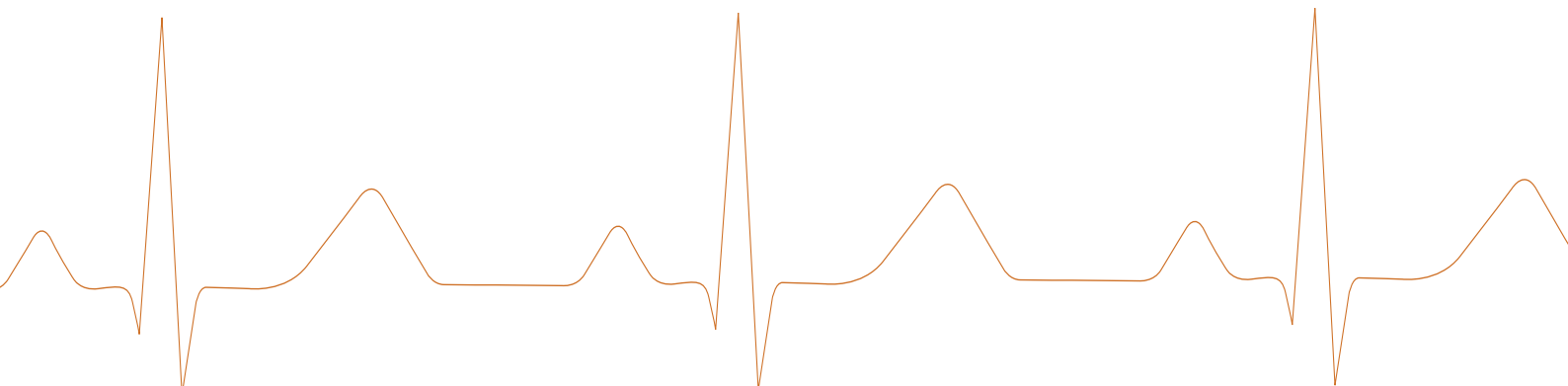
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WHEN YOU NEED TO BE SURE

SGS