

# Biomarkers at PRA's Laboratories for Drug Development

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## Introduction

PRA understands that biomarker assays are not PK assays and that their Context of Use (CoU) must be defined prior to setting up a method. Since most often no representative blank matrix can be obtained and reference standards are often recombinant versions of the real analytes, biomarker assays require a unique approach. It is of utmost importance to understand the biology of the biomarker to be able to build a high-quality assay.

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## Innovation

As the regulatory requirements for biomarker measurements are not as clear as for PK or ADA assays, it is important to consider what level of assay qualification or validation is required. PRA has a set of biomarker SOPs in place providing flexibility for the level of assay characterization to be applied and the acceptance criteria to meet the assay's CoU. Also, the way data are reported can be adjusted to meet your project needs.

We routinely monitor biomarker assay performance using true matrix samples to ensure delivery of high-quality data. This allows us to show the assay was performing consistently for the entire duration of the analytical study, even when critical reagents or commercial kits went through lot changes. The levels of these endogenous QC samples and the number of repeats are flexible and open for discussion with Sponsors.

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## Capabilities and Equipment

Equipment is shared with PK, ADA, Flow Cytometry and Clinical Chemistry departments. Therefore the biomarker team has access to state-of-the-art LC-MS/MS equipment, several Ligand Binding Assay (LBA) platforms (including ELISA, ECLIA, ELLA, CBA and SMC Pro), qPCR, and Flow Cytometry instruments.

In addition, PRA's analytical laboratory has access to the internal Clinical Chemistry Laboratory of the CRU, which enables us to offer analysis of more routine biomarkers in a highly standardized and affordable manner.

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## Capacity and People

Our laboratories are of sufficient size to absorb large studies with many different biomarkers using different technologies. We have a team of skilled project managers and scientists that are trained to understand the challenges that biomarker analysis bring. They are supported by local and global internal experts who are overseeing that procedures are used in a consistent manner and that good science serves as the basis for all our biomarker work.



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## Experience

Over the years, we have worked on many biomarker assays, ranging from simple kit implementations to long-running research projects in collaboration with pharma Sponsors. We have the capability to run multiplex assays where possible, for example, using our ELLA platform that is a robust and affordable way to measure up to 8 different biomarkers from a minute sample.

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## Contact Our Expert

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