

## QUESTIONNAIRE – DEVELOPMENT OF A MONOCLONAL ANTIBODY BASED PHARMACOKINETIC ASSAY AGAINST A PROTEIN

*Please fill out this form as a prerequisite for planning and specifying the major steps of the respective project.*

*It will also be used as the basis for quotation and further discussion of project details.*

*All information provided including the client information at the end of this questionnaire will be treated strictly confidentially. A nondisclosure agreement can be signed upon request.*

### 1. ANTIGEN INFORMATION – PROTEIN

**Protein name:** \_\_\_\_\_

**Protein family:** \_\_\_\_\_

**Protein function:** \_\_\_\_\_

**Origin of protein:**  Human

Other, please specify: \_\_\_\_\_

**Please specify species information:** \_\_\_\_\_

**Expression system:**

Please specify the expression system: \_\_\_\_\_

**If recombinantly expressed, is the protein a fusion protein?**

Yes

No

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**If yes, which tag has been used as fusion partner:**

His-Tag, please add sequence of the tag: \_\_\_\_\_

GST-Tag, please add sequence of the tag: \_\_\_\_\_

Other, please specify tag sequence and provide molecular weight (in kDa): \_\_\_\_\_

**Please provide molecular weight of the antigen protein (in kDa):** \_\_\_\_\_

**Purity:** \_\_\_\_\_

**Is the protein available in buffer?**

Yes

No

**If yes, please answer the following questions:**

Soluble

Precipitated

**Does the buffer contain a preservative?** (BioGenes does not recommend the use of preservatives)

No

Yes. Please specify preservative: \_\_\_\_\_

**Homology to mouse:**

Yes

No

**If yes, please indicate degree of homology:**

< 70%

> 70%

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### 2. ANTIBODY DEVELOPMENT

#### 2.1 CROSS-REACTIVITIES

**Should cross-reactivities be included or excluded?**

Yes                       No                       I am not sure yet

**If yes, please indicate kind of selection:**

Positive                       Negative                       Cross-reactivity test for characterization only

**Are cross-reactants (commercially) available?**

Yes                                       No

**Are further information about cross-reactants available?**

Yes                                       No

Please provide name if applicable: \_\_\_\_\_

### 3. INTENDED ADDITIONAL PURPOSES OF THE DEVELOPED MONOCLONAL ANTIBODIES

**Western Blot**                       Yes                       No                       I am not sure yet

**ELISA**                                       Yes                       No                       I am not sure yet

**Immunohistochemistry**                       Yes                       No                       I am not sure yet

**Immunofluorescence assay (IFA)**                       Yes                       No                       I am not sure yet

**Immunoassay development**                       Yes                       No                       I am not sure yet

**Other, please specify:** \_\_\_\_\_

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### 4. PREPARATION OF CELL CULTURE SUPERNATANT FOR TESTING

**Do you wish us to add a preservative to cell culture supernatant before shipment?**

- Yes, please add the following:  No
- NaN<sub>3</sub>  ProClin  Other, please specify: \_\_\_\_\_
- 0.2 µm filtrated  Not filtrated

### 5. INFORMATION ABOUT THE INTENDED PHARMACOKINETIC ASSAY

**Please estimate the expected determination range of the ELISA**

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**Please estimate the expected life span of the assay and the number of tests (per year)**

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**Did you already contact a CRO? If yes, please provide details**

An early contact with CRO is necessary in order to discuss specific requirements and plans regarding the assay.

If no CRO has been selected yet, BioGenes recommends its preferred partner for these services FyonBio, Berlin/Germany, [www.fyonibio.com](http://www.fyonibio.com).

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### **Are serum samples already available (i.e., from early stages of clinical trials)?**

Serum samples are necessary for the characterisation and selection of the antibody pairs for the assay.

If no serum samples are available, please provide information about patient specification (i.e., gender, age, disease, additional medication). BioGenes will purchase sera with the respective specifications and spike them with the drug.

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## **6. FURTHER ASSAY INFORMATION**

### **6.1 ESTABLISHMENT AND IMPLEMENTATION OF AN ASSAY CONTROL SAMPLE**

Yes                       No                       I am not sure yet

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**7. PLEASE SHARE ADDITIONAL INFORMATION ON:**

Planned timelines

Purchasing planned directly or via a  
purchasing platform (e.g. Scientist.com)

How did you find out about BioGenes?

Other information not previously  
covered?

**CLIENT INFORMATION**

Company/Institution name:

Contact person:

Address:

Phone:

Email:

Date: