

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

*Please fill out this form as a prerequisite for planning and specifying the major steps of your 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. ANTIBODY INFORMATION

#### 1.1 GENERAL INFORMATION

**Name:**

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**Isotype, and subclass (Heavy chain, light chain, genetic modification):**

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**Antibody is available as:**

Whole molecule

F(ab')<sub>2</sub>-Fragment

Fab-Fragment

scFv/Fv-Fragment

Other, please specify:

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**Fragmentation requested?**

Fab-Fragment

F(ab')<sub>2</sub>-Fragment

No

I am not sure yet, please provide advice.

**The antibody or functional parts thereof are derived from which host species:**

Human

Other, please specify:

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**Modification of the antibody:**

Humanized

Chimeric, please specify:

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Antibody conjugate

Other, please specify:

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### 1.2 ANTIBODY-DRUG-CONJUGATE INFORMATION (IF APPLICABLE)

Please specify the structure of the conjugate (hapten), including the linker, or specify the group that is used for conjugation to the antibody, respectively (if applicable):

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Please enter additional information on structure or characterization of the drug substance if available:

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Is the drug substance a cell toxin?

No                       Yes, please specify:

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### 1.3 ANTIBODY PREPARATION

Is the antibody, or the antibody-conjugate available in buffer?

Yes     No

Soluble     Precipitated

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

No                       Yes, please specify preservative:

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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 the kind of selection:**

Positive                       Negative                       Cross-reactivity test for characterization only

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

Yes                                       No

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

Yes                                       No

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

#### 2.2 CHARACTERIZATION OF MONOCLONAL ANTIBODIES

**Identification of monoclonal anti-idiotypic antibodies recognizing the antibody binding site requested? (Competitive ELISA with original antigen)**

Yes                                       No

**Are there antibodies against the selected antigen commercially available?**

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

Which additional immunochemical techniques are to be used with the antibodies to be developed?

- |                                       |                              |                             |  |
|---------------------------------------|------------------------------|-----------------------------|--|
| <b>Western Blot</b>                   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> I am not sure yet |
| <b>ELISA</b>                          | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> I am not sure yet |
| <b>Immunohistochemistry</b>           | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> I am not sure yet |
| <b>Immunofluorescence assay (IFA)</b> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> I am not sure yet |
| <b>Immunoassay development</b>        | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> I am not sure yet |

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

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

Should preservatives be added to the cell culture supernatant or not?

- Yes, please add the following:
- |   |  |   |
|---|--|---|
| <input type="checkbox"/> NaN <sub>3</sub> | <input type="checkbox"/> ProClin       | <input type="checkbox"/> Other, please specify: _____ |
| <input type="checkbox"/> 0.2 µm filtrated | <input type="checkbox"/> Not filtrated |   |

### 5. INFORMATION ABOUT THE INTENDED PK ASSAY

Please estimate the required detection range of the ELISA

Please estimate the expected shelf life 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 characterization and selection of the antibody pairs during assay development.

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 PROVIDE 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?

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**CLIENT INFORMATION**

Company/Institution name:

Contact person:

Address:

Phone:

Email:

Date:

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