

## QUESTIONNAIRE – PERFORMANCE STUDY

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 confidential. A nondisclosure agreement can be signed upon request.

### 1. INFORMATION ABOUT ASSAY PURPOSE

**What is your specific request? / What is the purpose of the Performance Study?**

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### 2. PERFORMANCE STUDY INFORMATION

#### 2.1 PERFORMANCE STUDY USING BIOGENES' GENERIC |360-HCP ELISA ANTIBODIES/KITS

##### E. coli|360 HCP ELISA

- Type A 2G       Type C  
 Type D 2G       Type E  
 all of the above

##### CHO|360 HCP ELISA

- Type A       Type B  
 Type C       Type D  
 all of the above

#### 2.2 PERFORMANCE STUDY USING ANOTHER HCP ELISA ANTIBODY/KIT

Which antibody/ ELISA kit?  
Please specify:

What is the antibody origin  
(species)? Please specify:

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**The anti-HCP antibody will be provided as:**

- Affinity purified       Total IgG

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**Concentration of the provided antibody [ $\mu\text{g/ml}$ ]:** \_\_\_\_\_

**Working concentration/ dilution factor of the antibody in Western Blot:** \_\_\_\_\_

### 3. SAMPLE INFORMATION

#### 3.1 SAMPLE CHARACTER

Cellular lysate                       Cell culture supernatant                       Other (please specify):

\_\_\_\_\_  
**Estimated protein concentration and method of determination (please specify):**

\_\_\_\_\_  
**Buffer composition (please specify):**

\_\_\_\_\_  
**What is the nature of the drug substance (please specify)?**

Recombinant protein                       Humanized antibody  
 Other, please specify:

#### 3.2 ANTI-DRUG ANTIBODY CHARACTERISTICS

**Are you able to provide a drug substance-specific antibody (anti-drug antibody)?**

No                       Yes                      If yes, the antibody origin is (species):

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**The anti-drug antibody will be provided as:**

- |  |  |
|--|--|
| <input type="checkbox"/> Affinity purified   | <input type="checkbox"/> Total IgG           |
| <input type="checkbox"/> Monoclonal antibody | <input type="checkbox"/> Polyclonal antibody |

**Concentration of the provided anti-drug antibody [ $\mu\text{g/ml}$ ]:**

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**Working concentration/ dilution factor of the anti-drug antibody in Western Blot:**

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### 4. FURTHER PERFORMANCE STUDY CHARACTERISTICS

**A Mock Sample is available:**

- |                              |                             |
|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|------------------------------|-----------------------------|

**The 2D analysis of HCP coverage should be performed by:**

- |  |
|--|
| <input type="checkbox"/> 2D Western Blot   |
| <input type="checkbox"/> Immunoaffinity chromatography (IAC) and subsequent 2D DIGE analysis |

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### 5. PLEASE PROVIDE ADDITIONAL INFORMATION ON:

Planned timelines

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

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How did you find out about BioGenes?

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Other information not previously covered

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### CLIENT INFORMATION

Company/Institution name:

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Contact person:

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Address:

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Phone:

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Email:

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Date:

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