

Custom Conjugation Questionnaire

CUSTOM CONJUGATION QUESTIONNAIRE

Although completion of this form is not mandatory we would be grateful for the following information regarding the materials being sent for conjugation. The information you provide will help us to deliver the gold conjugate you require, and any further information you have would also be appreciated. Please note that BBI Custom Conjugation Service does not follow BBI Design Control Procedure.

Please try to return the completed form ahead of any materials to <u>markpendered@bbisolutions.com</u>. This gives us opportunity to review the form and clarify any concerns prior to shipment/receipt of materials.

A minimum of 3mg of antibody is normally required for a custom conjugation. Please also note the section regarding antigens for testing of the gold conjugate.

BBI Use Only- Code:

Please mark all parcels for the attention of Mark Pendered and ship to: BBI Group, Unit 2, Parkway,Pen-y-Fan Industrial Estate, Crumlin,NP11 3EF, UK

CUSTOMER DETAILS				
Company Name				
Contact Name and Position/Role				
Telephone Number				
Fax Number				
Email Address				
Order Number				
Which QA system do you comply with?	ISO13485 / 21CFR Part 820 / NA * *(delete as applicable)			

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Custom Conjugation Questionnaire

MATERIAL FOR LABELLING DETAILS

Further information about the test system that	
will be used in your laboratory.	
What is the intended use of the conjugate(e.g -	
Lateral flow)	
Also, how will you assess the material we send	
you? (e.g –Dry down testing, liquid testing)	
Have you worked with gold colloid before either	
in-house or commercial.	
Material Provided – full name	
Material type – antibody or protein etc	
Indicate if Monoclonal/Polyclonal	
Indicate Purification Method (Protein A/	
Protein G, ammonium sulphate precipitation,	
affinity purified)	
Host animal (goat, rabbit, mouse, sheep etc)	
Molecular Weight of protein if not an antibody	
Product Code	
Lot Number	
Expiry Date (if known)	
Amount Provided (Min. 3mg)	
Volume & Concentration. (min concentration	
greater than 1mg/ml)	
Vehicle Buffer (Please indicate any	
preservative present) Please avoid thimerosal	
where possible	
Storage Requirements	
(Room Temperature / 4°C/ -20°C/ -80°C)	
Gold size required (nm)	
Final Volume required	
Final OD required at 520nm	
Target Sensitivity	
Final buffer required if different from 2mM Borax	
+ 0.095% sodium azide at pH7.2/pH8.2/pH9.0	
Delivery Date required	
Has this material been supplied to BBI	YES/ NO
previously?	,
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CAPTURE MATERIAL DETAILS If a sandwich assay is being developed, we will need a minimum of 1mg of capture antibody to test the conjugate on a membrane based system. Material Name Material Type Antibody/ protein/ other If antibody indicate if Monoclonal / Polyclonal Etc.) Product Code Lot Number Expiry date (if known) Amount Provided (Min. 1mg) Volume (ml) Concentration (mg/ml) (Preference of 1mg/ml or greater) Vehicle Buffer (Please indicate any preservative present). Please avoid thimerosal where possible Storage Requirements (Room Temperature / 4°C/ -20°C/ -80°C) Has this material been supplied to BBI YES/ NO previously?

CONTROL/ANTIGEN/ ANALYTE DETAILS

In order for BBI to provide the best quality gold conjugates we need to develop a test system using the appropriate antigen. Approx. 100-200ug/ml at 100ug/ml (minimum) is normally required. Please note, we are not equipped to handle any material more hazardous than Biohazard level 2.

Material Provided	
Product Code	
Lot Number	
Expiry Date (if known)	
Amount Provided Volume & Concentration	
Vehicle Buffer (Please indicate any preservative present)	
Storage Requirements (Room Temperature / 4ºC/ -20ºC / -80°C)	
Has this material been supplied to BBI previously?	YES/ NO





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<u>Appendix</u>

Title

Health and Safety Questionnaire. To be completed before the submission of bio hazardous materials for conjugation or for any other process at BBI.

Please answer the following questions as completely as possible. This will enable us to risk assess the materials that are being sent to BBI for any potential Biohazard.

Please note that BBI cannot receive bio hazardous materials above Class II. Class II materials are as defined by "Categorisation of biological agents according to hazard and categories of containment" latest edition. Advisory Committee on Dangerous Pathogens. HSE. ISBN 0 7176 1038 1.

	Control/Antigen/Antibodies of human origin
Material Type: e.g. antibody,	
serum, chemical:	
Material source: e.g. Human,	
animal, chemical.	
	
Biohazard category:	
Have any materials of human	
origin been tested for HIV, Hep	
B, HCV or any other disease	
(please specify):	
Have the materials been	
attenuated in any way? e.g.	
heat treatment or U.V.	
sterilisation:	
List any special disposal	
requirements for the material:	
C.A.S. number if available:	
MSDS available yes/no-delete	Yes / No*
as applicable	
If yes please include with	
shipment or attach	
If no please comment on the	
rationale for choosing	
biohazard classification	
Specify any additional	
information regarding the	
nature of the material (use a	
separate sheet if necessary):	

The above information is, to the best of my	Signed:	Date:
knowledge, a true and representative description		
of the material submitted to BBI for processing:		

USA: 1-800-423-8199 | International: +44 (0)1495 363 000 | info@bbisolutions.com | www.bbisolutions.com