Customer-Supplied Sample Process

Samples may **not** be shipped to Takara Bio USA, Inc. (TBUSA) until Parts 1, 2 and 3 are completed and emailed to TBUSA\_QA\_Dept@takarabio.com for review and approval. **Please return the completed Word file, as well as a PDF copy of the signed completed form.**

If necessary and where applicable, TBUSA will communicate to the customer any instructions relevant to the amount and/or concentration of the sample material(s) to be sent (i.e., X number of vials containing a minimum of 1 x 106 viable cells/vial of each cell line to be analyzed, etc.).

The TBUSA QA team will review the information and communicate with the customer to resolve open questions, as necessary. When the sample(s) are approved for shipment, TBUSA QA will complete and sign Part 4. QA will email a signed copy of this form, plus a shipping label to the customer to prepare their samples for shipment. The shipping label provided is for overnight courier charged to TBUSA’s freight account. For questions or additional information, contact TBUSA\_QA\_Dept@takarabio.com.

**IMPORTANT CUSTOMER RESPONSIBILITY**:

**Samples must be free of pathogens and mycoplasma.** **NOTE: Mycoplasma status is relevant only to those samples that are to be cultured for any length of time within the TBUSA facilities.**

* If you have conducted safety and sterility testing on your samples, please provide results from an accredited laboratory as indicated in Part 2.
* If you have not conducted safety and sterility testing, see Part 2 for information on recommended accredited laboratory testing services.

**Please note the types of potentially infectious materials listed below:**

## Blood- human blood, human blood components, and products made from human blood.

## Bloodborne pathogen – pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens can include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

## Other Potentially Infectious Materials (OPIM) –

## The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

## Any unfixed tissue or organ (other than intact skin) from a human (living or dead)

## Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

## Cell, tissue, or organ cultures from humans or experimental animals.

## Blood, organs, or other tissues from experimental animals

## Culture medium or other solutions.

**Part 1: Sample/Customer Information – Customer to Complete**

**Name of Customer:**

**Quote Number (if applicable):**

**TBUSA Order Number (if applicable):**

**Customer PO Number (if applicable)**:

**Instructions:**

* **Indicate N/A for any information that does not apply to this sample.**
* **Collection of cells should be performed aseptically to prevent contamination of samples**.
* All the vials must **be clearly labeled with the original name of the cell material and number of cells per vial.**
* **If you are sending samples with the ESM Collection Kit (Cat #634775), follow instructions detailed in the user guide for labeling and submitting samples.**
* **If sending more than one type of material sample, provide additional information for each sample in the Comments section below, or make additional copies of this form with each individual sample information.**

|  |  |
| --- | --- |
| Original name of cell material on vial label:**NOTE**: If you are sending samples for the **ESM Collection** **Kit** (Cat #634775), simply write a note here to refer to the **ESM Sample Information Sheet** submitted.  |  |
| Freezing medium used for cell material: |  |
| Species: |  |
| Gender (if applicable): | [ ]  Male [ ]  Female [ ]  N/A |
| Origin (blood, fibroblast, CD34+): |  |
| Short Description: |  |
| Genetic modified microorganism (GMM): | [ ]  Yes [ ]  No |
| If GMM = yes, short description & classification: |  |
| Frozen cells will be shipped on dry ice, stored @ LN2 | [ ]  Yes [ ]  No |
| Indicate total number of vials to be shipped and number of shipping boxes. |  |

**Comments: Provide additional information below, if necessary.**

**Part 2: Customer’s Sample Safety and Legal Responsibility**

**NOTE: TBUSA will not be able to accept samples that are not free from pathogens or mycoplasma.**

If safety testing has **not** been performed, we recommend the following services from the accredited laboratory listed below.

IDEXX BioResearch, 4011 Discovery Drive, Columbia, MO 65201

Tel: 800-669-0825, Website: [http://www.idexxbioresearch.com/biological-testing](http://www.idexxbioresearch.com/biological-testing%20)

* For human pathogen and mycoplasma testing – select h-IMPACT I (*lead time: 3-5 business days*)
* For sterility testing – select Profile 2C Centrifugation Concentration Method (*lead time: up to 14 business days*)

**Instructions:**

* **If Yes, reference the contract number or attach document evidence. Attach mycoplasma and sterility testing test results or provide explanation on how this information can be verified.**
* **If No, Unknown, or N/A, provide a brief explanation**.

|  |  |  |
| --- | --- | --- |
| **Topic** | **Yes, No, N/A, Unknown** | **Explanation** |
| 1. Service Agreement in place | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 2. CDA (or MTA) in place | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 3. Any known ethical requirements?  | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 4. Any known regulatory requirements? | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 5. Human pathogen testing complete | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 6. Human mycoplasma testing complete | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |
| 7. Sterility testing complete | [ ]  Yes [ ]  No[ ]  N/A [ ]  Unknown |  |

**Part 3: Customer’s Signature and Confirmation of Accuracy**

**The information provided on this form is true and accurate to the best of my knowledge.**

|  |  |
| --- | --- |
| Printed Name |  |
| Contact Information (email and phone) |  |
| Company Name |  |
| Company Address |  |
| Signature |  |
| Date |  |

**TBUSA INTERNAL USE ONLY: Parts 4 - 6**

**Part 4: QA Review of Sample Information**

**For “No” answers, please provide comments below.**

|  |  |
| --- | --- |
| Sample information complete | [ ]  Yes [ ]  No |
| Business documents 1-2 confirmed by Corp Dev | [ ]  Yes [ ]  No |
| Regulatory documents 3-4 confirmed by QA | [ ]  Yes [ ]  No |
| Safety testing required (items 5-6) | [ ]  Yes [ ]  No |
| Sterility Testing required (item 7) | [ ]  Yes [ ]  No |
| Printed Name of QA Associate |  |
| Date Reviewed and Approved |  |

**Comments:**

**Part 5: Sample Receipt – To be Completed by TBUSA Staff**

Receiving Staff:

|  |  |
| --- | --- |
| Printed Name of Receiver |  |
| Date of Receipt |  |
| Delivered to (name of employee) |  |
| Date Delivered |  |

Field Support or other relevant TBUSA staff:

|  |  |
| --- | --- |
| Location of Sample(s) |  |
| Storage Temperature |  |
| Number of samples received |  |
| Condition of samples | [ ]  At desired temp [ ]  Not at desired temp |
| Labels complete and intact | [ ]  Yes [ ]  No |
| Samples approved for processing | [ ]  Yes [ ]  No |
| Samples must be destroyed (see Part 6 and provide instructions in the Comments section below) | [ ]  Yes [ ]  No[ ]  N/A |
| Printed Name of TBUSA Staff |  |
| Date Reviewed and Approved |  |

**Comments:**

**Part 6: Confirmation of Sample Destruction – To be completed by EH&S (if applicable)**

|  |
| --- |
| **Samples contaminated and must be destroyed** [ ]  N/A |
| EH&S notified of sample to be destroyed (enter date) |  |
| Customer notified of sample destruction (enter date) |  |
| Rejected samples autoclaved (enter date) |  |
| Disposal & destruction completed by (enter name and date) |  |

**Comments:**