# Supplementary Data

## Supplementary Table 1. Steps to Prevent Contamination of Plasma and Urine Samples

| Precautions                        | Prevention steps                                                                                                                                                                                                 |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Priming**                        | Separate rooms should be used for priming of the device, inhalation of study drug, and PK procedures.  
Priming of the Respimat® inhaler should take place in a different room from where the drug inhalation takes place.  
The patient should not be present in the same room during the priming procedure of the Respimat® inhaler.  
Study personnel should wear laboratory coats during priming and remove them after.  
Study personnel should handle the Respimat® inhaler while wearing gloves, and then change and discard their gloves immediately after priming. |
| **Inhalation**                     | Patients and study personnel should handle the Respimat® inhaler while wearing gloves, and then change and discard their gloves immediately after a patient completes inhalation.  
Study personnel should cover the site of cannulation (by a short piece of elastic bandage with affixed clips) while the patient is in the room where inhalation is planned.  
The covering should be removed only once the patient has been moved to the room where blood sampling is planned.  
No more than one patient should be in the inhalation room at the same time. |
| **Preparing the blood, plasma, and urine samples** | The PK procedures (blood and urine sampling or sample preparation) should not take place in the same room where priming of the Respimat® inhaler or drug inhalation is taking place.  
Only study personnel who are not present during priming of the Respimat® inhalers in the priming room, and who are not present during drug inhalation in the inhalation room, should be allowed to collect and process blood, plasma, and urine samples.  
Study personnel should immediately discard the covering; before drawing the post-dose blood samples, study personnel should then wash their hands and put on fresh gloves (i.e., before any containers for PK samples are handled).  
They should change their gloves as soon as the PK samples are obtained.  
They should also change their gloves as soon as the plasma is obtained from the blood.  
Patients should be advised to wash their hands thoroughly before touching the urine containers and also after finishing urine collection.  
Study personnel must change their gloves before handling urine samples.  
PK tubes, pipettes, etc. should not be stored in the same room where drug inhalation is taking place.  
Plasma and urine containers should be stored closed and should be opened only if necessary for collection. |

PK, pharmacokinetic.