



Value of inhaled treatment with  
aztreonam lysine in bronchiectasis

## Lab Samples



## Blood Samples

- Blood samples should be obtained as per Laboratory Manual
- NHS samples Visit 1:
  - Results should be reviewed by a doctor on the Delegation Log in a timely manner
  - A copy of the results signed and dated by a delegated doctor must be filed in the participant's medical notes
- Research samples Visits 2, 5, 6 and any unscheduled visit:
  - Processed as per Laboratory Manual
  - Stored at site and transferred to University of Dundee at the end of the trial

## Pregnancy Test

### Visit 1

- Blood should be sent to local NHS lab for a serum pregnancy test

### All other visits

- Urine pregnancy test should be carried out
- A copy of the results signed and dated by a delegated doctor should be filed in the participant's medical notes.

## Sputum samples

- Sputum samples should be obtained as per Laboratory Manual

### Visit 1

- *P. aeruginosa* in sputum, bronchoalveolar lavage or another airway sample at least once in the **12 months prior to screening** and
















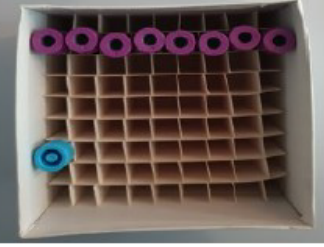




A sputum sample that is culture or PCR positive for *P. aeruginosa* sent at the screening visit and **within 35 days of randomization**. Sputum sample should be sent to your local lab for culture.

OR






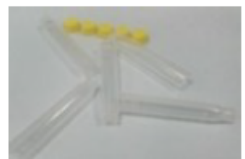










- A participant who does not have a positive sample for *P. aeruginosa* in the previous 24 months may submit further samples, during the 35-day screening period. If further samples are positive for *P. aeruginosa* then inclusion criteria will be deemed met and the patient may be enrolled.

Results should be reviewed by a doctor on the delegation log, signed, dated and a copy filed in the participant's medical notes.

# Research Samples Visits 2, 6 & unscheduled (baseline, month 12 & as required)

Tubes	Invert tube	Allow to stand	Centrifuge	Transfer	Store	Freeze at <b>-80C</b>
 <p>4-5 mls blood required.</p>	 <p>5 times</p>	 <p>Min 30 minutes Max 60 minutes</p>	 <p>1000g for 15 mins</p>	 <p>MAX 0.5ml per Fludix tube</p>	 <p>Up to 5 Fludix tubes</p>	
 <p>4 mls blood required</p>	 <p>8-10 times</p>	 <p>Max 60 minutes</p>			 <p>Freeze tube</p>	
 <p>Nasal swab</p>		 <p>Max 60 minutes</p>			 <p>Freeze tube upright</p>	
 <p>Sputum sample</p>		 <p>Max 60 minutes</p>			 <p>Freeze pot</p>	

# Research Samples Visit 5 (24 weeks/months 6)

Tubes	Invert tube	Allow to stand	Centrifuge	Transfer	Store	Freeze at <b>-80C</b>
 <b>4-5 mls blood required.</b>	 5 times	 Min 30 minutes Max 60 minutes	 1000g for 15 mins	 <b>MAX 0.5ml</b> per Fludix tube	 Up to 5 Fludix tubes	
 <b>4 mls blood required</b>	 8-10 times	 Max 60 minutes			 Freeze tube	
 <b>Sputum sample</b>		 Max 60 minutes			 Freeze pot	

## Sample Labelling

- All study samples should be labelled with labels provided
- Each sample label must be completed with the sample ID and date of collection
- Sample ID is made up of:
  - site number – participant number – visit number – sample number
  - e.g. sample ID 01-001-02-01 would be site 01 – participant 001- visit 02- sample number 01
  - Date format DD/MM/YYYY
- Samples should be stored in separate boxes according to sample type.
- Storage boxes should be labelled with trial title, site number, sample type and box number.
- Sample type, date of collection and storage location should be recorded on the VitalBE Sample Log.

### VitalBE

Site: \_\_

Participant no: \_\_\_\_

Visit: \_\_ Date: \_\_\_\_

Sample: \_\_\_\_\_