

## PreVent-ACaLL instruction

## Collection of study samples

## TMF/ISF section 19

## 1. Booking of study visit

- a) Book study visit with patient
- b) Notify date of visit to sponsor at least 1 week in advance by completing eCRF 'Booking of study visit' in REDCap  
For the screening/baseline visit, the eCRF can be found in the pre-screening project
- c) For sites where samples are picked up by courier: Courier must also be booked (for further details see the Laboratory Manual or REDCap)

## 2. Preparation of study visit


Study visit preparation can be done whenever it suits you the best but must be done before sample material is collected into the tubes.

- a) Prepare PreVent-ACaLL labels to place on sample tubes (make sure the label match with correct study visit and sample content)
  - i. Fill in participant ID (PID) and sampling date
  - ii. Place label on correct tube
- b) Place barcode labels on the TruCulture (TC), Feces (FE) and Saliva (SA) tubes (make sure the barcode label match with correct sample content, study visit and sample ID)
- c) Fill out Specimen & Shipping Logs with PID and sampling date

PreVent-ACaLL	BASELINE
<b>PID:</b> _____ - _____	
<b>Date:</b> _____ - _____ - _____	
Peripheral blood - FLOW	

← Study visit

← Sample content

Specimen & Shipping Log	
PreVent-ACaLL	Site
	
PAC-TC-BL-000	












## 3. Study visit (sampling day)

1. For sites where samples are not picked up by courier: Arrange sample pick up (for further details see Laboratory Manual or local instructions)
2. Collect samples from participant and fill out Specimen & Shipping Logs with sampling time **NB: TruCulture must be sampled last!!**
3. Take a copy of all the completed Specimen & Shipping Logs
4. Pack the collected samples as indicated in the Laboratory Manual (tubes in the biological bags which must be packed in the pre-labeled plastic bags together with the matching Specimen & Shipping Log)
5. Ship samples as described in the Laboratory Manual for your country/site

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	Screening	C1D8	C1D15	C2D1	C3D1	EOT 12 weeks	24 weeks	1 year	2 years	Progressive disease
Bone marrow – flow 	X						X			X
Bone marrow – biobank 	X						X			X
Peripheral blood – flow 	X					X	X	X	X	X
Peripheral blood – Biobank 	X	X	X	X	X	X	X	X	X	X
Lymph node biopsy										X
Peripheral blood – TruCulture 	X					X	X			X
Peripheral blood – DuraClone 	X					X	X			X
Saliva – microbiome 	X					X	X			
Feces – microbiome 	X					X	X			
Skin swab – forearm 	X					X	X			
Skin swab – axillary 	X					X	X			
Buccal swab 	X									