



Rigshospitalet



PreVent-ACaLL

Laboratory Manual

For sites

Version 4.0

Carsten U Niemann, MD, PhD

A handwritten signature in black ink, appearing to be 'C. Niemann'.

22MAR2023

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Summary of changes from previous version

Besides minor changes to the text in the laboratory manual, following have been changed in the new version:

- Section 10.3.2 Transport instructions has been updated
- Pictures in section 10.1.1 and 10.3.1 Packing of study samples have been updated
- Study visits should take place preferably on Tuesdays or Wednesdays for sites outside Denmark. A study visit can take place a Monday if not at all possible for the participant to come in Tuesday or Wednesday. This is due to transport of the transport material since this must be shipped from Denmark the day before the study visit. If the study visit take place on a Monday, the transport material must be shipped from Denmark Friday the week before, which is not ideal for the temperature elements.
- Courier contact information has been deleted, since sponsor is the one booking the transport for the samples that must arrive to Copenhagen within 24 hours.

1 Introduction

The purpose of this laboratory manual is to outline the procedures that will be undertaken at sites for the collection and transport of study samples for the PreVent-ACaLL study.

This Laboratory Manual must be used alongside the current version of the PreVent-ACaLL study protocol. This document ONLY covers the sample collection aspects of the protocol. The manual will be updated throughout the course of the trial if amendments become necessary.

The PreVent-ACaLL study collects biological material from CLL patients with increased risk of infections and/or CLL treatment. Participants have consented to have biological material collected.

At following time points: baseline/screening, 12 weeks after C1D1 (EOT) and 24 weeks after C1D1 we ask for bone marrow aspiration, peripheral blood, saliva, feces, skin swabs and buccal swab (baseline/screening only).

At following time points: C1D8 (treatment arm only), C1D15 (treatment arm only), C2D1, C3D1, 1 year after C1D1 and 2 years after C1D1 we ask for peripheral blood only.

At disease progression we ask for bone marrow, peripheral blood and lymph node biopsy.

For an overview of these study visits, please see Sampling schedule (section 5 page 5).

Section 10 "Shipment of samples" is divided into three further sections 10.1, 10.2 and 10.3. Each of these sections describes how to handle shipment of samples depending on where the TruCulture samples are shipped to immediately after collection (either Rigshospitalet in Denmark or your country's local central lab). Section 10.2 "Specific for Rigshospitalet" describes how samples are to be handled when collected at Rigshospitalet.

2 Participant Privacy Protection

Do not note participant name or personal identification number e.g. CPR on blood collection tubes. The blood collection tubes will be labeled with the participant's study identification number (PID).

3 Protect yourself











Follow all your institution's safety guidelines when collecting, processing or handling biological samples, including the use of personal protective equipment (PPE) gown or laboratory coat and gloves. The institution is responsible for providing all PPE.

4 Definitions

Central lab = laboratory at Rigshospitalet in Denmark (the sponsor's lab)

Local central lab = local national laboratory (the site's lab where TruCulture is handled)

5 Sampling schedule

	Screening/ Baseline ¹	C1D8 ²	C1D15 ²	C2D1	C3D1	12 weeks (End Of Treatment)	24 weeks	1 year	2 years	Progressive disease
Bone marrow – flow 	X						X			X
Bone marrow – biobank 	X						X			X
Blood – flow 	X					X	X	X	X	X
Blood – biobank 	X	X	X	X	X	X	X	X	X	X
Lymph node biopsy										X
Blood – TruCulture 	X					X	X			X
Blood – DuraClone 	X					X	X			X
Microbiome – saliva 	X					X	X			
Microbiome – feces 	X					X	X			
Microbiome – skin swabs 	X					X	X			
Microbiome – buccal swab 	X									

¹ Baseline samples are collected in the 42 days screening period after informed consent has been signed and must be collected before start of treatment/observation

² Treatment arm only

6 Materials Provided

6.1 Equipment needed by sites

- Access to an internet linked computer
- Material required for blood collection (except blood collection tubes)
- Sterile NaCl solution for skin swabs
- Collection tubes for peripheral blood and bone marrow if those packed in the study kits expired

6.2 Materials provided by CHIP

Sample material for all study visits:

- 9 ml Li-Hep VACUETTE collection tubes
- 3 ml K2-EDTA VACUETTE collection tubes
- 3,5 ml sodium citrate VACUETTE collection tubes
- Barcode scanner
- OM-200 OMNIgene GUT feces collection kits and OM-AC1 Toilet accessoires
- OME-505 OMNIgene ORAL saliva collection kits
- Isohelix SK-3: 1 swab and 2 ml Isohelix tube prefilled with BuccalFix
- Isohelix SK-1: 1 swab, 5 ml tube and cap and Isohelix Dri-Capsule
- PreVent-ACaLL labels
- Barcode labels for saliva, feces and TruCulture

Transport material:

- Transport tubes for feces and TruCulture samples
- Biological bags for the collected sample material
- Plastic bags pre-labeled with address for the laboratory that will receive the sample(s)
- Specimen & Shipping Logs
- Transport box

6.3 Supply delivery

The PreVent-ACaLL coordination center CHIP will assemble and ship all materials in study kits to sites upon automatic notification of enrolled participant and communication with the site's study team.

First shipment will include material for following study visits: baseline, C1D8*, C1D15*, C2D1, C3D1, 12 weeks after C1D1 and 24 weeks after C1D1. In case sample material expires before planned study visit, this material will be shipped later. **Only if participant is randomized to the treatment arm.*

Materials for 1 year and 2 years after C1D1 will be shipped prior to these study visits.

Materials for progressive disease will be shipped upon notification from study team at the site in case the participants disease progresses.

Notification and order of additional study material is done by writing to the CHIP project email:

chip-prevent.rigshospitalet@regionh.dk

7 Study kits

Each study kit containing sample and transport material will be delivered in a brown plastic bag labeled with study visit and PID. All sample material is packed into plastic bags containing biological bags pre-labeled with delivery address for the laboratory that must receive the sample(s). Barcode labels for TruCulture, saliva and feces are also included in these pre-labeled plastic bags. PreVent-ACaLL labels are all included in the baseline study kits.

Sampling instructions for saliva, feces, skin swabs and buccal swab are included in the study kit.

Specimen & Shipping Logs are included in each plastic bag and must be filled out and saved in your Investigator Site File. A copy must be included in the shipment when samples are shipped. For further explanation on how to fill out these Specimen & Shipping Logs, please see section 7.3.

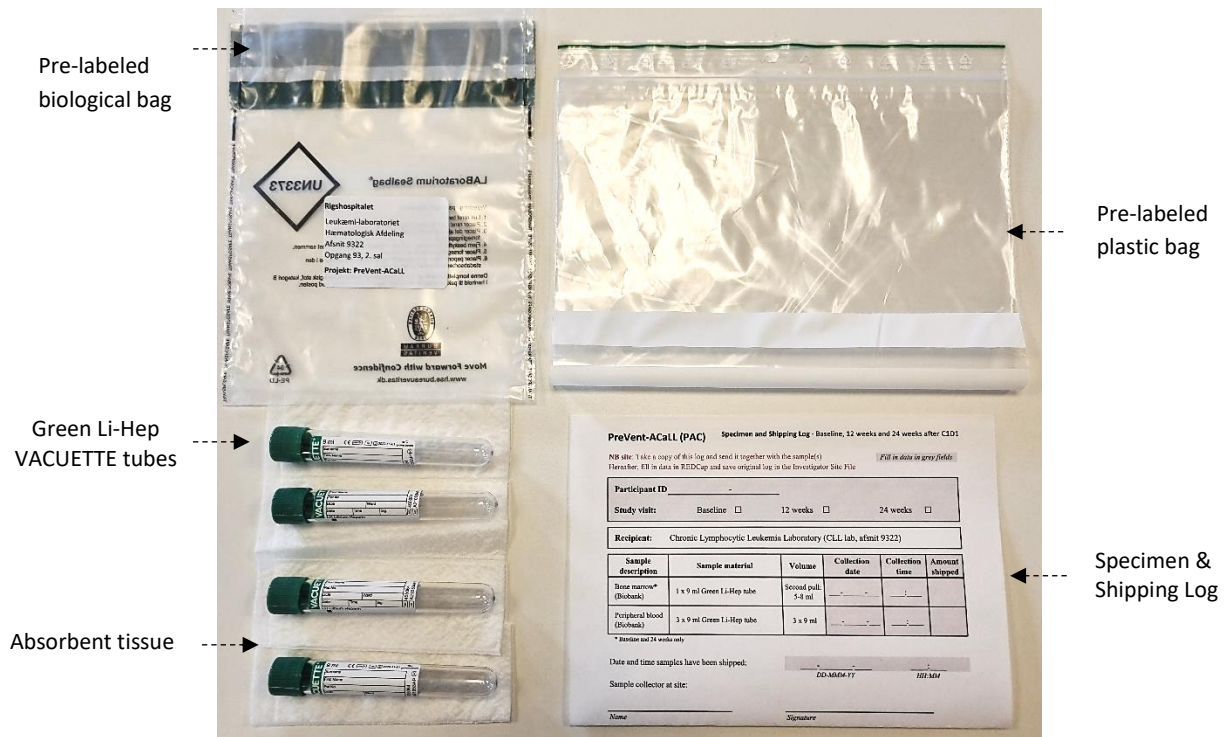


7.1 Components of the study kits

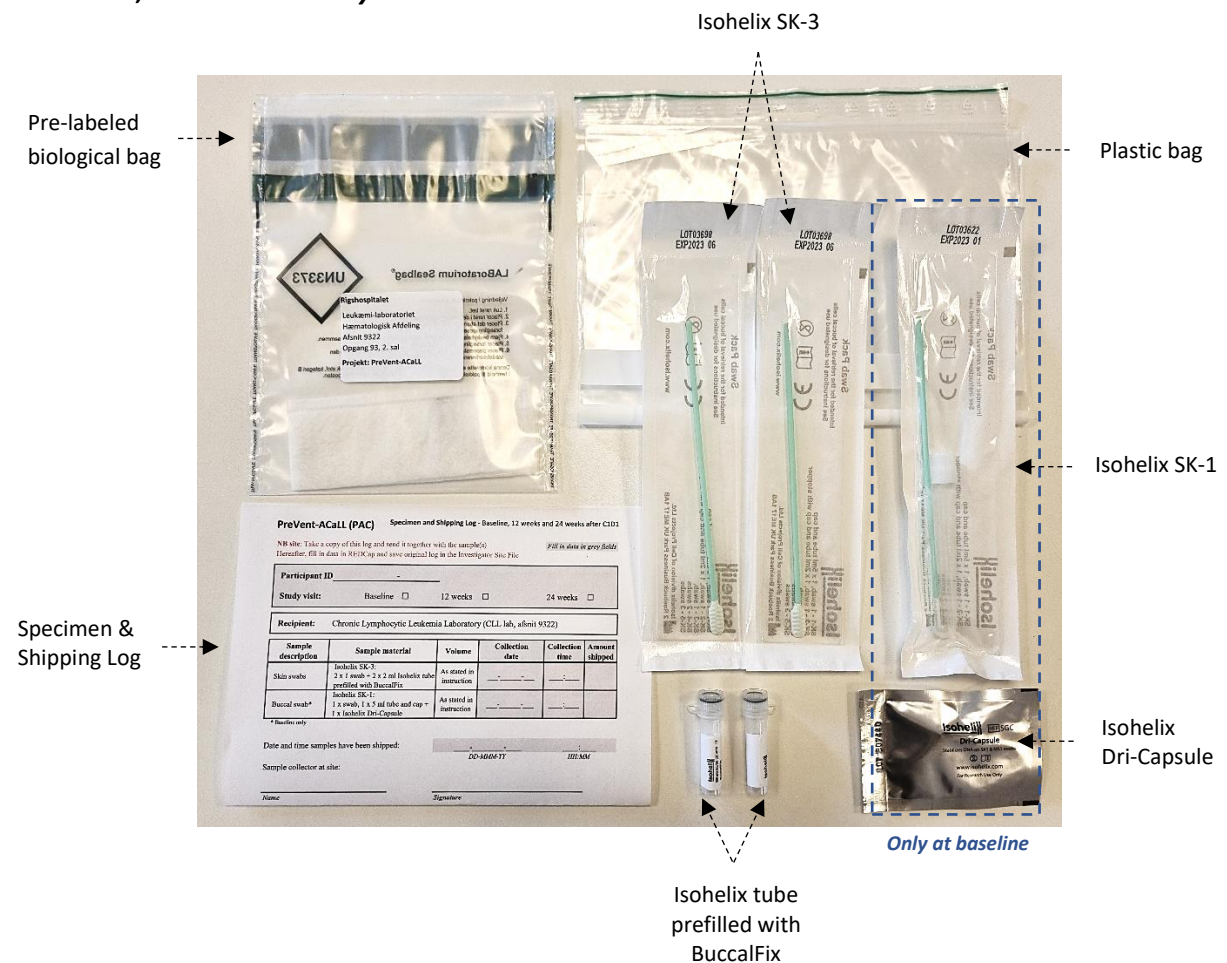
Component lists and corresponding images for study kits currently distributed to all sites are presented on pages below. Please note that the components included in the study kit can vary a bit from the pictures.

Study visit: Baseline, 12 weeks after C1D1 and 24 weeks after C1D1		
Components	Quantity per study kit	
Biological bag	7	
Pre-labeled plastic bag	7	
Specimen & Shipping Log	7	
Green Li-Hep VACUETTE tube	6 / 7	
Purple K2-EDTA VACUETTE tube	1	
Blue Sodium Citrate VACUETTE tube	1	
Isohelix SK-3: 1 x swab	2	
Isohelix tube prefilled with BuccalFix	2	
Isohelix SK-1: 1 x swab, 1 x 5 ml tube	0 / 1	Baseline only
Isohelix Dri-Capsule	0 / 1	Baseline only
OMNIgene GUT (OM-200)	1	
Toilet accessory (OM-AC1)	1	
Feces barcode labels	1	
OMNIgene ORAL (OME-505)	5	
Saliva barcode labels	4	
Transport tube	2	
Absorbent tissue	7	
See next pages		

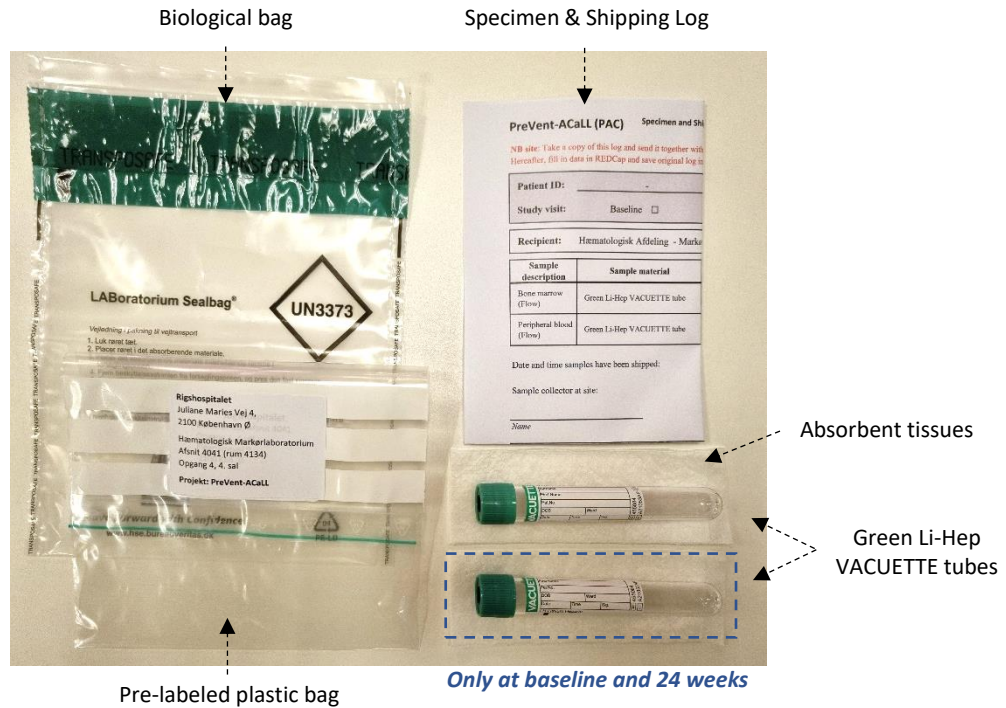
Peripheral blood (Biobank), bone marrow (Biobank)



Skin swabs, buccal swab - only at baseline



Peripheral blood (Flow), Bone marrow (Flow) - only at baseline and 24 weeks after C1D1



Feces:



Saliva:

Biological bag Specimen & Shipping Log Sampling Instruction

Pre-labeled plastic bag OMNIgene ORAL (OME-505) Barcode labels

Peripheral blood (DuraClone):

Biological bag Specimen & Shipping Log

Pre-labeled plastic bag Absorbent tissues Purple K2-EDTA VACUETTE tube Blue Sodium Citrate VACUETTE tube

Peripheral blood (TruCulture):

Biological bag

Specimen & Shipping Log

Barcode labels (site)

Barcode labels (central lab)

LABoratorium Sealbag®

UN3373

Nigshospitalet
Inge Lehmanns Vej 7
2100 København Ø
Klinisk Immunologisk Afdeling
Afsnit 2031
Opgang 2, 3. sal
Projekt: PreVent-ACaLL

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www.fda.usdoj.gov

PELD

Pre-labeled plastic bag

TruCulture Transport tube

Green Li-Hep VACUETTE tube

PreVent-ACaLL (PAC) Specimen and Shipping Log

NB site: Take a copy of this log and send it together with the sample. Hereafter, fill in data in REDCap and save original log in the folder.

Patient ID: _____

Study visit: Baseline ☐

Recipient: Klinisk Immunologisk Afdeling

NB: Last one to be sampled!

Sample description	Sample material	Volume
TruCulture	Green Li-Hep VACUETTE tube	9 ml

Date and time samples have been shipped: _____

Sample collector at site: _____

Name: _____

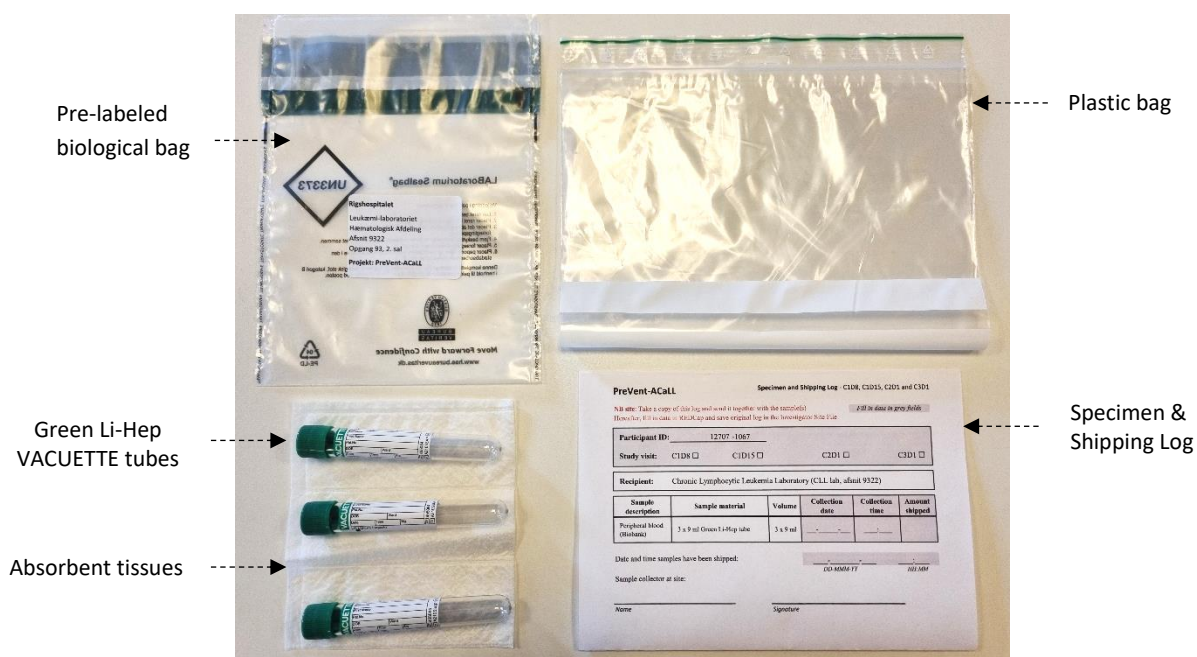
Barcode labels (site)

Barcode labels (central lab)

Study visit: C1D8 & C1D15 (treatment arm only), C2D1 & C3D1

Components	Quantity per study kit
Biological bag	1
Pre-labeled plastic bag	1
Specimen & Shipping Log	1
Green Li-Hep VACUETTE tube	3
Absorbent tissue	3

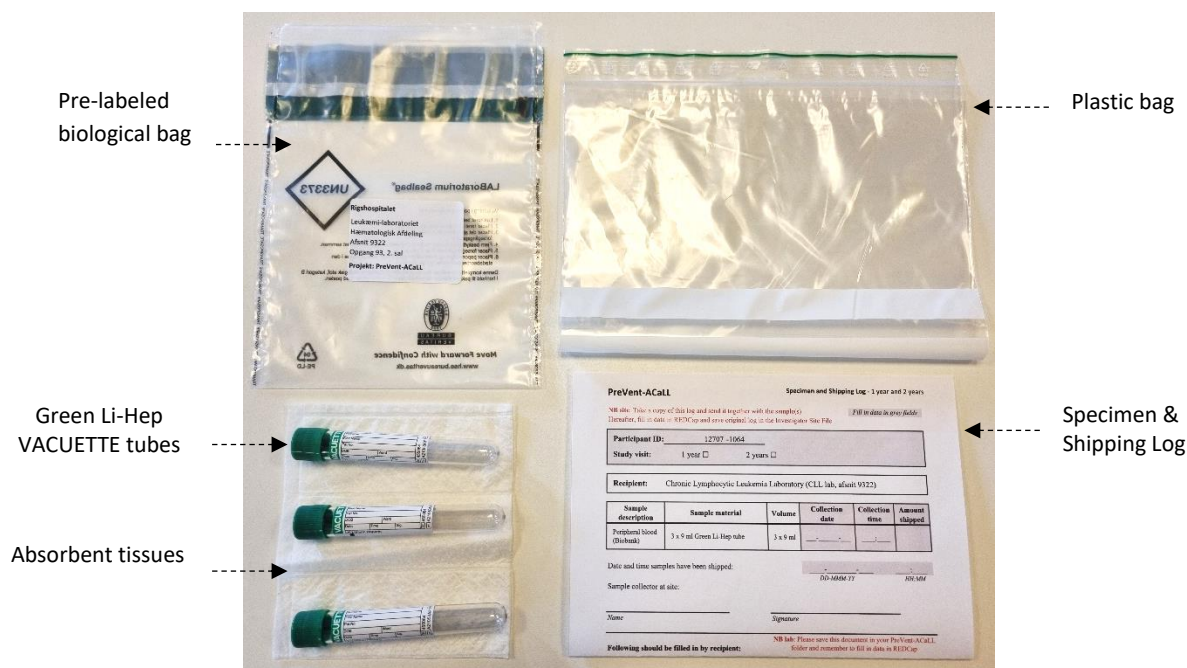
Peripheral blood (Biobank):



Study visit: 1 year after C1D1 and 2 years after C1D1

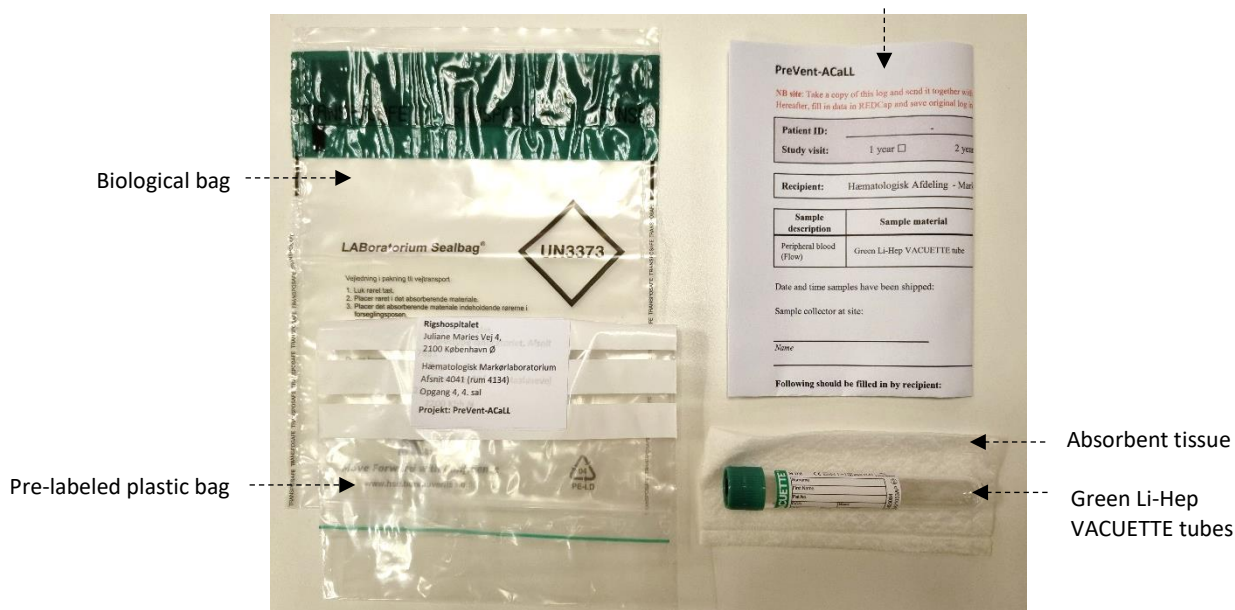
Components	Quantity per study kit
Biological bag	2
Pre-labeled plastic bag	2
Specimen & Shipping Log	2
Green Li-Hep VACUETTE tube	4
Absorbent tissue	4

Peripheral blood (Biobank):



Peripheral blood (Flow):

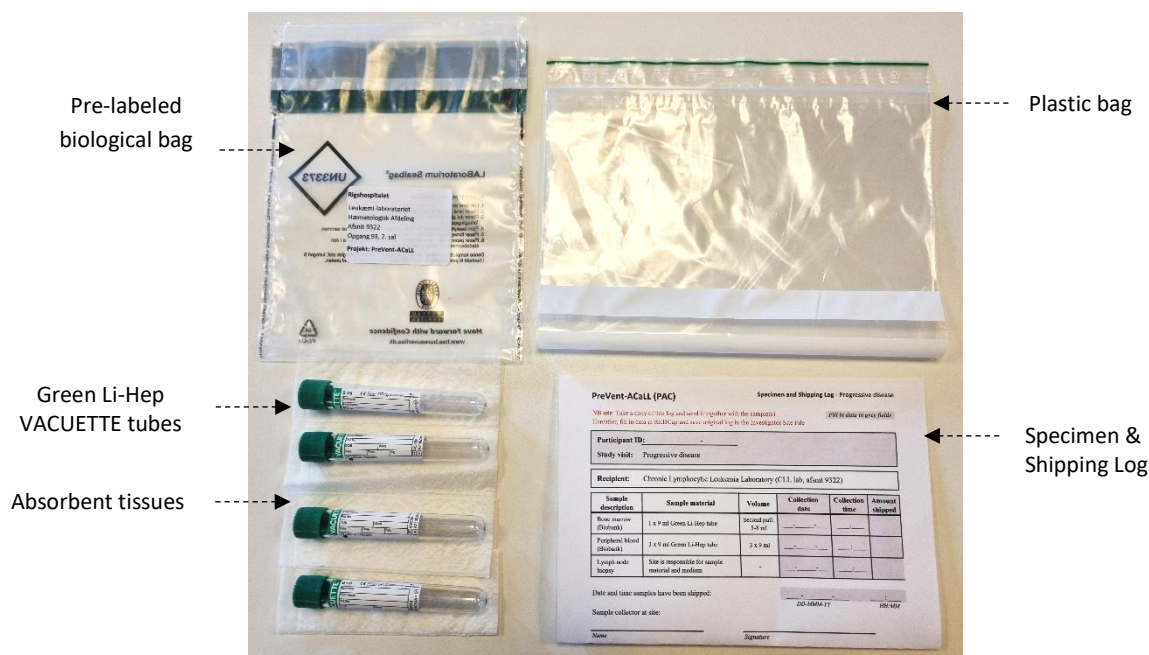
Specimen & Shipping Log



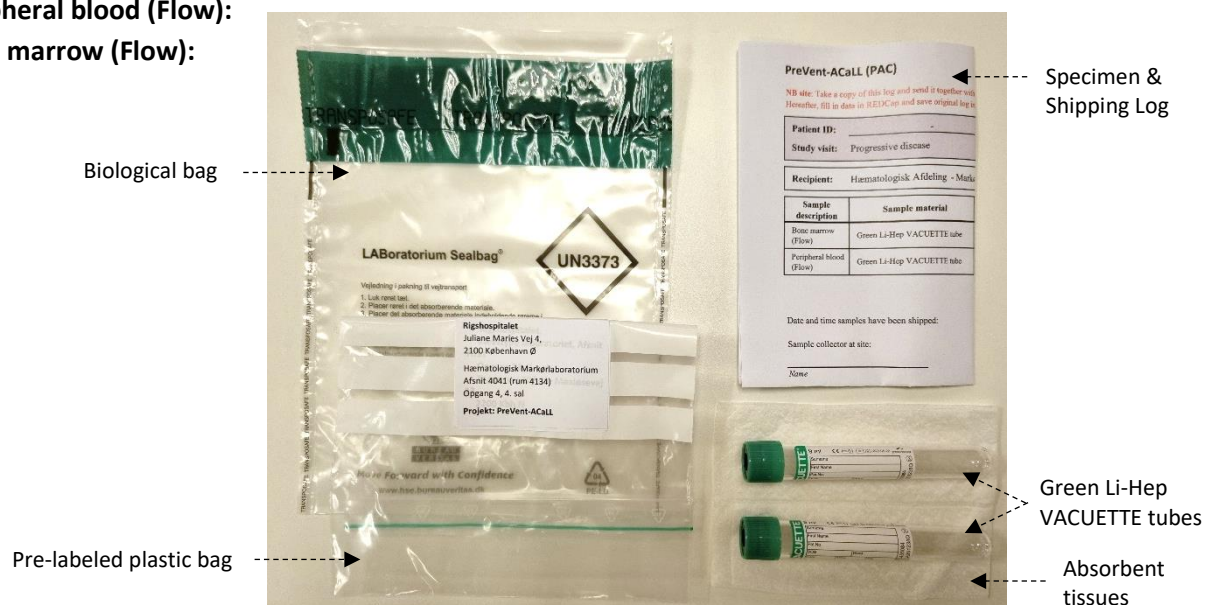
Study visit: Progressive disease

Components	Quantity per study kit
Biological bag	4
Pre-labeled plastic bag	4
Specimen & Shipping Log	4
Green Li-Hep VACUETTE tube	6
Purple K2-EDTA VACUETTE tube	1
Blue Sodium Citrate VACUETTE tube	1
Transport tube	1
Absorbent tissue	6

Peripheral blood (Biobank):



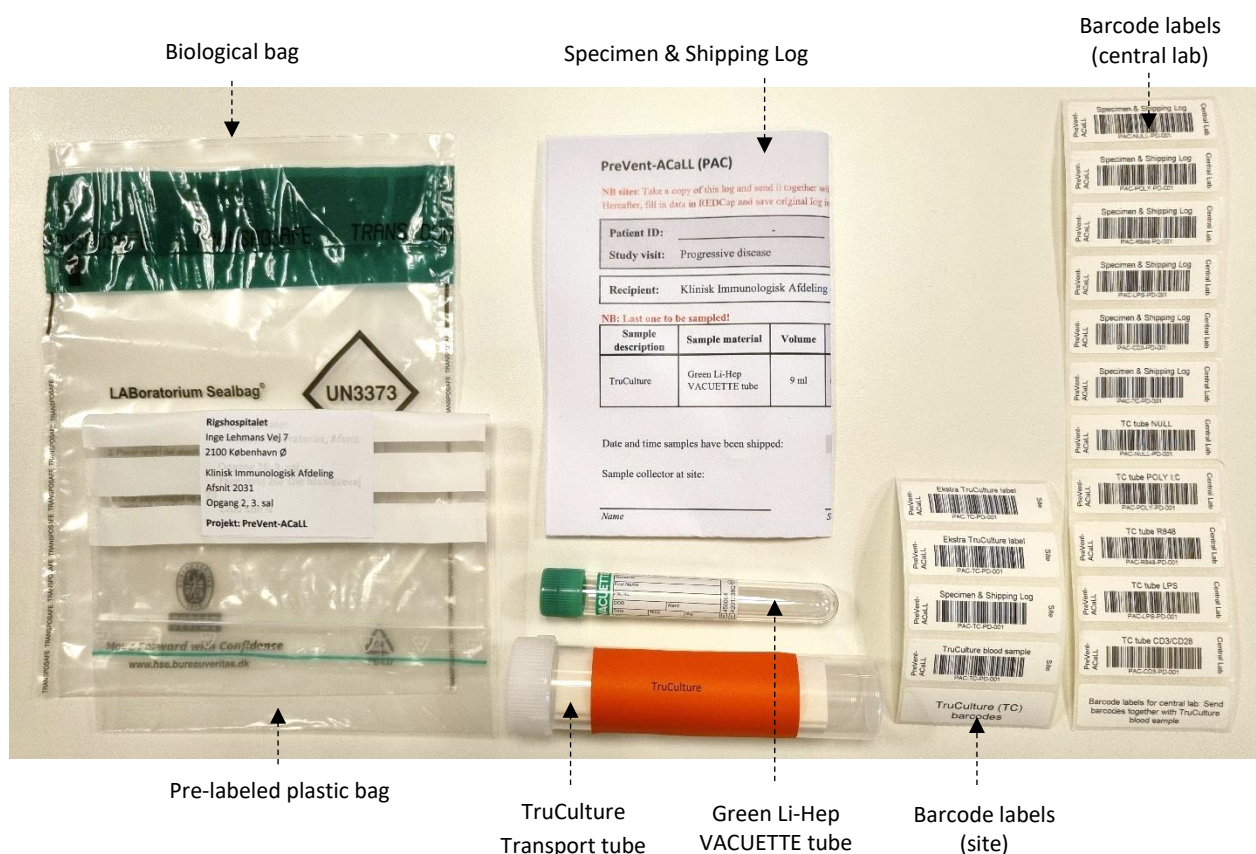
Peripheral blood (Flow): Bone marrow (Flow):



Peripheral blood (DuraClone):



Peripheral blood (TruCulture):



Extra lab material	
Components	Quantity per study kit
Isohelix SK-3: 1 x swab	2
Isohelix tube prefilled with BuccalFix	2
Isohelix SK-1: 1 x swab, 1 x 5 ml tube	1
Isohelix Dri-Capsule	1
OMNigene GUT (OM-200)	2
Toilet accessory (OM-AC1)	2
OMNigene ORAL (OME-505)	1
Absorbent tissue	1

7.2 Other supplies

PreVent-ACaLL labels

[illegible]

7.3 Specimen & Shipping Logs

The plastic bags in each study kit contain a Specimen & Shipping Log. This log must be filled out when samples are collected. When the logs are filled out, a copy must be taken and included in the sample shipment. The original Specimen & Shipping Log must be placed in your Investigator Site File. Below you can see an example of the Specimen & Shipping Log for the feces sample. The topmost half are filled out by the site, the lowermost half are filled out by the recipient (the lab). All Specimen & Shipping Logs have the same structure.

PreVent-ACaLL (PAC) Specimen and Shipping Log - Baseline, 12 weeks and 24 weeks after C1D1

NB site: Take a copy of this log and send it together with the sample(s)
Hereafter, fill in data in REDCap and save original log in the Investigator Site File

Fill in data in grey fields

Participant ID: _____

Study visit: Baseline ☐ 12 weeks ☐ 24 weeks ☐

Recipient: Klinisk Immunologisk Afdeling - Biobank (2031)

Sample description	Sample material	Collection date	Collection time	Barcode label	Amount shipped
Feces	OMNigene GUT (OM-200) and toilet accessory (OM-AC1)	DD-MM-YY	HH:MM	Place feces (FE) barcode label for specimen & shipping log here	

Date and time samples have been shipped: DD-MM-YY HH:MM

Sample collector at site:

Name _____ Signature _____

Following should be filled in by recipient:

Date and time samples have been received: DD-MM-YY HH:MM

Lab recipient:

Name _____ Signature _____

Contact information study team:

Email: prevent-acall.rigshospitalet@regionh.dk
eva.rebecka.svanberg@regionh.dk
tereza.fai tova@regionh.dk

Tel: +45 35 45 57 57 (CHIP)
Tel: +45 35 45 06 51 (Lab)




States laboratory receiving the sample(s)

1) Fill out collection date and time

2) Place barcode label (only applies for the feces, saliva and TruCulture samples)

3) Write amount of collection tubes that are shipped for this sample

Fill out date and time sample(s) are shipped

PreVent-ACaLL_Specimen and Shipping Log_Baseline, 12 weeks and 24 weeks – Version 2 – 22SEP2021

7.4 Label format

7.4.1 PreVent-ACaLL labels

All sample tubes must be labeled with one PreVent-ACaLL label specific for the sample content (Figure 7.4.1). The labels are shipped from CHIP together with the sample material in the study kits. At site, the PreVent-ACaLL labels must be filled out with PID and date of sampling.

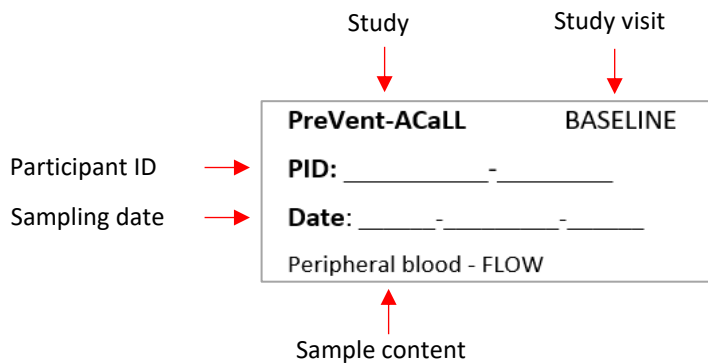


Figure 7.4.1: Explanation of PreVent-ACaLL label

7.4.2 Barcode labels

The samples **TruCulture**, **Saliva** and **Feces** require a unique sample-ID barcode label (Figure 7.4.2) beside above-mentioned PreVent-ACaLL labels. These barcode labels are shipped from CHIP together with the sample material in the study kits. For the TruCulture sample, barcode labels for your local central lab are also included in the study kit (does not apply for Rigshospitalet and Roskilde). **It is very important that these central lab barcode labels are shipped together with the TruCulture blood sample to the lab.**

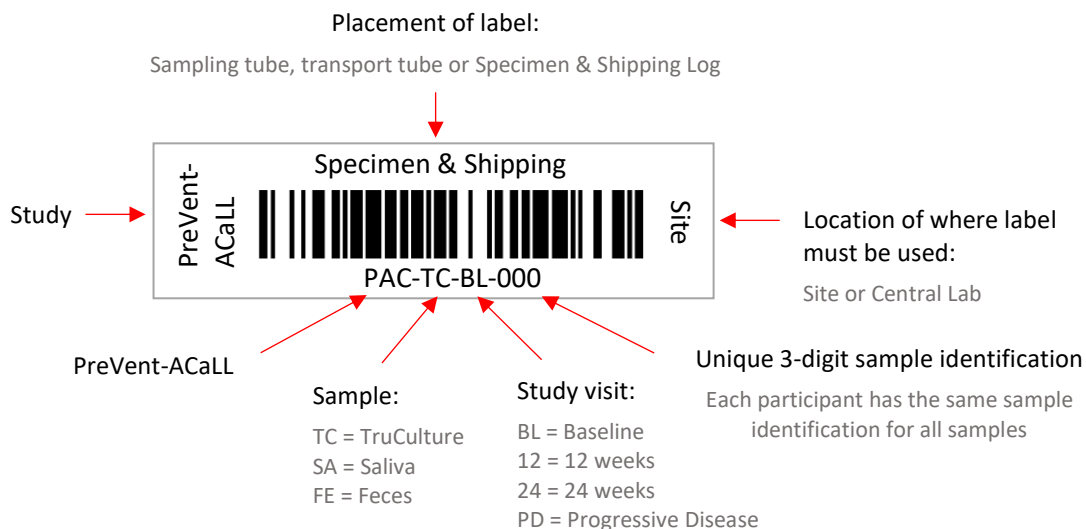


Figure 7.4.2: Explanation of barcode label

8 Study visit preparations

8.1 Arrangement of study visit

When a participant has been enrolled into the trial by signing the informed consent for randomization, the first study visit must be arranged to collect the participant's baseline samples. Collection of baseline samples does not necessarily have to be at the same day as screening for in- and exclusion criteria. The important thing is that baseline samples are collected before start of treatment/observation (cycle 1 day 1, C1D1). However, still in good enough time for samples to be re-collected in case some of the samples cannot be used (the feces sample as an example, since this sample can be a bit tricky to collect correctly – therefore, make sure to instruct the participant thoroughly). A study visit schedule can be created for rest of the study visits when date for the C1D1 study visit has been entered into REDCap. For further information, please see the PreVent-ACaLL REDCap Guide.

IMPORTANT

Due to analysis conduct and sample pick up, participants can only be booked for study visits on:

Sites inside Denmark: Monday to Thursday

Sites outside Denmark: Tuesday and Wednesday (preferably)

Mondays can be booked ONLY if completely impossible for the participant otherwise.

Sites shipping the TruCulture sample directly to Rigshospitalet (DK):

Please remember that collected samples must arrive at Rigshospitalet within 1 hour from sampling time. Taxa must be ordered prior to start of sampling.

Sites shipping the TruCulture sample to their local central lab:

Samples must be collected before 14:00, since samples are picked up by courier between 14:00 and 16:00.

Sponsor must be notified about the study visit at least **1 week before** the study visit.

The TruCulture sample must arrive at the local central lab within:

Denmark: 1 hour from sampling time

Holland: 2 hours from sampling time

Sweden: 3 hours from sampling time

Site that collects the TruCulture blood sample is responsible for this transport.

Bone marrow biopsies and lymph node biopsies are booked locally according to your hospital's local guidelines.

8.2 Notification of arranged study visit to sponsor and laboratories

All central laboratories receiving study samples must be **notified at least 1 week in advance** for arrival of study samples. The laboratories will by sponsor be notified when the eCRF "Booking of study visit (*notification to sponsor*)" in REDCap is filled out with study visit date and time and saved as *Complete*. For further details, please see the PreVent-ACaLL REDCap Guide.

8.3 Booking of courier (does not apply to Rigshospitalet and Roskilde)

Courier must be booked to pick up study samples at sites who is sending TruCulture to their local central lab. Sponsor is responsible for booking of the courier, but site must notify sponsor about the study visit through REDCap.

All samples besides TruCulture are transported to Rigshospitalet via transport company chosen by sponsor. Date for study visit must be reported in the REDCap eCRF "Booking of study visit (notification to sponsor)" when study visit date has been arranged and no later than one-week prior study visit date. Sponsor will hereafter book sample pick-up with transport company.

Transport material will be delivered to the site same day as the study visit (between 08:00 and 12:00 am) and picked up again between 14:00 and 16:00 pm containing the study samples (further description regarding transport can be found in section 11.3.2).

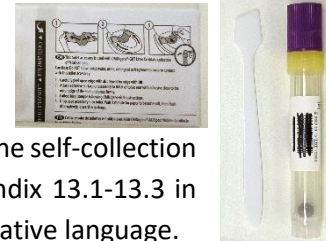
9 Sampling instructions

The sampling schedule in section 5 indicates which samples that must be sampled at each study visit. Below you find instructions on how to collect each of the different samples. Pictures to the right show what sample material that should be applied for the specific sample.

Important: Remember to order sample pick-up prior sampling! For country/site specific packing and transport instructions, please see section 11. TruCulture must be the last sample to be collected!

9.1 Microbiome – feces

- Hand out OMNIgene GUT (OM-200) feces collection kit, toilet accessory (OM-AC1) and sample instruction to participant before the study visit. Participant must bring along the sample when coming in for the study visit. The self-collection instruction is packed together with the kit but can also be found in Appendix 13.1-13.3 in Danish, Dutch and Swedish, which will also be included in the study kits in native language.
- When receiving the feces sample from participant:
 - Check if the sample is collected OK – no loss of fluid and feces dissolved/mixed properly
 - If sample is not OK: Handout a new feces collection kit to the participant
 - If sample is OK: Label the collection tube and feces transport tube with correct PreVent-ACaLL label and barcode label as shown in section 10



9.2 Microbiome – skin swabs

1. Use Isohelix swabs SK-3S + 2 ml tubes Prefilled with BuccalFix
2. Put on gloves and prepare sterile NaCl solution to wet swabs
3. Follow instructions below:



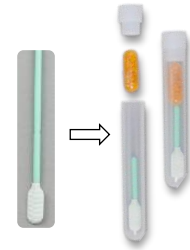
1	Pull open the package from one end.
2	Remove the swab from the wrapper, taking care not to touch the white swab head with your fingers. Wet swab using standard sterile NaCl solution
3	Rub the wet swab firmly back and forth onto skin in marked area of the right arm . Use separate swabs for each region: 1) volar forearm 2) axillary region Rub for at least 30 seconds to 1 minute. Important – use reasonable, firm and solid pressure
4	Place the small groove set in the swab stick against the rim of the tube, then snap the swab stick at the break point by bending to one side. Let the swab head fall into the tube.
5	Replace the tube cap making sure the tube is securely sealed. For SK-4S and MS-03 swab kits, repeat the swabbing procedure with the second swab.

IMPORTANT: Since two separate regions are swabbed, the procedure must be performed from step 1 for each of the two skin swabs!





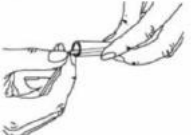
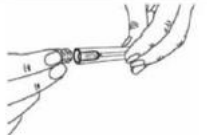
4. Label both tubes with correct PreVent-ACaLL label as shown in section 10

9.3 Microbiome – buccal swab

1. Use the SK-1S swabs + 5ml tubes + Isohelix Dri-Capsule
2. Put on gloves
3. Follow instructions below:



Take your DNA sample at least one hour after eating, drinking or cleaning your teeth.
For best results, rinse mouth with water immediately prior to sampling.

1 	Pull open the package from one end.
2 	Remove the swab from the tube, taking care not to touch the white swab head with your fingers.
3 	Insert the swab into your mouth and rub firmly against the inside of your cheek or underneath lower or upper lip. For standard DNA collection rub for 1 minute Important – use reasonable, firm and solid pressure
4 	Place the swab back into the tube. Do not touch the swab head with your fingers.
5 	Place your thumbnail in the small groove set in the handle, then snap the handle in two by bending to one side. Let the swab head fall into the tube.
6 	Remove the silica gel capsule from the foil wrapper and place in the tube so that the capsule sits on top of the swab shaft. Seal the tube securely with the cap provided.

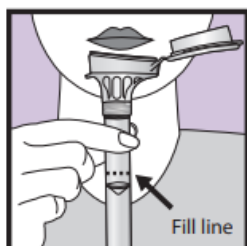
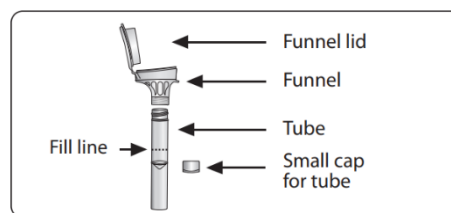
Note: The fresh silica gel is coloured orange and turns green when moisture is absorbed. In the event that the capsule is coloured green on removal from the foil pack, this indicates that the capsule has already been exposed to moisture and is not suitable for use.

4. Label tube with correct PreVent-ACaLL label as shown in section 10

9.4 Microbiome – saliva

1. Use saliva collection kit: OMNIgene ORAL (OME-505)

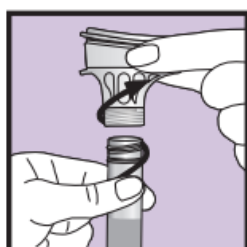
Instruction is packed together with the kit but can also be found in Appendix 13.4-13.6 in Danish, Dutch and Swedish, which will also be included in the study kits in native language. Below is the English instruction:



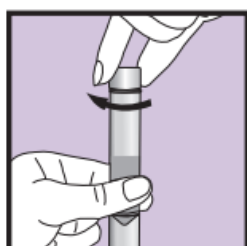
- 1 Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.



- 2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.



- 3 Hold the tube upright. Unscrew the funnel from the tube.



- 4 Use the small cap to close the tube tightly.



- 5 Shake the capped tube for 5 seconds. Discard or recycle the funnel.

2. Label tube with correct PreVent-ACaLL label and barcode label as shown in section 10

9.5 Bone marrow

9.5.1 Aspirate for flow & biobank

1. Use 2 x green Li-Hep 9 mL VACUETTE tubes
2. Do a first aspiration called “first pull” where you briefly aspirate **2 mL** of bone marrow, which you deposit into the first tube
3. Do a second aspiration called “second pull” where you aspirate **5 to 8 mL** of bone marrow, which you deposit into the second tube
4. Label tubes with correct PreVent-ACaLL label as shown in section 10



9.5.2 Biopsy and aspirate – local

1. In addition to the PreVent-ACaLL samples, routine bone marrow smears, crista biopsy and crista imprints are taken and send to the local pathology department at your hospital. Results must be entered into REDCap (eCRF: Bone Marrow).

9.6 Peripheral blood for biobank

1. Use 3 x green Li-Hep 9 mL VACUETTE tubes
2. Draw peripheral blood into the tubes
3. Label tubes with correct PreVent-ACaLL label as shown in section 10



9.7 Peripheral blood for flow

1. Use 1 x green Li-Hep 9 mL VACUETTE tube
2. Draw peripheral blood into the tube
3. Label tube with correct PreVent-ACaLL label as shown in section 10



9.8 Peripheral blood for DuraClone

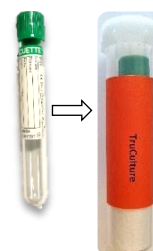
1. Use 1 x purple K2-EDTA 3 ml VACUETTE tube and 1 x blue sodium citrate 3,5 ml VACUETTE tube
2. Draw peripheral blood into the tubes
3. Label tubes with correct PreVent-ACaLL label as shown in section 10



9.9 Peripheral blood for TruCulture

Important: Make sure blood for TruCulture VACUETTE tube is the last to be collected!


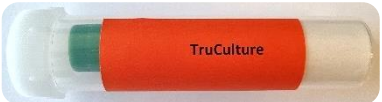
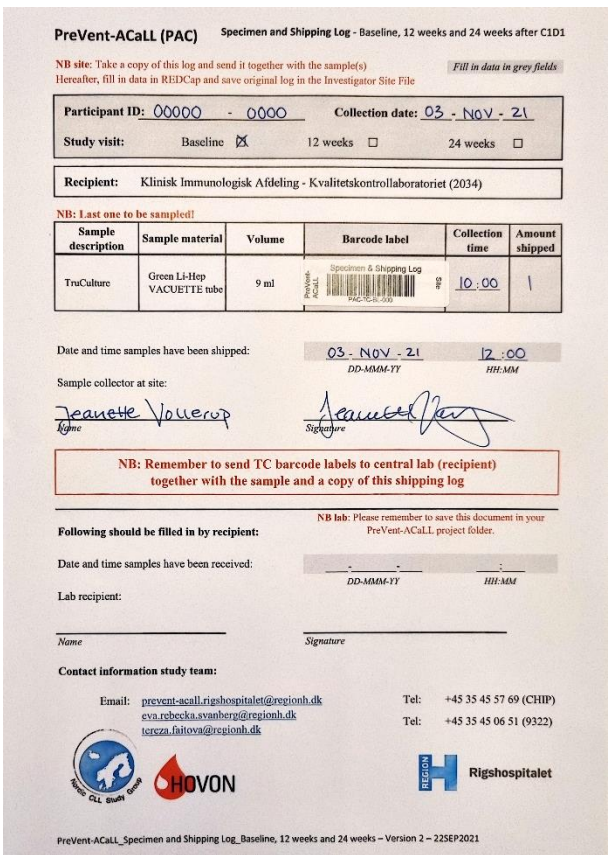
1. Use 1 x green 9ml Li-Hep VACUETTE tube
2. Draw peripheral blood into the tube
3. Label tube with correct PreVent-ACaLL label and barcode label as shown in section 10


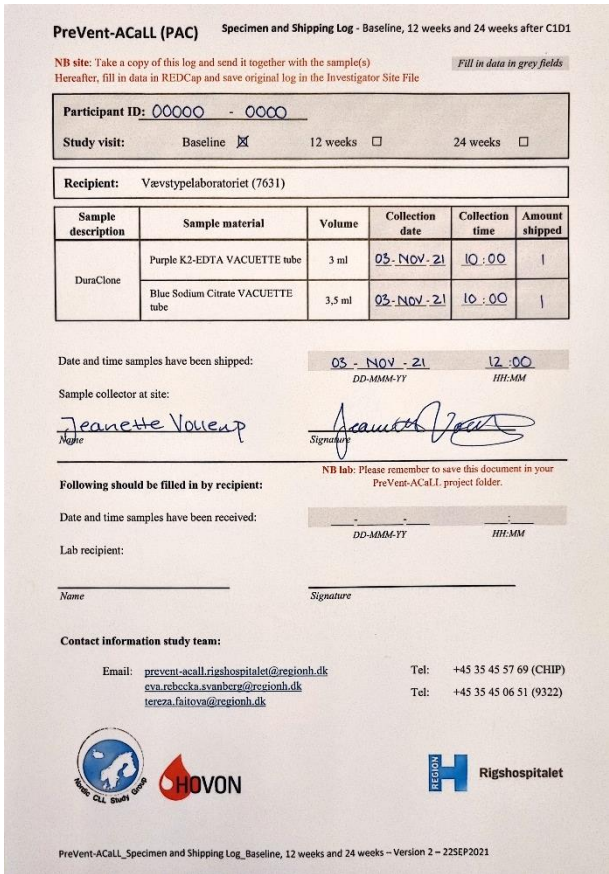



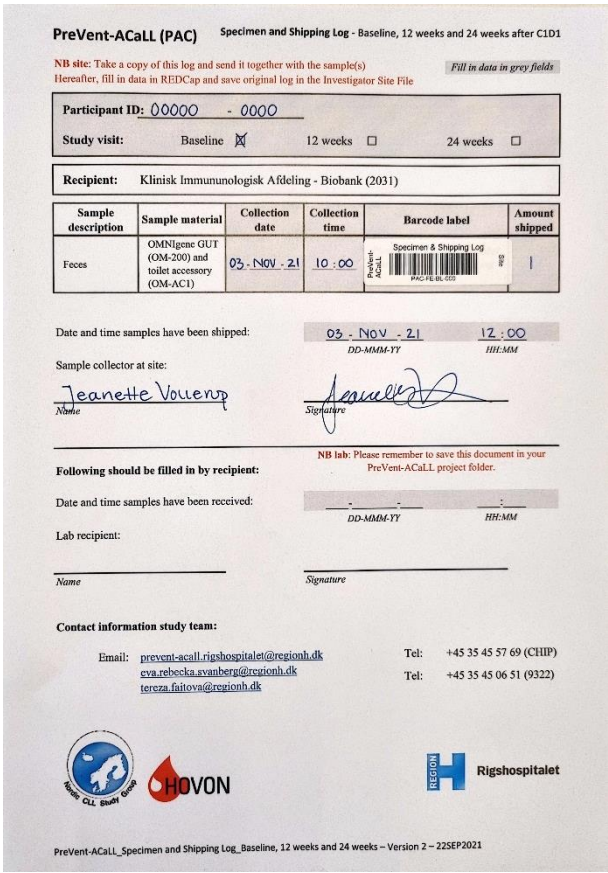
10 Placement of labels

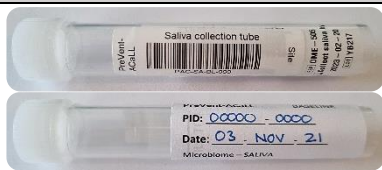
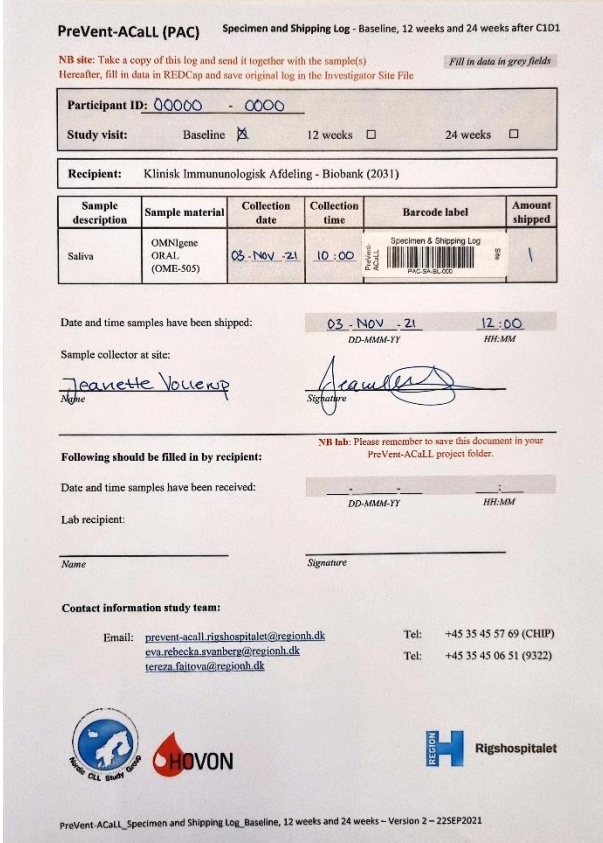
PreVent-ACaLL labels must be placed on all sample tubes and the feces transport tube. A barcode label must be placed on the feces, saliva and TruCulture sample tube as well as the feces transport tube. Identical barcode labels for these three samples must be placed on the appertaining Specimen & Shipping Log. Tables below show how and where to place the PreVent-ACaLL and barcode labels.

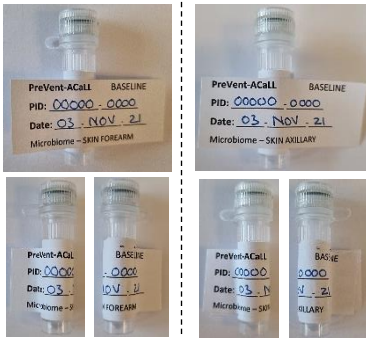
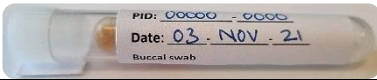
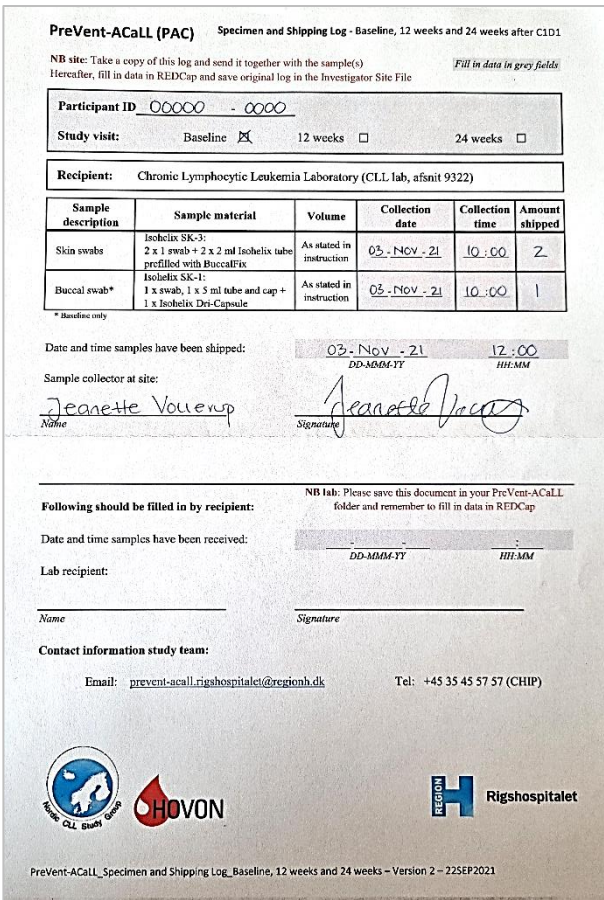
Important: Ensure that PreVent-ACaLL labels include: PID as well as collection date and time. Make sure to use label that matches the concerning study visit and sample content and that the labels does not overlap

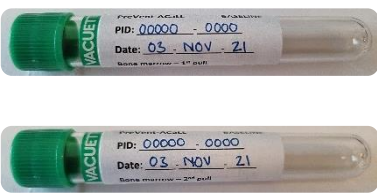
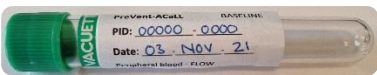

Placement	Image	Explanation
1 x 9 ml Li-Hep VACUETTE tube		Place the 'Peripheral blood – TruCulture' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube. Place the 'TruCulture blood sample' barcode label right above the PreVent-ACaLL label. Ensure that it is possible to see the blood from top to bottom of the tube.
1 x TruCulture transport tube		The transport tube for TruCulture are pre-labeled with a 'TruCulture' label. No further labels should be placed on this transport tube.
Specimen & Shipping Log		Place the TruCulture (TC) 'Specimen & Shipping Log' barcode label on the TruCulture Specimen & Shipping Log (identical barcode ID as on the tube label) and fill in needed sample information (grey fields). When barcode is placed and information filled in, a copy must be taken of the Specimen & Shipping Log. Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment. Reporting of sample info in REDCap: Scan Specimen & Shipping Log barcode label into the REDCap eCRF (section 12) and report sample information in the eCRF "Study samples shipped to central lab".

Placement	Image	Explanation
1 x 3 ml K2-EDTA VACUETTE tube 1 x 3,5 ml Sodium citrate VACUETTE tube		<p>Place the 'Peripheral blood – DuraClone V05/19' PreVent-ACaLL label on top of the VACUETTE label that is already placed on tube.</p> <p>Place the other 'Peripheral blood – DuraClone V05/19' PreVent-ACaLL label on top of the VACUETTE label that is already placed on the tube.</p>
Specimen & Shipping Log		<p>Fill in needed sample information on the DuraClone Specimen & Shipping Log (grey fields). Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment.</p> <p><u>Reporting of sample info in REDCap:</u></p> <p>Report sample information in the eCRF "Study samples shipped to central lab".</p>

Placement	Image	Explanation
1 x Feces collection tube 1 x Feces transport tube		<p>Place the 'Feces collection tube' barcode label on top of the other barcode that is already on the tube. Place the 'Microbiome – FECES' PreVent-ACaLL label on top of one of the barcodes that is already on the tube.</p> <p>Place the other feces PreVent-ACaLL label 'Microbiome – FECES transport tube' and the barcode label 'Feces transport tube' on the transport tube.</p>
Specimen & Shipping Log		<p>Place the Feces (FE) 'Specimen & Shipping Log' barcode label on the TruCulture Specimen & Shipping Log (identical barcode ID as on the tube label) and fill in needed sample information (grey fields). When barcode is placed and information filled in, a copy must be taken of the Specimen & Shipping Log. Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment.</p> <p><u>Reporting of sample info in REDCap:</u></p> <p>Scan Specimen & Shipping Log barcode label into the REDCap eCRF (section 12) and report sample information in the eCRF "Study samples shipped to central lab".</p>

Placement	Image	Explanation
1 x Saliva collection tube		Place the 'Saliva collection tube' barcode label on top of the barcode that is already printed on the tube. Place the 'Microbiome - SALIVA' PreVent-ACaLL label on the tube.
Specimen & Shipping Log		<p>Place the Saliva (SA) 'Specimen & Shipping Log' barcode label on the TruCulture Specimen & Shipping Log (identical barcode ID as on the tube label) and fill in needed sample information (grey fields). When barcode is placed and information filled in, a copy must be taken of the Specimen & Shipping Log. Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment.</p> <p><u>Reporting of sample info in REDCap:</u></p> <p>Scan Specimen & Shipping Log barcode label into the REDCap eCRF (section 12) and report sample information in the eCRF "Study samples shipped to central lab".</p>

Placement	Image	Explanation
2 x 1 ml Isohelix tube prefilled with BuccalFix		<p>Place the 'Microbiome – SKIN FOREARM' PreVent-ACaLL label on the Isohelix tube with forearm swab as shown at the pictures to the left.</p> <p>Place the 'Microbiome – SKIN AXILLARY' PreVent-ACaLL label on the Isohelix tube with axillary swab as shown at the pictures to the left.</p>
1 x 5 ml Isohelix tube		Place the 'Buccal swab' PreVent-ACaLL label on the Isohelix 5 ml tube.
Specimen & Shipping Log		<p>Fill in needed sample information on the Specimen & Shipping Log (grey fields). Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment.</p> <p><u>Reporting of sample info in REDCap:</u> Report sample information in the eCRF "Study samples shipped to central lab".</p>

Placement	Image	Explanation
2 x 9 ml Li-Hep VACUETTE tube		<p>Place the '<i>Bone marrow 1st pull</i>' PreVent-ACaLL label on top of the VACUETTE label that's already on the tube.</p> <p>Place the '<i>Bone marrow 2nd pull</i>' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube.</p>
1 x 9 ml Li-Hep VACUETTE tube		<p>Place the '<i>Peripheral blood – FLOW</i>' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube.</p>
3 x 9 ml Li-Hep VACUETTE tube		<p>Place the '<i>Peripheral blood – BIOBANK #1</i>' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube.</p> <p>Place the '<i>Peripheral blood – BIOBANK #2</i>' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube.</p> <p>Place the '<i>Peripheral blood – BIOBANK #3</i>' PreVent-ACaLL label on top of the VACUETTE label that's already placed on the tube.</p>

Fill in needed sample information on the two appertaining Specimen & Shipping Logs (grey fields). Make sure to save the original Specimen & Shipping Log in your Investigator Site File and include the copy in the sample shipment.

Report sample information in the eCRF
"Study samples shipped to central lab".

PreVent-ACaLL Laboratory Manual sites Version 4.0 2023Mar01

11 Shipment of samples

11.1 Sites shipping TruCulture directly to Rigshospitalet

This section describes how study samples are packed and shipped for sites that ship the TruCulture sample directly to Rigshospitalet after collection.

When samples are collected and labeled, a copy of all the completed Specimen & Shipping Logs must be taken and shipped together with the samples to the laboratories. The original Specimen & Shipping Log must be saved in your Investigator Site File.

Samples must be packed as shown in section 11.1.1 next page. Below, packing instruction is described in words:

All samples must be packed in the same way as sample material are received in the study kits: pack the samples in the appertaining biological bag and hereafter in the pre-labeled plastic bag together with a copy of the matching Specimen & Shipping Log for the sample(s).

- Following samples are shipped to department of **Clinical Immunology** (Afdeling for Klinisk Immunologi):

Plastic bag labeled Department 7631:

- Peripheral blood for DuraClone

Plastic bag labeled Department 2031:

- Peripheral blood for TruCulture

- Following samples are shipped to the **Chronic Lymphocytic Leukemia Laboratory** (CLL lab):

Plastic bag labeled Department 2031:

- Feces
- Saliva

Plastic bag labeled Department 9322:

- Bone marrow for biobank (2nd pull)
- Skin swabs
- Buccal swab (baseline only)
- Peripheral blood for biobank

Plastic bag labeled Department 4041:

- Bone marrow for flow (1st pull)
- Peripheral blood for flow

Remember to hand over delivery instruction to taxi driver.

11.1.1 Packing of study samples



11.1.2 Transport instructions

By taxi

The study visits baseline, 12 weeks after C1D1, 24 weeks after C1D1 and progressive disease include sampling of peripheral blood for TruCulture. Since the analysis for TruCulture needs to be initiated within 1 hour from sampling time, all samples collected at these study visits must be delivered to Rigshospitalet by taxi.

The envelope including the TruCulture sample are to be prioritized. The prioritization is indicated on the envelope with the label “**Første prioritet!**” so that taxi driver can see which envelope that must be delivered to Rigshospitalet first.

By internal transport

The samples collected at study visits C1D8 (treatment arm only), C1D15 (treatment arm only), C2D1, C3D1, 1 year after C1D1 and 2 years after C1D1 are shipped by internal transport from your hospital to Rigshospitalet.

11.2 Specific for Rigshospitalet

All laboratories receiving samples are located at Rigshospitalet, therefore Rigshospitalet as a site has their own internal procedure regarding delivery of samples to the laboratories. If in doubt, please contact study nurse or the lab coordinators, Rebecka or Tereza. Below is listed where samples must be delivered.

- Following samples are delivered to 2031 (Kvalitetskontrollaboratoriet):
 - Peripheral blood for DuraClone and TruCulture
 - From 2031 DuraClone samples will be delivered to Vægstypelaboratoriet 7631
 - Microbiome Feces and Saliva
- Following samples are shipped to 4041 (Hæmatologisk Markørlaboratorium):
 - Peripheral blood for Flow analysis
 - Bone marrow for Flow analysis
- Following samples are shipped to 9322 (Chronic Lymphocytic Leukemia Laboratory, CLL lab):
 - Peripheral blood for Biobank
 - Bone marrow for Biobank
 - Microbiome Skin swabs and Buccal swab

11.3 Sites shipping TruCulture to their local central lab

This section describes how study samples are packed and shipped for sites that ship the TruCulture sample to their local central lab after collection e.g. NOT Rigshospitalet.

When samples are collected and labeled, a copy of all the completed Specimen & Shipping Logs must be taken and shipped together with the samples to the laboratories. The original Specimen & Shipping Log must be saved in your Investigator Site File.

Samples must be packed as shown in section 11.3.1 next page. Below, packing instruction is described in words:

All samples must be packed in the same way as sample material are received in the study kits: pack the samples in the appertaining pre-labeled biological bag and hereafter in the plastic bag together with a copy of the matching Specimen & Shipping Log for the sample(s).

Important: The TruCulture sample must arrive to the local central laboratory in your country within as fast as possible Therefore, shipment of the TruCulture sample must be prioritized!

Rest of the samples are shipped via a courier company to the **Leukemia Laboratory** (Leukæmi-laboratoriet) at Rigshospitalet in Denmark. Samples are packed in the plastic bags as stated below and hereafter packed into the transport box delivered by the transport company:

Bag labeled Department 2031 (Afdeling for Klinisk Immunologi):

- Feces
- Saliva

Bag labeled Department 9322 (Chronic Lymphocytic Leukemia Laboratory, CLL lab):

- Bone marrow for biobank (2nd pull)
- Skin swabs
- Buccal swab (baseline only)
- Peripheral blood for biobank

Bag labeled Department 4041 (Hæmatologisk Markørlaboratorium):

- Bone marrow for flow (1st pull)
- Peripheral blood for flow

Bag labeled Department 7631 (Vævstypelaboratoriet):

- Peripheral blood for DuraClone

For further details see section 11.3.2.

11.3.1 Packing of study samples



11.3.2 Transport instructions

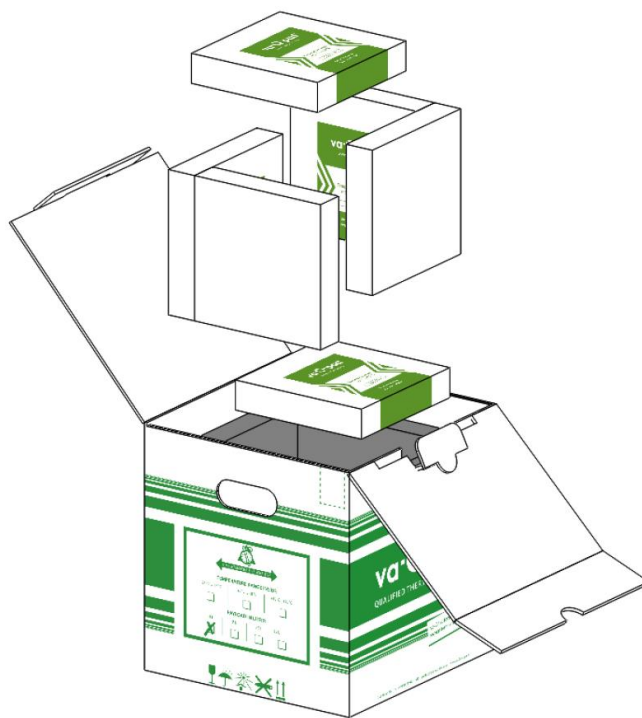
All samples besides TruCulture are transported to Rigshospitalet via DSV Global Transport and Logistics.

Transport material will be delivered to the site by the transport company the same day as the study visit (between 08:00 and 12:00 am).

The transport material consists of a box with three layers. From the outside to the inside there is the protective cardboard, an insulation layer made of 40 mm thick vacuum insulation panels and special sized temperature elements which surround the inner volume completely and – in conjunction with the adjacent vacuum insulation panels – lead to an outstanding temperature stability, thus keeping the temperature stable at 15-25°C during transport.

The samples must be packed into the small inner cardboard box. The transport company will pick up the transport material containing the study samples at the same day as the study visit (between 14:00 and 16:00 pm).

Shipment of the TruCulture sample to your local central lab in your country is arranged by the site (if in doubt, contact the national coordinator in your country). The TruCulture sample must arrive to your local central lab within 1 hour for sites in Denmark, within 2 hours for sites in Holland and within 3 hours for sites in Sweden. It is important that all time points regarding the TruCulture sample are reported in REDCap and on the Specimen & Shipping Log (e.g. sample collection date and time, transport date and time, incubation date and time).

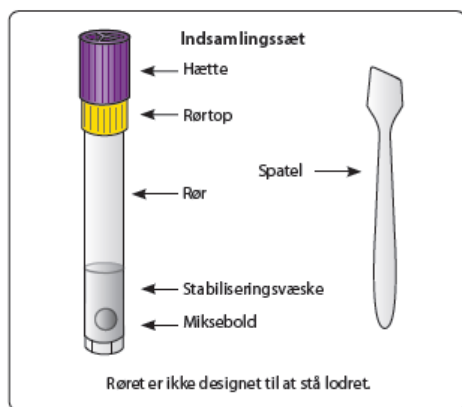


12 Sample registration in REDCap

When samples have been collected, packed and shipped, sample information must be registered in the eCRF "Samples shipped to central lab" in REDCap. In this form, sample time and date for all collected samples as well as shipment date and time must be reported. Additionally, the barcode labels from TruCulture, feces and saliva must be scanned into REDCap. In case a sample has not been collected, an explanation is required.

When all information has been reported in REDCap, the form status must be changed to *Complete* and saved.

For a more detailed description on how to report data in the eCRF, please explore the PreVent-ACaLL REDCap Guide.



Resume og forklaring af sættet:

OMNIGENE®-GUT leverer materiale og vejledning til indsamling og stabilisering af mikrobiel DNA fra en afføringsprøve.

Advarsler og forholdsregler:

- KUN TIL UDVORTES BRUG.
- Fjern IKKE den gule rørtop fra røret.
- Hæld IKKE stabiliseringsvæske ud af røret.
- Skyl med vand, hvis øjne eller hud kommer i kontakt med væsken. Slug IKKE.
- Hvis afføringsprøven er flydende se separat leveret brugervejledning.
- Små dele kan føre til kvælning.

Opbevaring: Opbevares ved stuetemperatur (15°C til 25°C), før og efter indsamling.

Forsendes i henhold til de relevante regler vedrørende transport af biologiske prøver. Se MSDS på www.dnagenotek.com

Etiketforklaring:

	Indsamling af prøve inden (Mindst holdbar til)
	Katalognummer
	Producent
	Opbevaringsinstruktioner
	Advarsel, indhent instrukser for anvendelsen
	Lot nummer

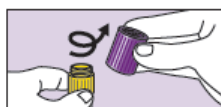
BRUGERVEJLEDNING

Læs alle instruktioner før indsamlingen

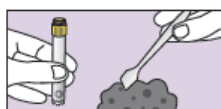
Procedure:



- 1 VIGTIGE FORBEREDELSE:**
- Tøm din blære før du tager prøven.
 - Tag afføringsprøven uden urin eller toiletvand.
 - Toilettepapir eller servietter kan være nødvendigt.



- 2** Mens du holder den gule rørtop, skru KUN det violette låg af, og sæt denne til side til senere brug.
- VIGTIGT:** Fjern IKKE den gule rørtop. Hæld IKKE stabiliseringsvæske ud af røret.

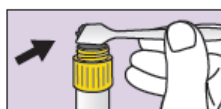


- 3** Brug spatlen til at indsamle en lille afføringsprøve.



- 4** Overfør afføringsprøven ind i den gule rørtop. Fortsæt indtil prøven har fyldt den gule rørtop op.

VIGTIGT: Skub IKKE prøven ind i røret.



- 5** Skrab vandret hen over rørets top for at jævne prøven og fjern overskydende mængder.

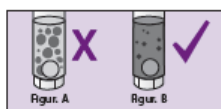
Aftør røret udvendigt og toppen med toilettepapir eller en serviet, hvis nødvendigt.



- 6** Tag den violette hætte ved den massive ende pegende nedad og skru den på den gule rørtop indtil den er lukket godt til.



- 7** Ryst det lukkede rør så kraftigt og hurtigt som muligt frem og tilbage i mindst 30 sekunder.



- 8** Afføringsprøven blandes sammen med stabiliseringsvæsken i røret; ikke alle partikler opløses.

VIGTIGT: Fortsæt med at ryste, hvis der er store partikler som på i figur. A.




- 9** Læg spatlen tilbage i originalemballagen eller pak den ind i toilettepapir, og smid den ud med affaldet.

VIGTIGT: Indsend prøven til videre bearbejdning ved at følge leveringsinstrukserne, som leverandøren har sendt separat med sættet.

13.2 Feces sampling instruction (self-collection) - DUTCH

OM-AC1 toiletaccessoire

Gebruikt in combinatie met  **OMNIGENE[®]GUT**

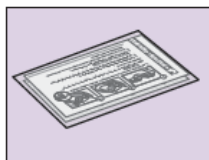
GEBRUIKSIINSTRUCTIES

Dit toiletaccessoire wordt gebruikt in combinatie met de OMNIgene®-GUT set voor het eenvoudig opvangen van fecesmonsters.

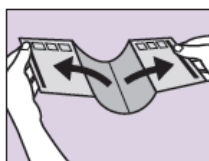
Let op: er mag GEEN water uit het toilet, urine, schoonmaakmiddel of toiletverfrisser met dit toiletaccessoire in contact komen.

Bewaren bij: 15 °C tot 25 °C

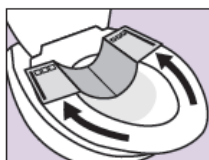
Procedure:



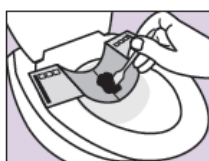
- 1** Er worden twee toiletaccessoires geleverd voor het geval het u bij de eerste poging niet lukt om ontlasting op te vangen.



- 2** Trek voorzichtig de hoek met de markering ▲ open en herhaal dit bij de hoek met de ■.



- 3** Bevestig het zelfklevende oppervlak van het toiletaccessoire aan de **ACHTERKANT van de toiletzitting** met het zelfklevende deel dicht tegen de buitenrand van de zitting aan en duw stevig aan.



- 4** Neem een fecesmonster volgens de OMNIgene•GUT gebruiksinstructies.



- 5** Laat het gebruikte accessoire in het toilet vallen. Wacht 1 minuut, zodat het papier zacht wordt en spoel dan door. U kunt het ook weggooien.



OM-AC1 wordt in Nederland gemaakt
voor DNA Genotek Inc
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2

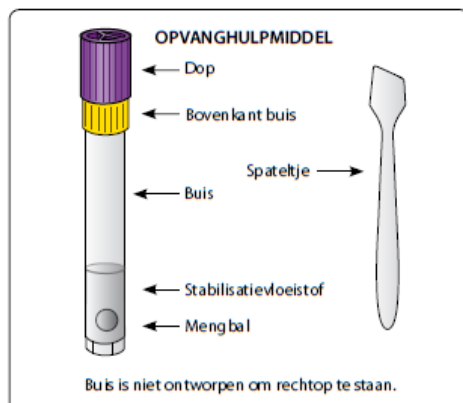
Superieure monsters
Bewezen prestaties

Tel.: +1.613.723.5757
Fax: +1.613.723.5057
Info@dnagenotek.com
www.dnagenotek.com

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Octrod (www.dnagenetk.com/legalnotices)
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PD-PR-00689 (NL - Dutch) Issue 2/2018-08





Samenvatting en uitleg van de set:

OMNigene-GUT levert de materialen en aanwijzingen voor afname en stabilisatie van microbiële DNA uit een fecesmonster.

Waarschuwingen en voorzorgsmaatregelen:

- **UITSLUITEND VOOR UITWENDIG GEBRUIK.**
- De gele bovenkant van de buis **NIET** verwijderen.
- De stabilisatievloeistof in de buis **NIET** morsen.
- Als de vloeistof in contact komt met de ogen of huid, wassen met water. **NIET** inslikken.
- Voor afname van een vloeibaar monster, de afzonderlijk geleverde gebruiksinstructies raadplegen.
- Kleine voorwerpen kunnen verstikkingsgevaar opleveren.

Opslag: 15 °C tot 25 °C

Verzenden conform de geldende regelgeving voor het vervoer van biologische monsters. Zie VIB op www.dnagenotek.com.

Legenda bij etiket:

- Monster uiterlijk a finemen op (uiterste gebruiksdatum)
- REF Catalogusnummer
- Fabrikant
- 15°C / 25°C Instructies voor opslag
- Let op, raadpleeg gebruiks aanwijzing
- LOT Lotnummer

GEBRUIKSINSTRUCTIES

Lees vóór de afname alle instructies

Procedure:

- 1 BELANGRIJKE VOORBEREIDINGEN:**

 - Leeg uw blaas voordat met afname wordt begonnen.
 - Vang het fecesmonster op, zonder urine of wc-water.
 - Toilet papier of papieren zakdoekjes kunnen nodig zijn.
- 2** Houd de gele bovenkant van de buis vast, schroef **ALLEEN** de paarse dop los en leg deze weg voor later gebruik.

BELANGRIJK: Verwijder **NIET** de gele bovenkant van de buis. Mors **GEEN** stabilisatievloeistof in de buis.
- 3** Gebruik het spateltje om een klein fecesmonster te nemen.

Fecesmonster op werkelijke grootte.
- 4** Breng het fecesmonster over in de gele bovenkant van de buis. Herhaal dit totdat het monster de gele bovenkant van de buis vult.

BELANGRIJK: Duw het monster **NIET** in de buis.
- 5** Schraap horizontaal langs de bovenkant van de buis om het monster vlak te maken en overtollig materiaal te verwijderen.

Veeg de buitenkant en de bovenkant van de buis indien nodig af met toilet papier of papieren zakdoekjes.
- 6** Pak de paarse dop vast met het harde uiteinde omlaag gericht en draai de dop stevig op de gele bovenkant van de buis.
- 7** Schud de afgesloten buis zo hard en snel mogelijk heen en weer gedurende minimaal 30 seconden.
- 8** Het fecesmonster wordt in de buis met de stabilisatievloeistof gemengd; niet alle deeltjes lossen op.

BELANGRIJK: Blijf schudden als er grote deeltjes overblijven, zoals weergegeven in afbeelding A.
- 9** Plaats het spateltje in de originele verpakking of wikkel het in toilet papier en gooi het weg bij het afval.

BELANGRIJK: Verstuur het monster voor verwerking volgens de afleverinstructies van de leverancier van de set.

13.3 Feces sampling instruction (self-collection) - SWEDISH

OM-AC1 Toalettillbehör

Används med  **OMNigene®-GUT**

BRUKSANVISNING

Detta toalettillbehör används med OMNigene®-GUT-kit för att underlätta insamlingen av fekalprov.

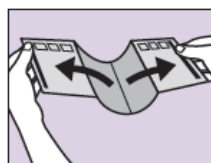
Varning: Låt INTE toalettvattnen, urin, rengöringsmedel eller doft komma i kontakt med detta toalettillbehör.

Förvaring: 15 °C till 25 °C

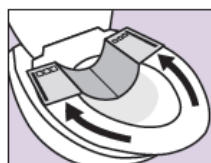
Procedur:



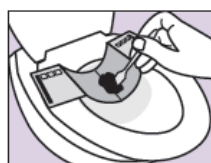
- 1** Två toalettillbehör ingår om du inte kan samla in något prov på det första försöket.



- 2** Öppna kanten försiktigt med ▲; upprepa för kant med ■.



- 3** Fäst tillbehörets klistriga yta i **toalettstolens BAKSIDA** med klistret nära sitsens ytterkant och tryck till.



- 4** Samla in fekalprovet genom att följa bruksanvisningen för OMNigene-GUT.



- 5** Släpp ned förbrukat tillbehör i toaletten. Vänta 1 minut tills pappret har blivit mjukt och spola sedan. Du kan också kasta det i papperskorgen.

DNAgenotek



OM-AC1 tillverkas i Nederländerna
för DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2

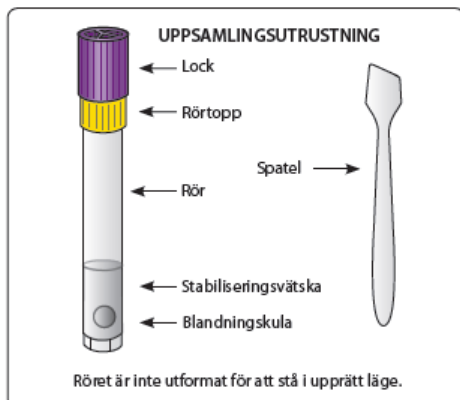
Överlägsna prover Bevisad prestanda

Tel.: +1 613 723 5757
Fax: +1 613 723 5057
info@dnagenotek.com
www.dnagenotek.com

*OMNigene är ett varumärke registrerat av DNA Genotek Inc.
Vissa DNA Genotek-produkter är kanske inte tillgängliga i alla geografiska regioner, kontakta
din försäljningsrepresentant för detaljer.
Alla DNA Genotek's protokoll, policyer och hänvisningar finns under sup portavdelningen på
vår webbplats www.dnagenotek.com.

Patent (www.dnagenotek.com/legal/notice)
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PD-PR-00797 (SV - Swedish) Issue 1/2018-07





Sammanfattning och förklaring av utrustningen:

OMNIGENE-GUT innehåller material och instruktioner för att samla upp och stabilisera mikrobiologiskt DNA från ett avföringsprov.

Varning och försiktighetsåtgärder:

- ENDAST FÖR EXTERNT BRUK.
- Ta inte av den gula rörtoppen från röret.
- Spill inte stabiliseringsvätskan i röret.
- Tvätta med vatten om du får vätskan i ögonen eller på huden. Får EJ förtäras.
- Om avföringsprovet är löst, se separat anvisning.
- Små föremål kan utgöra kvävningsfara.

Förvaring: 15°C till 25°C

Frakta i enlighet med gällande bestämmelser för transport av biologiska prover. Se MSDS på www.dnagenotek.com

Etikettförklaring:

- Samla in prov senast (använd senast)
- Katalognummer
- Tillverkare
- Förvaringsinstruktioner
- Observera, läs bruksanvisning
- Referensnummer

BRUKSANVISNING

Läs alla instruktioner före provtagning

Tillvägagångssätt:



1 VIKTIGA FÖRBEREDELSE:

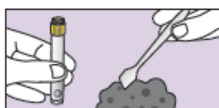
- Töm blåsan innan du börjar med uppsamlingen.
- Ta ett avföringsprov som inte innehåller urin eller toalettatten.
- Toalettpapper eller servetter kan behövas.



2 Håll i den gula rörtoppen medan du skruvar av ENDAST det lilla locket och sparar det till senare.

VIKTIGT:

Ta inte av den gula rörtoppen från röret. Spill inte stabiliseringsvätskan i röret.



3 Använd spateln för att ta ett litet avföringsprov.



Rätt storlek på avföringsprovet.



4 För över avföringsprovet till den gula rörtoppen. Upprepa tills provet fyller den gula rörtoppen.

VIKTIGT: Provet ska inte tryckas ihop i röret.



5 Skrapa av horisontellt över röret för att jämna av provet och avlägsna överskott.

Torka av utsidan av röret och toppen med toalettpapper eller servett om så behövs.

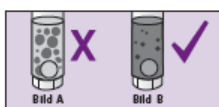


6 Plocka upp det lila locket med den solida sidan nedåt och skruva på det tills det sitter tätt på den gula rörtoppen.



7 Skaka det förslutna röret så hårt och snabbt som möjligt i minst 30 sekunder.

30 sekunder



8 Avföringsprovet ska blandas med stabiliseringsvätskan i röret. Alla beståndsdelar kommer inte att lösas upp.

VIKTIGT: Fortsätt skaka om det återstår stora bitar som på bild A.



9 Lägg spateln i originalförpackningen eller linda in den i toalettpapper och släng i soporna.

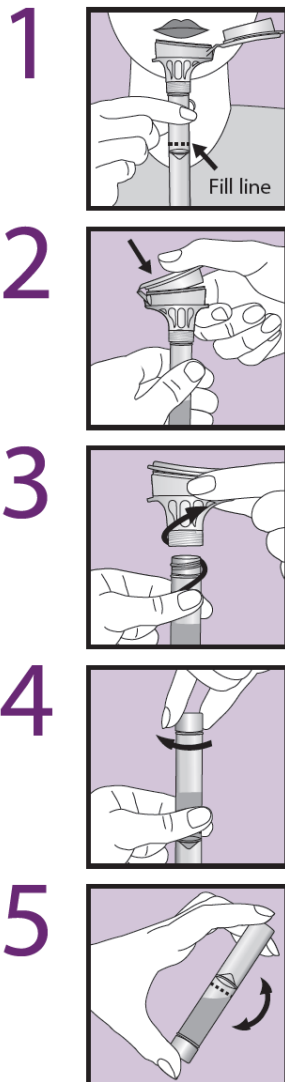
VIKTIGT: Skicka in provet för behandling genom att följa fraktinstruktionerna som tillhandahålls separat av tillverkaren.

13.4 Saliva sampling instruction - DANISH

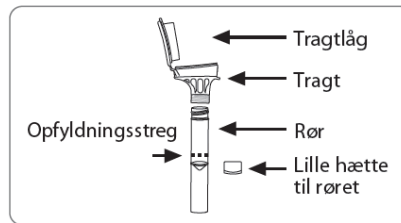


For the collection and stabilization
of nucleic acids from saliva

For In Vitro Diagnostic Use



DA DANSK Brugervejledning



Læs alle vejledninger inden indsamling.

Tilsigtet anvendelse: OMNigene-ORAL er beregnet til opsamling og stabilisering af nukleinsyrer fra spyt.

Indhold: Sættet indeholder stabiliserende væske.

Advarsler og forholdsregler: Skyl med vand hvis den stabiliserende væske kommer i kontakt med øjne eller hud. Må IKKE indtages. Se Sikkerhedsdatablad på www.dnagenotek.com.

Lille hætte, kvælningsfare.

Opbevaring: 15 °C / 30 °C

Resumé og forklaring af sættet:

OMNigene-ORAL er et sæt til selv-indsamling, der leverer materiale og vejledningen til at indsamle og stabilisere spytprøver.

Forholdsregler ved indsamling:

UNDLAD at spise, drikke, ryge eller tygge tyggegummi i 30 minutter inden afgivelse af prøven.

Fjern IKKE plastfilmen fra tragtens låg.

Procedure:

For de fleste personer tager det mellem 2 og 5 minutter at aflevere en prøve, når de følger trin 1 til 5.

- 1 Spyt i tragten, indtil mængden af væske (uden bobler) når markeringslinjen vist på billede 1.
- 2 Hold røret lodret med en hånd. Luk låget med den anden hånd (som vist) ved at trykke fast ned på låget, indtil du hører et højt klik. Væsken i låget vil blive frigivet så den løber ind i røret og blandes med prøven. Sørg for, at låget er lukket tæt.
- 3 Hold røret lodret. Skru tragten af røret.
- 4 Brug den lille hætte til at lukke røret tæt til.
- 5 Ryst røret med hættens påsat i 5 sekunder. Kassér tragten eller aflever den til genbrug.

En indsamlet prøve er potentielt infektiøs og skal håndteres i overensstemmelse med passende forholdsregler for miljømæssig sikkerhed.

Forsendes i henhold til gældende regler vedrørende transport af biologiske prøver.

DNagenotek™

Made in Canada
DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2

Tel.: +1.613.723.5757
info@dnagenotek.com
www.dnagenotek.com

PD-PR-00996 Issue 2/2020-07

Symbolforklaring:

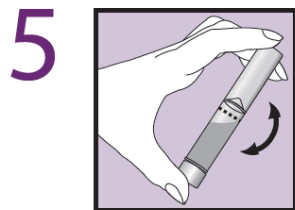
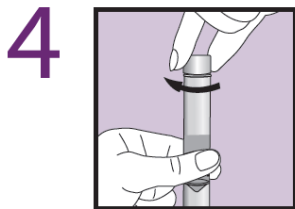
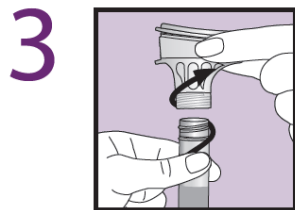
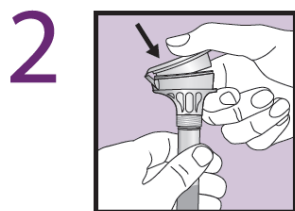
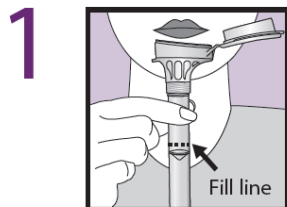
	Prøve skal indsamles inden (Anvendes inden)
	Medicinsk udstyr til in vitro-diagnostik
	Katalognummer
	CE-mærkning
	Forsigtig, se brugsvejledningen
	Opbevaringsvejledning
	Autoriseret repræsentant
	Fabrikant
	Partinummer

13.5 Saliva sampling instruction - DUTCH



For the collection and stabilization
of nucleic acids from saliva

For In Vitro Diagnostic Use



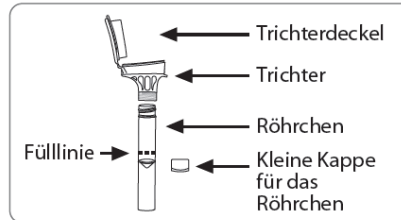
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Ottawa, ON, Canada K2V 1C2

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DE DEUTSCH Benutzeranleitung



Vor der Probenahme alle Anweisungen lesen.

Verwendungszweck: OMNigene-ORAL ist für die Entnahme und Stabilisierung von Nukleinsäuren aus Speichel bestimmt.

Inhalt: Kit enthält Stabilisierungsflüssigkeit.

Warnhinweise und Vorsichtsmaßnahmen: Mit den Augen oder der Haut in Kontakt gekommene Stabilisierungsflüssigkeit mit Wasser abwaschen. NICHT verschlucken. Siehe MSDS (Sicherheitshinweise für den Umgang mit gefährlichen Substanzen) unter www.dnagenotek.com.

Kleine Kappe, Erstickungsgefahr.

Lagerung: 15 °C / 30 °C

Zusammenfassung und Erläuterung des Kits:

OMNigene-ORAL ist ein Selbstentnahme-Kit, das die Materialien und Anweisungen zur Entnahme und Stabilisierung von Speichelproben enthält.

Vorsichtsmaßnahmen bei der Probenahme:

Für 30 Minuten vor der Probenahme NICHT essen, trinken, rauchen oder Kaugummi kauen.

NICHT die Kunststoffolie vom Trichterdeckel entfernen.

Verfahren:

Bei den meisten Personen dauert die Abgabe der Probe nach Schritt 1 bis 5 zwischen 2 und 5 Minuten.

- 1 Solange in den Trichter spucken, bis die Menge der Flüssigkeit (ohne Luftbläschen) die in Bild 1 gezeigte Fülllinie (Fill Line) erreicht.
- 2 Das Röhrchen mit einer Hand aufrecht halten. Mit der anderen Hand den Deckel schließen (wie abgebildet), indem der Deckel fest angedrückt wird, bis ein lautes Klicken zu hören ist. Die Flüssigkeit im Deckel wird in das Röhrchen freigegeben und vermischt sich mit der Probe. Sicherstellen, dass der Deckel fest verschlossen ist.
- 3 Das Röhrchen aufrecht halten. Den Trichter vom Röhrchen abschrauben.
- 4 Das Röhrchen mit der kleinen Kappe fest verschließen.
- 5 Das verschlossene Röhrchen 5 Sekunden lang schütteln. Den Trichter wegwerfen oder recyceln.

Die entnommene Probe ist potenziell infektiös und muss unter Anwendung geeigneter biologischer Sicherheitspraktiken gehandhabt werden.

Die Probe muss unter Einhaltung der anwendbaren Vorschriften für den Transport von biologischen Proben gesendet werden.

Etikettenlegende:

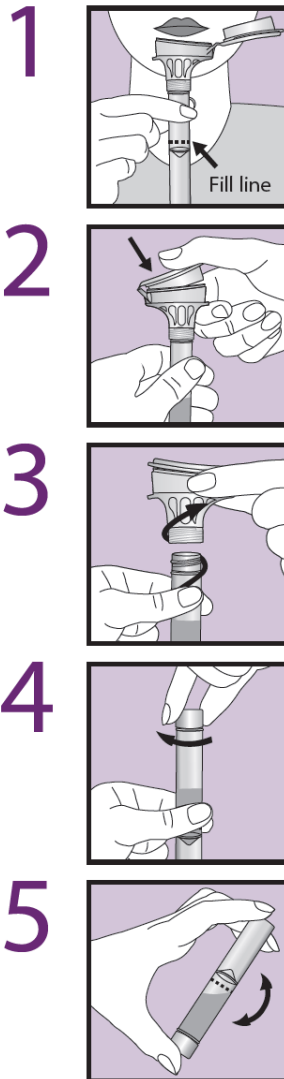
	Probenentnahme bis (Verwendbar bis)
	Medizinisches In-vitro-Diagnosegerät
	Katalognummer
	CE-Kennzeichnung
	Achtung, Gebrauchsanweisung lesen
	Lagervorschriften
	Autorisierter Vertreter
	Hersteller
	Losnummer

13.6 Saliva sampling instruction - SWEDISH



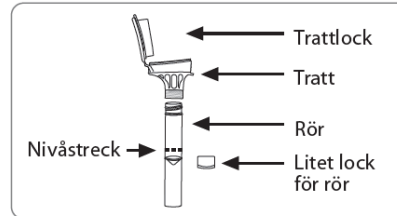
For the collection and stabilization
of nucleic acids from saliva

For In Vitro Diagnostic Use



SV SVENSKA

Bruksanvisning



Läs hela anvisningen innan provet avges.

Användningsområde: OMNigene-ORAL är avsedd för insamling och stabilisering av nukleinsyror från saliv.

Innehåll: Satsen innehåller stabiliseringsvätska.

Varningar och försiktighetsåtgärder: Tvätta med vatten om stabiliseringsvätskan kommer i kontakt med ögon eller hud. Får EJ förtäras. Se säkerhetsdatablad på adressen www.dnagenotek.com.

Litet lock, kvävningrisk.

Förvaring: 15°C / 30°C

Sammanfattning och förklaring av satsen:

OMNigene-ORAL är en sats för egenprovtagning med material och anvisningar för insamling och stabilisering av salivprover.

Försiktighetsåtgärder vid insamling:

Vänta MINST 30 min efter att du ätit, druckit, rökt eller tuggat tuggummi innan du ger provet.

Ta INTE bort plastfilmen från trattlocket.

Procedur:

För de flesta personer tar det mellan 2 och 5 minuter att ge ett salivprov enligt punkterna 1 till 5.

- 1 Spotta i tratten tills mängden vätska (utan bubblor) når upp till nivåstrecket som visas i figur 1.
- 2 Håll röret upprätt med ena handen. Stäng trattlocket med den andra handen (enligt figur) genom att trycka till så att ett skarpt klick hörs. Vätskan i locket släpps ner i röret för att blandas med provet. Se till att locket sluter tätt.
- 3 Håll röret upprätt. Skruva loss tratten från röret.
- 4 Sätt på det lilla locket så att det sluter tätt mot rörets öppning.
- 5 Skaka det tillslutna röret i 5 sekunder. Kasta tratten i sopor eller återvinning.

Insamlade prov är potentiellt smittsamma och ska behandlas med lämplig biosäker omsorg.

Skicka enligt gällande bestämmelser gällande transport av biologiska prover.

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Ottawa, ON, Canada K2V 1C2

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info@dnagenotek.com
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Symbolförklaringar:

	Samla saliv senast (använd före)
	In vitro medicinteknisk produkt avsedd för diagnostik
	Katalognummer
	CE-märkning
	Varning, se instruktion för användning
	Anvisning för förvaring
	Behörig representant
	Tillverkare
	Referensnummer