

Operating Manual for the preparation and shipment of centralised biological samples for the study:

EU-SolidAct Study

In case of problems or questions concerning the preparation and the shipment of the samples, please contact THERADIS PHARMA:

Email: solidact@theradispharma.com

Tel: +33 (0)4 97 02 09 39 / Fax: +33 (0)4 97 10 08 78

Contacts: Tu Van Pham (Project Leader) and the Coordination Team





Summary

1.	Sample schedule	Page 3
2.	Documents for the biological samples.	Page 4
3.	Material for the biological samples	Page 5
4.	Identification of cryotubes	Page 6
5.	Sampling material and transfer material details	Page 7
6.	Completion of the Patient Requisition Form for the centralised analyses	Page 8
7.	Data Clarification Form / Query resolution process	Page 10
8.	Important Sampling Information	Page 11
10.	Sampling / Preparation of samples	Page 13
11.	Shipment of frozen samples	Page 16
12.	Shipment of frozen samples to THERADIS PHARMA	Page 17



Study title: Multinational, European, Adaptive Platform trial used for new clinical trials targeting SARS-CoV-2 in short-term and other emerging infectious diseases in the longer term.

A double bind, multicentre, randomized, placebo-controlled, phase III trial to investigate the safety and efficacy of baricitinib + standard of care (SoC) compared with placebo + SoC on the occurrence of death in male and female participants aged > 18 years with severe COVID-19

The patients will be sampled for the centralised analyses at the **following visits**:

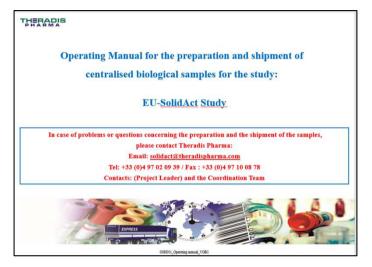
Visits	Baseline (D1)	D3	D8	D15	D22
EDTA-Plasma sample	X*	X	X	X	X
Serum sample	X*	X	X	X	X
Naso-oropharyngeal swab **	X*	X	X	X	

^{*} Before drug intervention

^{**} If nasopharyngeal sample is not possible, an oropharyngeal sample is an alternative

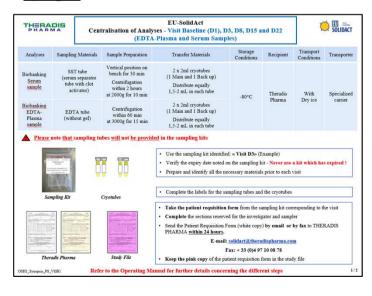


Operating Manual



One operating manual per site (in local language)

Synopsis



A synopsis in
English which will
summarise the main
steps to prepare the
samples, inserted in
each sampling kit

Patient Requisition Form

			U-SolidAct St on Form (RF)			7	SOLIDACT
Investigator section:	The day of the visit,	complete th	is section and tr	Int.	Ref.: OSH001		
Investigator (or Deleg	Name // / / / / / Centre N°		Date (DO'MM/7773)	Syn	uure		R code
Sampling section: To	be completed by the	sampler					
Date of Sampling: /	/ // / / / DD MMM	// 2 / (0 / / /	Time of Sampl	ling: /////_	/ Mas Mas	1
30.00.00	8 8 99	Tick if	Tubes to	be stored	20 7000	8	Transport
Analysis	Sampling tube	sampling is done	MAIN (white copy)	BACK-UP (yellow copy)	Theradis Pharma	section	Destination
Biobanking Serum	SST tube	0	1 cryotube 2mL	I cry otube 2mL			Transport wi dry ice organised b Theradis
Biobanking Plasma	EDTA tube	0	l cryotube 2mL	1 cry otube 2mL			Pharma Theradis
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- ➤ One requisition form in English per patient inserted in each sampling kit
- ➤ The requisition form is a duplicate or triplicate document according to the visit
- ➤ The requisition form must be completed at the time of sampling

In case of problems regarding the material provided and for all other requests, please contact THERADIS PHARMA immediately



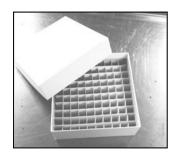
Biological Sampling Kits



Sampling kits, identified by visit:

- Serum and EDTA-Plasma samples (Biobanking)
- Naso-oropharyngeal swab

Cryoboxes "81 positions"



Cryoboxes for 2ml cryotubes for storage on-site and for shipment to Theradis Pharma:

- ➤ A cryobox for Main cryotubes
- ➤ A cryobox for Back-up cryotubes



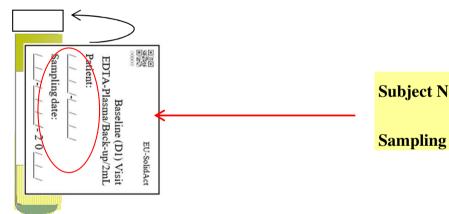
Please note that sampling tubes for Plasma and Serum will not be provided in sampling kits

In case of problems regarding the material provided and for all other logistic requests, please contact THERADIS PHARMA immediately





IMPORTANT: Prior to sampling, complete all the labels already stuck on each cryotube



Subject N° = 6 digits e.g. : $\frac{/}{/}$ $\frac{/}{/}$ $\frac{/}{/}$ Patient N°

Sampling Date (Collection date) = DD/MMM/YYYY e.g. : 01/APR/2021

Labels already stuck on the cryotubes



Sampling tubes and transfer tubes details

Analyses	Visit	Sampling Material *	Sample Preparation	Transfer Material	Storage Conditions	Transport Conditions	Destination
Biobanking Serum sample	Baseline (D1), D3, D8, D15, D22			2 x 2ml cryotubes (1 Main and 1 Back up) Distribute equally 1,5-2 mL in each tube			
Biobanking EDTA-Plasma sample	Baseline (D1), D3, D8, D15, D22	EDTA tube (without gel)	Centrifugation within 60 min at 3000g for 15 min	2 x 2ml cryotubes (1 Main and 1 Back up) Distribute equally 1,5-2 mL in each tube	-80°C	With Dry ice	THERADIS PHARMA
Naso- oropharyngeal swab	Baseline (D1), D3, D8, D15	1 sampling flocked swab + Transport medium 3ml	NA	2x 2ml cryotubes Distribute equally 1,5 mL in each tube			

^{*} Please note that sampling tubes for Plasma and Serum will not be provided in sampling kits



6 – Completion of the Patient Requisition Form for Biobanking

							• At the time of sampling, complete all the information required:		
THERADIS			EU-SolidAct St	*	(SOLIDACT	Investigator Section:		
Investigator section:					the sampler 1	nt. Réf.: OSH001	Name of the Investigator		
Investigator (or Deleg						QR code	➤ Patient Identification		
Patient: /	Name	, , ,	Date (DD/MM/YYYY)	Sign	nu ure		➤ Date and signature		
aucin: ¿	/ / /-/ Centre N*	Patient N*			osi	H-D3-Laxxxx-xxx	Sampling Section:		
Sampling section: To	be completed by the	sampler					► Date of Sampling		
Date of Sampling: /	1 11 1 1	1/2/	0 / / /	Time of Samp	ling: / / // /				
	DO SOMO	Tick if		be stored	101 Min Min	Transport	Time of Sampling		
Analysis	Sampling tube	sampling is done	MAIN (white copy)	BACK-UP (yellow copy)	Theradis Pharma section		Name and signature of the Sampler		
iobanking Serum	SST tube		1 cryotube 2mL	17.		Transport with dry ice	Comments		
		+				organised by Theradis Pharma	Processing Section:		
Biobanking Plasma	EDTA tube		1 cryotube 2mL	1 cry otube 2mL		→ Theradis	Centrifugation Start Time		
Name:	Visa		Comments:						
Trails.			Commens,				> Time of Freezing		
Processing section: T	o be completed by th	ne Technicia	an who handles th	ne samples			➤ Name and signature of the Technician		
Centrifugation Start	Γime: / / //	/ / Min Min		Time of Freezin	g: / / // / Min Min	1	Comments		
Name:	Visa: .		Comments:	***************************************			• Send the Patient Requisition Form (white copy) by email or by fax to		
MPORTANT	Complete and in	amadiataly a	and the white conv	to Thursdie Phone	ma after promoting compl		THERADIS PHARMA within 24 hours.		
MPORIANI					na <u>after processing sampl</u> +33 (0)4 97 10 08 78		THERADIS I HARMA WIGHT 24 HOURS.		
	be joined with the M						Email solidact@theradispharma.com		
	o be joined with the E be archived in the stud		ubes sent to Thera	idis Pharma (in a	separate stupment)		Fax: +33 (0)4 97 10 08 78		
			or questions, pleas						
Theradis Pharma sec					(0)4 97 02 09 39		• White copy to be joined with the MAIN tubes sent		
			samples at Th		a		to THERADIS PHARMA		
	samples: //	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							
Number of samples n	eceived: //(Pi	ease complete	e the table above)	Received in g	ood condition: Yes	No 🗖	• Yellow copy to be joined with the BACK-UP tubes sent		
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6 – Completion of the Patient Requisition Form for Naso-oropharyngeal samples

	• At the time of sampling, complete all the information required
EU-SolidAct Study Requisition Form (RF) for Naso-oropharyngeal sample for Visit D3	Investigator Section:
Investigator section: The day of the visit, complete this section and transmit the RF to the sampler Int. Ref. : OSH001	Name of the Investigator
Investigator (or Delegate) Date (DDAMN/7777) Sinnaire QR code	> Patient
Patient: [[] - [] [] Centre N* Patient N*	> Date and signature
Centre N° Patient N° OSH1-D3NOP-Laxxxx-xx	Sampling Section:
Sampling section: To be completed by the sampler	☐ Date of Sampling
Date of Sampling: / / / / / / 2 / 0 / / Time of Sampling: / / / / Mn Min Time of Sampling: / / / / / Mn Min Min Min Min Min Min Min Min Min	➤ Time of Sampling
Please tick the box corresponding to the sample type: Nasopharyngeal sample Note: The same procedure should be followed at all time points for the same patient for reproducibility.	Type of sample
Analysis Sampling tube Tick if sampling Tubes to be stored Theradis Pharma section conditions &	Name and signature of the Sampler
is done Destination Transport with	Comments
Nasopharyngeal or I Nasopharyngeal swab 2 covernibes 2ml dry ice organised by	
Oropharyngeal swab + Transport medium 3ml Pharma	Processing Section:
→ Theradis	➤ Time of Freezing
Name: Visa: Comments:	➤ Name and signature of the Technician
Processing section: To be completed by the Technician who handles the samples	Comments
Time of Freezing: / / / / / Mm Min /	
Name:	
IMPORTANT Complete and immediately send the white copy to Theradis Pharma after processing samples: Email: solidact@theradispharma.com or Fax: +33 (0)4 97 10 08 78	• Send the Patient Requisition Form (white copy) by email or by fax THERADIS PHARMA within 24 hours.
✓ White copy to be joined with the tubes sent to Theradis Pharma	THERADIS THARMA Within 24 hours.
✓ Pink copy to be archived in the study file In case of problems or questions, please contact Theradis Pharma	
Email: solidact@theradispharma.com or Tel: +33 (0)4 97 02 09 39	Email solidact@theradispharma.com
Theradis Pharma section: Reception of samples at Theradis Pharma	Fax: +33 (0)4 97 10 08 78
Date of receipt of the samples: / / / / / / / / / / / / / / / / / / /	
Number of samples received: // (Please complete the table above) Received in good condition: Yes 🗖 No 🗖	White copy to be joined with the MAIN tubes sent
Received by: Name Signature Date (DDMMM7777)	to THERADIS PHARMA
Comments:	
White copy to be joined with the tubes sent to Theradis Pharma; Pink copy to be archived in the study file FDL.CRY07010505VF1 OSHEOL_RF_D3NP_VGB4 Page 1/1	• Pink copy to be archived in the study file



7- Data Clarification Form / Query resolution process

	DCF N°:
SPONSOR: OSLO UNIVERSITY HOSPITAL	PROTOCOL: EU-SolidAct
INVESTIGATOR:	CENTRE N°:
Section reserved for Theradis Pharma:	
Date of query request (DIMMM/TY):	From:
Patient N°: / / / /-/ / Patient N°	Visit:
Sampling date (DIMMMYTT):	
MISSING DATA OR I	DATA TO BE CONFIRMED
Comments:	
Section reserved for CRA and/or Investigator: CORR	ECT DATA
	EECT DATA
CORR	

Anomalies: incorrect, missing, unreadable data on the Patient Requisition Form

- In case of discrepancies, a Data Clarification Form (DCF) will be
 - issued by THERADIS PHARMA
 - and sent by email or by fax to the centre responsible for the anomaly (copy to CRA Responsible and Sponsor)
- Immediately after receiving the DCF, please complete the "Section reserved for CRA and/or Investigator":
 - ➤ Correct data
 - ➤ Any comments
 - ➤ Date and signature
- Send the DCF by email or by fax to THERADIS PHARMA within 24 hours.

Email: solidact@theradispharma.com Fax: +33 (0)4 97 10 08 78

• DCFs non resolved after **1 week** will be sent again by email or by fax to the centre (copy to CRA Responsible and Sponsor)



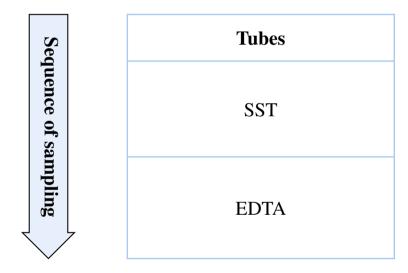


ATTENTION! Important Information

- ➤ It is essential to respect the process described on the following pages for each analysis
- Check the expiry date noted on the sampling kit. Never use a kit which has expired!
- > Use the kit corresponding to the visit
- ➤ Prepare all the material prior to each sampling. Write the Patient N° and the sampling date on the label stuck on each cryotube.
- Respect the sequence for sampling the tubes as described on page 12
- Aliquoting must be done **immediately after centrifugation** using one pipet per sampling tube type
- ➤ After each sampling, place the samples in the cryobox provided and store at -80°C until shipment
- If a sampling kit is not usable, please send the Patient Requisition Form which is in the sampling kit by email or by fax to THERADIS PHARMA









Please note that sampling tubes pictures (on pages 13 and 14) are for reference only. Tube and cap colours may differ depending on the manufacturers.



Serum samples for Biobanking at: Baseline (D1), D3, D8, D15, D22 Visits

Material



SST tube (serum separator tube with clot activator)



2 labelled cryotubes





Sampling, sample preparation and storage on site

Blood sampling:

- Take a blood sample using the SST tube (serum separator tube with clot activator)
- Note the time of sampling on the requisition form

Preparation:

- Immediately after sampling, **homogenise gently by inverting 8 to 10 times** the SST tube <u>without shaking it</u>
- Allow the blood content of the tube to clot in the upright position at room temperature for approximately 30 minutes
- Centrifuge within 2 hours for 10 minutes at 2000g
- Immediately after centrifugation of the tube use the pipet to distribute equally 1,5-2 mL of serum (leave approximately 0,5 cm above the cell layer) into each of the 2 transfer tubes labelled «Serum/Main/2mL» and «Serum/Back-up/2mL»

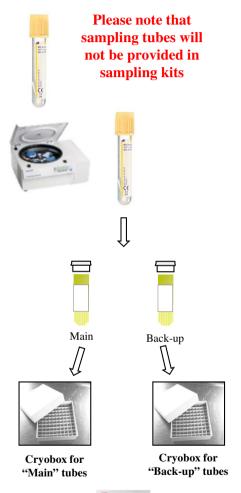
Note: Handling of serum tubes can be grouped if blood from several patients is drawn on the same day. In the meantime, store the sampling tubes at 4°C (vertical position for the coagulation of the serum) until centrifugation. Record the time from sampling to freezing in the eCRF.

Storage:

- Immediately place the "Main" cryotube in the cryobox identified for the study "2ml Main cryotubes" and the back-up cryotube in the cryobox identified for the study "2ml Back-up cryotubes"
- Store at -80°C until shipment (the cryotubes should be frozen at nominal 80°C, as soon as possible and latest within 12 hours)

Note: Short-term freezing at -20°C for up to one week is acceptable if -80°C freezer is not available.

- Keep the **white** copy of the patient requisition form. It will be placed in the front pouch of the diagnobag at the time of shipping the Main tubes
- Keep the **yellow** copy of the patient requisition form. It will be placed in the front pouch of the diagnobag at the time of shipping the Back-up tubes
- Keep the **pink** copy of the patient requisition form in the study file



Freezer



EDTA plasma samples for Biobanking at: Baseline (D1), D3, D8, D15, D22 Visits

Material



EDTA tube (preferably without gel)



2 labelled cryotubes

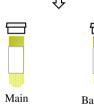


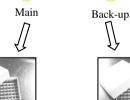


Sampling, sample preparation and storage on site









Cryobox for

"Main" tubes





Blood sampling:

- Take a blood sample using the EDTA tube (preferably without gel)
- Note the time of sampling on the requisition form

Preparation:

- After sampling, homogenise gently by inverting 8 to 10 times the EDTA tube without shaking it
- **Centrifuge** as soon as possible (preferably within 30 minutes, latest within 60 minutes) at 3000g for 15 minutes at **4° C**
- Immediately after centrifugation of the tube use the pipet to distribute equally 1,5-2 mL of plasma (leave approximately 0,5 cm above the cell layer) into each of the 2 transfer tubes labelled «EDTA-Plasma/Main/2mL» and «EDTA-Plasma/Back-up/2mL»

Note: Handling of plasma tubes can be grouped if blood from several patients is drawn on the same day. In the meantime, store the sampling tubes at 4°C until centrifugation. Record the time from sampling to freezing in the eCRF

Storage:

- Immediately place the "Main" cryotube in the cryobox identified for the study "2ml Main cryotubes" and the back-up cryotube in the cryobox identified for the study "2ml Back-up cryotubes"
- Store at -80°C until shipment (the cryotubes should be frozen at nominal 80°C, as soon as possible and latest within 12 hours)

Note: Short-term freezing at -20°C for up to one week is acceptable if -80°C freezer is not available.

- Keep the **white** copy of the patient requisition form. It will be placed in the front pouch of the diagnobag at the time of shipping the Main tubes
- Keep the **yellow** copy of the patient requisition form. It will be placed in the front pouch of the diagnobag at the time of shipping the Back-up tubes
- Keep the **pink** copy of the patient requisition form in the study file



Naso-oropharyngeal sample: Baseline (D1), D3, D8, D15 Visits

Material



Naso-oropharyngeal swab + Transport medium 3ml





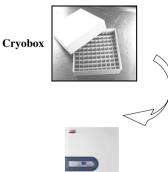
2 labelled cryotubes



Nas







Sampling, sample preparation and storage on site

Naso-oropharyngeal swab:

- Perform the nasopharyngeal sample with the swab provided
- Gently insert the swab along the nasal septum, just above the floor of the nasal passage, to the nasopharynx, until resistance is felt.
- Rotate the swab for 5-10 seconds to obtain cellular material.
- Break the swab into the corresponding transport medium 3mL tube and close the tube.
- Note the sampling time on the requisition form
- ➤ If nasopharyngeal sample is not possible, an oropharyngeal sample is an alternative. Again, rotate the swab for 5-10 seconds.

The same procedure should be followed at all time points for the same patient for reproducibility.

Preparation:

- **Immediately after sampling**, gently invert the transport medium 3mL tube 8 to 10 times without shaking it
- Then use the pipet to distribute equally approximately 1,5 mL of the transport medium from the tube into each of the 2 transfer tubes labelled «NP-OP/2mL»

Storage:

- Then place the tubes identified «NP-OP/2mL» in the cryobox identified "2ml Main cryotubes"
- Store the cryobox at -80° C until shipment
- Keep the **white** copy of the patient requisition form and place it in the front pouch of the diagnobag at the time of shipping
- Keep the **pink** copy of the patient requisition form in the study file



Pick-ups will be organised by THERADIS PHARMA from Tuesday to Thursday. 3 pick-up per site are planned

Before each pick-up, THERADIS PHARMA will notify the centre by email to validate the pick-up date

Information for the pick-up of the samples:

Analyses	Cryoboxes	Destination	Frequency	Carrier	Transport conditions
Biobanking (EDTA-Plasma/Serum) Naso-oropharyngeal swab	1 to 3 cryoboxes per transport	THERADIS PHARMA (France)	3 pick-up per site: o 1 shipment for Main tubes o 1 shipment Main & Back Up tubes o 1 shipment Back-up tubes	STARSERVICES/ TSE for France SAFETRANS or MARKEN for the other sites	With Dry ice

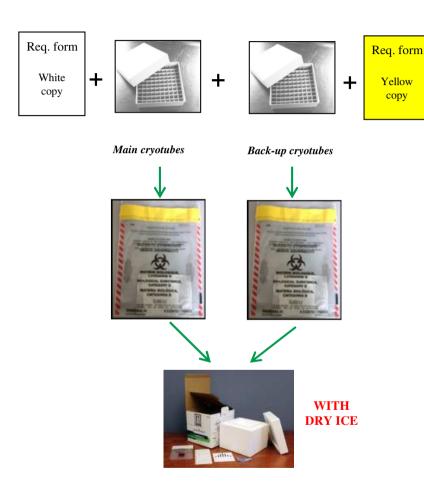
For one patient, the main and the back-up cryotubes for a same patient must be sent separately (two different shipments)



Reminder: White copy to be joined with the MAIN tubes Yellow copy to be joined with the BACK-UP tubes



Material brought by Safetrans, MARKEN or TSE (for France) on the day of shipment: a transport kit, dry-ice, a diagnobag, an airwaybill



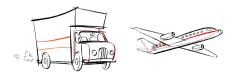
When the carrier arrives:

- Take the cryobox identified for the study "2ml Main cryotubes"
- Take the cryobox identified for the study "2ml Back-up cryotubes" (if applicable) of the previous patients
- Take the white and yellow copies of the patient requisition forms, completed and signed, for all the samples to be sent



For a same patient, separate shipment for main and back-up cryotubes

- Place the cryoboxes in the diagnobag provided by the carrier (1 cryobox per diagnobag)
- Insert the patient requisition forms in the front pouch of the diagnobag
- Give the cryoboxes to the carrier who will place it in the transport kit
- Verify that dry ice is present
- Verify the destination noted on the airwaybill stuck on the transport kit: **THERADIS PHARMA** (France)
- In case of any problems or questions, immediately contact THERADIS PHARMA
- Keep a copy of the airwaybill in the study file





Yellow

copy

On the shipping day, please make sure the carrier has brought dry ice. Do not give the samples if there is no dry-ice