Sepsis Trials in Critical Care

SAMPLE HANDLING AND REPORTING MANUAL

Protocol No: 22SM8039

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Prepared by: **Name:**	**Title:**	**Signature & Date**
Ravinder Dhaliwal	**Clinical Trial Manager**	R. Dhaliwal Digitally signed by Ravinder Dhaliwal Date: 2026.02.02 15:10:20 Z
Approved by: **Name:**	**Title:**	**Signature & Date**
Janis Best-Lane	**Senior Trial Manager**	Janis Best-Lane Digitally signed by Janis Best-Lane Date: 2026.02.02 15:19:28 Z

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Associated Forms / Templates

1. Introduction

The purpose of this document is to describe the procedures for biological sample collection, handling and shipping in the SepTiC study.

2. Scope

This procedure is applicable to participating investigator sites.

3. Abbreviations

ICTU	Imperial Clinical Trials Unit
GM-CSF	Granulocyte-macrophage colony-stimulating factor
SSPM	Study Specific Procedure Manual
SST	Serum-separating tube

4. Responsibilities

Site staff (e.g.: Research Nurse, Investigators)	• Collect samples in accordance with protocol and sample collection manual • Ship collected samples to central lab following guidance in sample manual • Maintain oversight of kit levels at site and inform Trial Manager/Monitor when sample kits need to be replenished
Trial Manager/Monitor	• Maintain oversight of samples stored at central lab and master sample log • Create and ship sample kits to participating sites

5. References

- Good Clinical Practice (ICH- GCP) Guidelines
- Data Protection Act (2018)

6. Procedures for participating sites

6.1. Sample Timepoints

For **all** participants, up to 20ml of blood will be collected on inclusion and sent to the central lab for storage (Imperial College London). DNA, RNA and serum will be stored for future research.

- Baseline serum sample collected in a 5ml SST tube, yellow top
- Baseline DNA sample collected in a 4ml EDTA tube, purple top
- Baseline RNA sample collected in a 2.5ml PAX gene tube

For participants in the **Diagnostic arm** of the trial randomised to treatment (PCR test):

- An additional 10ml blood sample will be taken after randomisation for rapid PCR-based pathogen testing and sent to the central lab.
- Results will be sent to the site and the SepTiC study team.
- If participants are randomised to standard of care then **no** sample is taken

For participants in the **GM-CSF** arm of the trial an additional 3 x 2.5ml blood samples collected via PAX gene tubes for RNA storage will be collected at the following timepoints:

- At randomisation into the GM-CSF arm, before the first dose of the drug is administered (if patients are enrolled into the GM-CSF arm at the same time as they are enrolled into the fluid and diagnostic arms the both PAX gene tubes should be sent at the same time).
- Day 3 after randomisation.
- Day 5 after randomisation.

6.2. Sample Kits and Collection

The SepTiC study team will provide sites with all required consumables. Each site will receive the following consumables:

- 10ml EDTA tubes (if participating in Diagnostic Intervention)
- 4ml EDTA tubes
- 5ml SST serum tubes
- Paxgene tubes
- Blood tube labels
- Sample Shipping Box
- Royal Mail 24 hour tracking labels
- Sample collection and shipping form
- Sample ID labels for sample shipping form

6.2.1 Order of draw:

If collecting blood from an indwelling line (arterial or central line) draw 5ml of blood and discard prior to collecting research samples.

Collect the baseline blood samples in the following order (a-d):

a. **ALL PATIENTS:** 4ml EDTA tube for the baseline DNA sample

Collect 4ml of whole blood in the EDTA tube and gently invert 10 times. Post immediately following the instructions in section 6.8. If it is not possible to post on the same day as collection then refrigerate (4-8°C) and post the next day.

b. **ALL PATIENTS:** SST tube for the baseline serum sample

Collect 5ml of whole blood in the SST tube (yellow top) and gently invert 10 times. Post immediately following the instructions in section 6.8. If it is not possible to post on the same day as collection refrigerate (4-8°C) and post the next day.

c. **ALL PATIENTS:** PAX gene tube for baseline RNA sample

Collect 2.5ml of whole blood into each PAX gene tube.

Note: The fluid in the PAXgene RNA tube is toxic, as shown in the label. The manufacturer advises that the tube should always be held in the vertical position during blood collection, with the bung at the top and the fluid at the bottom. It is

important to make sure the spike in the vacutainer does not sit in the fluid during blood collection and that the tube is not positioned above the patient. In theory, if there was negative pressure in the vessel then the tube fluid could flow backwards towards the patient, if the tube was upside down.

After collection gently invert the tube 10 times to ensure mixing of the blood with the fluid in the tube. Post immediately following the instructions in section 6.8. If it is not possible to post on the same day as collection refrigerate (4-8°C) and post the next day.

The following sample is only for patients who have been randomised to 'Treatment' in the Diagnostic arm of the study.

Do not collect for patients randomised to standard of care in the Diagnostic trial.

d. 10ml EDTA tube for the PCR diagnostic test

Collect 10ml of whole blood in the EDTA tube and gently invert 10 times. **Please note: 10ml of blood is required for the PCR diagnostic test. Please ensure the bottle is filled when collecting blood for this test.** Post immediately following the instructions in section 6.8. If it is not possible to post on the same day as collection, refrigerate (4-8°C) and post the next day.

6.2.2 GM-CSF samples:

The following samples are only for patients who have been randomised to the GM-CSF arm of the study.

Additional PAX gene tubes should be taken, following the instructions in 6.2.1:

- At randomisation into the GM-CSF arm, before the first dose of the drug is administered.
- Day 3 after randomisation.
- Day 5 after randomisation.

Samples should be taken and sent on the same day they are collected. These samples may be sent separately to the samples in section 6.2.1.

6.3. Sample ID

Each sample kit will have a unique sample ID. Please ensure that only one kit is used per patient. The sample IDs will follow the following format:-

Study (**ST**) Site Number (e.g.: **123**) Sample ID* (e.g.:**1234**) . Sample type

** this will be different to the patient's trial ID.*

The sample types are:

- S – Serum Tube
- D – DNA (4ml EDTA) Tube
- T – Test (Diagnostic) Tube
- R – RNA (PAX gene) Tube

R1/ R2/ R3 – RNA (Pax gene) Tube – **GM-GSF patients only**

6.4. Blood Tube Labels

Labels will be provided per patient to the site with the consumables listed above.

- Each sample pack will contain white blood tube labels **with a barcode** and sample ID as the image.

- Once the sample is collected, the label will need to be attached to the associated tube **before** shipping.
- Each site will receive 7 white blood tube labels per patient

Example Label	Attach to…
ST1231234.**S**	 Serum tube Yellow-top
ST1231234.**D**	 4ml EDTA Purple top
ST1231234.**R**	 Pax gene tube
ST1231234.**T**	 10ml EDTA
ST1231234.**R1** ST1231234.**R2** ST1231234.**R3**	 Pax gene tube

- Each site will also receive 7 corresponding-coloured labels which will have a sample ID **only.** These are to be attached to the sample shipping form to avoid any errors of handwriting sample ID's.

ST3450303.D

- example label.

6.5. Sample Collection

Once the samples are collected, and correct labels attached, complete the sample collection and shipping form (see Attachment A).

All samples collected should be logged in the site sample tracker (see Attachment B). The tracker will be stored locally at site.

6.6. Processing

Sites will not process any samples. All processing will take place at the Imperial College MDU Lab/ SepTiC Study Team Lab.

6.7. Storage/ Out of hours collection

Samples can be stored at room temperature until posting, please **post as soon as possible**. If the samples cannot be posted on the same day, samples can be left at room temperature and posted the next day.

6.8. Sample shipping to central lab

6.8.1 Samples will be posted directly to the central lab at the following address:
Medical Diagnostic Unit, Faculty of Medicine
Room I.2.03 2nd Floor, Lift Bank D
Chelsea & Westminster Hospital
369 Fulham Road
LONDON
SW10 9NH

6.8.2 The lab can receive samples from Monday until Saturday (apart from bank holidays, see Section 6.9). If the sample is collected late on a Saturday, see Section 6.8.6. The Royal Mail 24 hour tracked labels provided will aim to deliver samples to the Central Lab for the next working day.

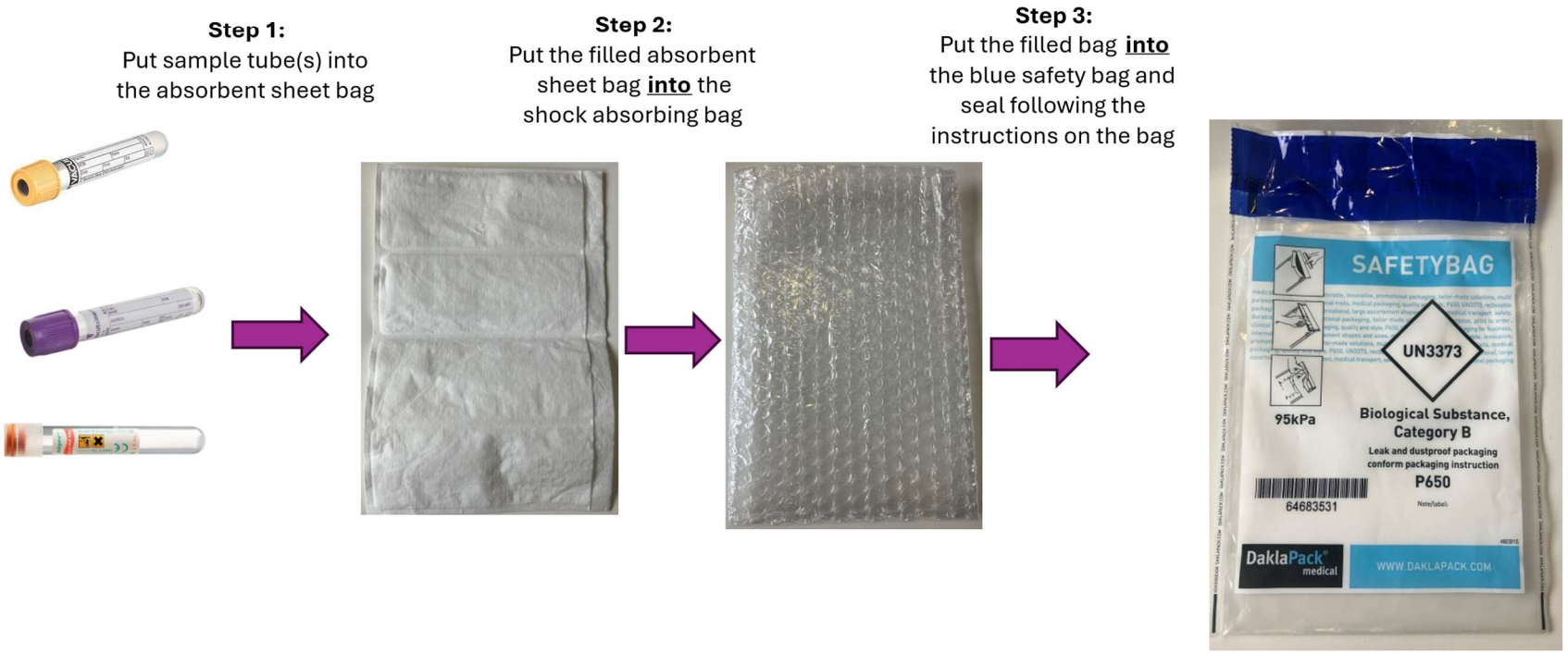
6.8.3 Samples will need to be sent to the central lab using a sample shipping cardboard box which will be provided by the study team.

6.8.4 The sample shipping box includes:

- Cardboard Outer Box (incorporating UN3373 Label)
- Leak-proof safetybag sealed plastic bag
- Absorbent Material Bag
- Shock absorbent padding

Please note: The total sample volume/mass in the box must not exceed 50ml

6.8.5 Follow the instructions included on how to package the samples and assemble the box:



CHECK all samples have been included before closing and ensure total sample volume **does not exceed** 50ml.

Step 4:
Place the completed blue safety bag and completed sample shipping form inside the cardboard outer box.

SepTiC

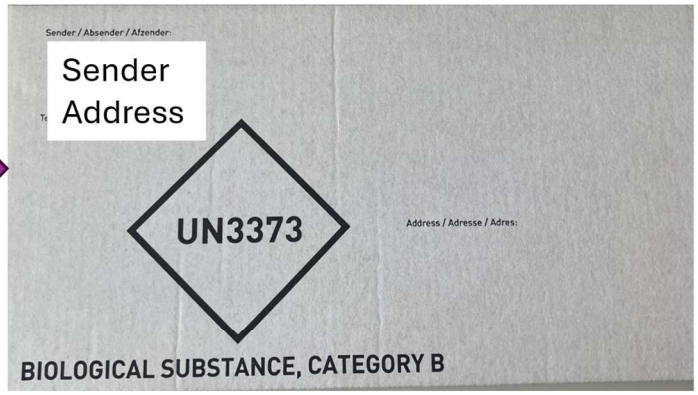
Date Shipped: ___/___/_____

SAMPLE SHIPPING FORM

Please fill in this form prior to sending out the sample.

Site name		Site number	
Site contact details (results will be sent to this contact)			
Name		Mobile	
Email *(more than one email can be entered)*			

Patient ID:		Patient month and year of birth:	MM/ YYYY
Sample ID (Please stick the corresponding sample label here)		Date sample taken	Description of sample (e.g.: PAX gene tube)



Step 5:
Close the sample shipping box and ensure the 24 hour tracked label is attached on top of the box

Email septic@imperial.ac.uk with the unique tracking ID found underneath the barcode

Please note: Once the samples are packed and ready for posting – <u>please ensure the sample box is sellotaped</u> to ensure it is secure during transit.

6.8.6 Preferred method for posting sample boxes

Samples can be sent using your hospital post room.

IMPORTANT: Check last collection time before sending – if you have a PCR sample and have missed the last collection time of the day at your hospital., then the following options are available.

Find your nearest post office (preferred) or **late collection** postbox. Please check your nearest late collection postbox by entering your site's postcode at:

https://www.royalmail.com/services-near-you#/

Late collection postboxes appear with a LATE icon: 

The majority of postboxes are collected by 9am Monday-Saturday, whereas late collection postboxes could be collected as late as 5.30pm on a weekday (please check your local postbox for exact times) and some have Saturday collections at 12 midday.

If it is too late to use these services (e.g.: Saturday night or Sunday), post the samples into a postbox.

6.9. Lab receipt hours

The lab is open to receive and process PCR samples Monday – Saturday, apart from some college closure dates.

The SepTiC team will inform sites via email of the final date that samples can be sent prior to closure dates. Any samples sent late on a Friday may not arrive until Monday.

6.10. Diagnostic PCR sample reporting

A copy of the results of the diagnostic PCR test will be sent to the site (details included on the sample shipping form) and the SepTiC study team (septic@imperial.ac.uk).

Ensure that the results are filed with the patient's electronic/paper notes.

The SepTiC Trial Manager/Monitor will enter the PCR test results onto the eCRF.

7. Revision History

SSPM Ref.	Date Effective	Reason for update (page and section of change)
V1.0	10 Nov 2023	First version
V2.0	01 Oct 2024	Removed references to PO Box address, updated with central lab address and sending instructions. Section 6.4 updated with table of which labels to attach to blood tubes. Section 6.8 updated with new sample collection boxes. Page 12 - Updated Imperial College Closure Days. Page 16 – Attachment B – sample tracker for sites
V3.0	02 Feb 2026	Page 12 – Removal of Imperial College Closure Days. Page 14-15 – Updated Sample Shipping Form to v2.0.

ATTATCHMENT A: SAMPLE SHIPPING FORM

SepTiC
Sepsis Trials in Critical Care

Date Shipped: __ __ / __ __ / __ __ __ __

SAMPLE SHIPPING FORM

Please fill in this form prior to sending out the sample.

Site name		Site number	
Site contact details (results will be sent to the email addresses listed)			
Name *(staff member sending the samples)*		Mobile *(emergency use only)*	
Email *(more than one email can be entered)*			
Patient Trial ID:	__ __ __ - __ __ __ __	Patient month and year of birth:	MM/ YYYY
Sample ID (Please stick the corresponding sample label here)		Date sample taken	Description of sample (e.g.: PAX gene tube)

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Patient Trial ID:	___ ___ ___ - ___ ___ ___ ___	Patient month and year of birth:	MM/ YYYY
Sample ID (Please stick the corresponding sample label here)		Date sample taken	Description of sample (e.g.: PAX gene tube)

FOR IMPERIAL MDU LAB ONLY

(Note: Lab Staff please retain copy of form once sample receipt is confirmed below):

Samples received by (*print name):*		Date received:	
Comments (e.g.: if sample arrived damaged):			

FOR SEPTIC TRIAL TEAM LAB ONLY:

Samples received by (*print name):*		Date received:	
Comments (e.g.: if sample arrived damaged):			

Please email a copy of the completed form to septic@imperial.ac.uk

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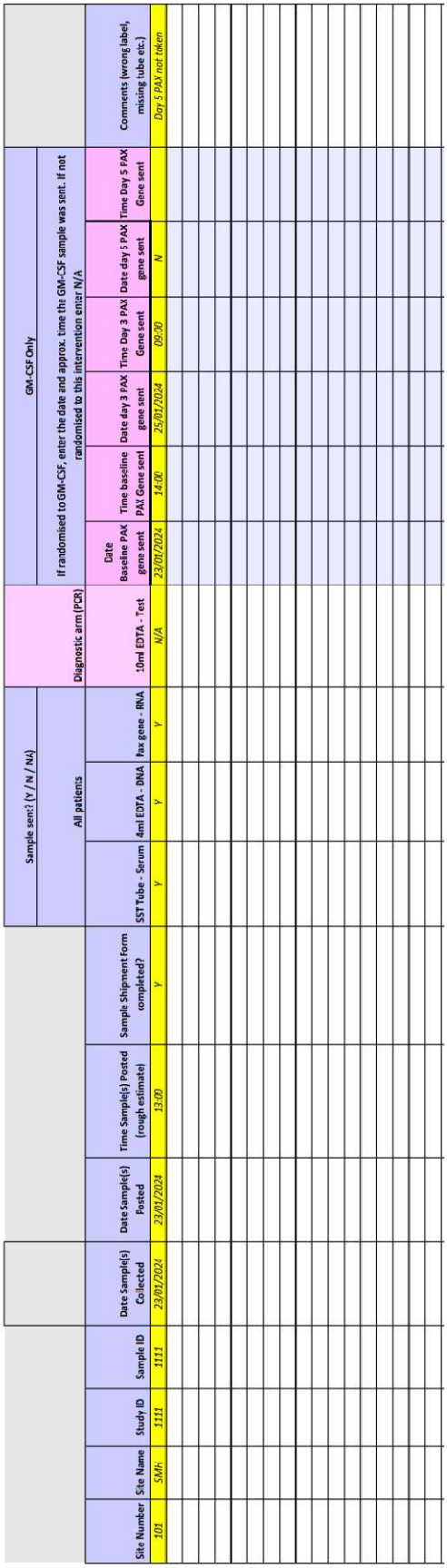
ATTATCHMENT B: SAMPLE TRACKER FOR SITES



Site Number	Site Name	Study ID	Sample ID	Date Sample(s) Collected	Date Sample(s) Posted	Time Sample(s) Posted (rough estimate)	Sample Shipment form completed?	Sample sent? (Y / N / NA)				GM-CSF Only							Comments (wrong label, missing tube etc.)
								All patients				Diagnostic arm (PCR)	If randomised to GM-CSF, enter the date and approx. time the GM-CSF sample was sent. If not randomised to this intervention enter N/A						
								SST Tube - Serum	4ml EDTA - DNA	hax gene - RNA		10ml EDTA - Test	Date Baseline PAX gene sent	Time baseline PAX Gene sent	Date day 3 PAX gene sent	Time Day 3 PAX Gene sent	Date day 5 PAX gene sent	Time Day 5 PAX Gene sent	
101	SMH	1111	1111	23/01/2024	23/01/2024	13:00	Y	Y	Y	Y		N/A	23/01/2024	14:00	25/01/2024	09:30	N		Day 5 PAX not taken