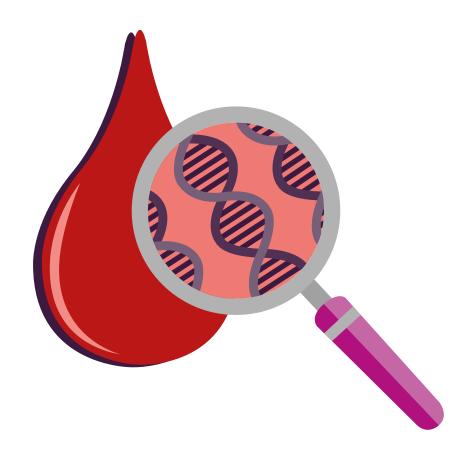




Instructions for use

Blood collection requirements





Ordering a Marsden360

For Test Requisition Form (TRF), Instruction leaflet, tube label template and enquiries, please email Marsden360@rmh.nhs.uk or telephone 020 8915 6565

For Streck tubes and Royal Mail Safeboxes (Special Delivery; UN3373 compliant) please contact your lead GMSA site.

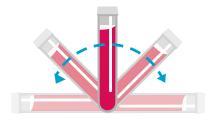


Blood draw instructions

Collect specimen
by venipuncture,
filling the two Streck
tubes completely



2 Mix by gentle inversion 8 to 10 times



3 Ensure tubes are labelled as instructed in step 2 on the following page



Do not refrigerate or freeze blood samples

Shipping instructions

Complete the Test Requisition Form (TRF)

- TREF)

 THE STALL MARGON METHODS:

 THE STALL MARGON METHODS:

 THE STALL MARGON METHOD S
- Fill out labels on each tube including:
 - Patient name
 - Hospital number
 - Date of birth (dd/mm/yyyy)
 - Collection date (dd/mm/yyyy)



Open the Safebox and wrap the sample tubes in the absorbent sheet and place into the grip seal bag and close. Please note one Safebox for two sample tubes only



Place the filled grip seal bag into the PathoSeal bag



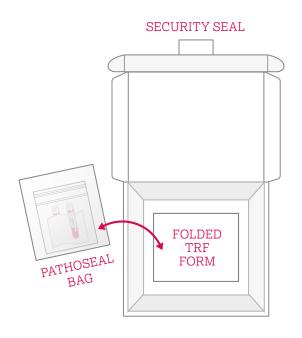
Close the PathoSeal bag following the instructions printed on the bag



PATHOSEAL BAG

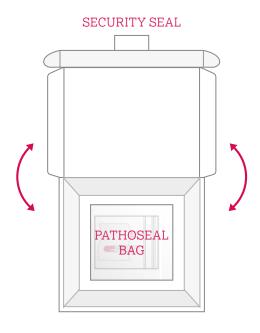
Shipping instructions

- 6 Place the completed PathoSeal bag and Test Requisition Form (TRF) into the Safebox
- CHECK all contents are included as required before closing





8 Close the Safebox ensuring the security tab is tucked in



Shipping instructions

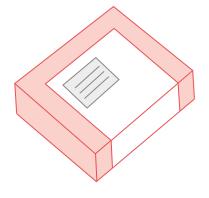
Omplete the Send and Return address details.
Clinical Genomics The Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust |
Cotswold Road Sutton Surrey | SM2 5PT



Apply prepaid postage label over these instructions ensuring it wraps round and over the tuck in security tab.

Please record the Tracking number, to enable the Safebox

to be tracked during transit



Please take the Safebox to your Trust Postroom for delivery to Clinical Genomics, The Royal Marsden NHS Foundation Trust.

Samples should be received within 48 hours of venepuncture



Intended use

Whole blood collection for further processing and testing of cell-free plasma DNA with the Marsden 360 test.

Principles of the procedure

Accurate analysis of cell-free DNA (cfDNA) can be compromised by sample handling and extreme shipping and processing conditions. The Cell-Free DNA BCT CE tube contains a formaldehyde-free preservative that stabilizes white blood cells, preventing the release of genomic DNA, allowing isolation of high-quality cell-free DNA.

Blood collection (Streck) tube

Cell-Free DNA BCT CE contains the anticoagulant K3EDTA and a cell preservative in a liquid medium.

Precautions and limitations

- 21G or 22G needle is advised for best result.
- A non additive or EDTA tube should be partially drawn first as a waste tube prior to collection in the cfDNA tube, particularly when using a winged (butterfly) collection set.
- Broken or expired tube should be disposed with infectious waste material.
- Overfilling or underfilling will result in an incorrect blood-to-additive ratio.
- Inadequate or delayed mixing may result in poor product performance.
- Do not freeze specimens collected in blood collection tube as breakage could result.
- Check expiration date prior to using the tubes for collection. Do not use tubes after expiration date.

- Glass has the potential for breakage; precautionary measures should be taken during handling.
- Do not use tubes for collection of materials to be injected into patients.
- Product is intended for use as supplied.
- Do not dilute or add other components to the blood collection tube.
- Cloudiness or precipitate visible in reagent of unused tube indicates product deterioration. Do not use tube.
- For single use only.
- Samples drawn in other anticoagulants or preservatives may cause coagulation in the blood collection tube.
- SDS for the blood collection tube can be obtained at www.Streck.com or by calling +44 (0)23 8048 3000

Storage and stability

- When stored at 2°C-30°C, unused blood collection tube is stable through expiration date. The general shelf life is 24 months and is printed on each individual tube.
- Do not freeze unfilled blood collection tube. Samples collected in the blood collection tube for processing and testing with Marsden360 are stable for up to 7 days when stored at ambient temperatures.

Blood collection requirements

- 1. Two 10.0 ml blood collection Streck tubes and a Royal Mail Safebox from your GMSA lead site.
- 2. Marsden360 test requisition form.

References

- Das K., Dumais J., Basiaga S., Krzyzanowski G. Carbon-13 nuclear magnetic resonance analysis of formaldehyde free preservatives. Acta Histochemica 2013; 115: 481-486.
- Das K., Fernando M.R., Basiaga S., Wigginton S., Williams T. Effects of a novel cell stabilizing reagent on DNA amplification by PCR as compared to traditional stabilizing reagents. Acta Histochemica 2014; 116: 55-60.
- Norton S.E., Lechner J.M., Williams T., Fernando, M.R. A stabilizing reagent prevents cell-free DNA contamination by cellular DNA in plasma during blood sample storage and shipping as determined by digital PCR. Clinical Biochemistry 2013; 46: 1561-1565.
- Norton S.E., Luna K.K., Lechner J.M., Qin J., Fernando M.R. A new blood collection device minimizes cellular DNA release during sample storage & shipping when compared to a standard device. Journal of Clinical Laboratory Analysis 2013; 27: 305-311.
- Qin J., Alt J.R., Hunsley B., Williams T., Fernando M.R. Stabilization of circulating tumor cells in blood using a collection device with a preservative reagent. Cancer Cell International 2014, 14:23.
- Clinical and Laboratory Standards Institute. H3-A6, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard - Sixth Edition.

Glossary of harmonized symbols

STERIL R	LOT	REF	(3)		愛
Sterilized using irradiation	Batch Code	Catalog Number	Do not Re-use	Use by	Biological risk
1	i		\sim	\sum	
Temperature limitation	Consult instructions for use	Manufacturer	Date of manufacture	Content sufficient for number of tests specified	