Blood components for non-clinical purposes: application form

This form is used to apply for a delivery permit for blood donated in the Blood Service and its parts, which the Blood Service cannot use for the treatment of patients (surplus material). A permit may be granted for purposes of significant impact on patient care related to the scope of the Blood Service, e.g. for training, method development, components of diagnostic methods, raw materials for medical devices and drugs, or reference material for clinical laboratory studies. A delivery permit is also applied for internal purposes of the Blood Service with this form.

The Blood Service also provides materials for research on blood donation and on health and disease. The supply of materials for research purposes is mainly carried out through biobanking. A research project is conducted as biobank research if the subject of the study is donor-derived biological material or information related to the donor.

Projects using a methodology that results in donor-identifying information will be directed to the Blood Service Biobank, regardless of the role of the sample in the research setting. Examples of such situations include technologies targeting genetic material or combining various omics data.

For biobank deliveries, the applicant can contact the Blood Service Biobank at <https://www.veripalvelu.fi/en/biobank/biobank-services-for-researchers/>. Biobank activities are described on the Blood Service’s website.

|  |  |
| --- | --- |
| New application |       |
| Application renewal |       |

**CONTACT INFORMATION**

|  |  |
| --- | --- |
| Intended purpose for blood components (for instance title of research project) |       |
| Customer number, if known |       |
| Applying organization  |       |
| Name of the contact person |       |
| Name of the responsible person |       |
| Address of applying organization |       |
| Delivery address of the products |       |
| Invoice address (if different from address of organization) |       |
| Phone number of the contact person |       |
| Email address of the contact person |       |
| Time/timeline of blood component need  |             |

 **INTENDED USE OF BLOOD COMPONENTS**

|  |  |
| --- | --- |
| Scientific research | Yes [ ]  No [ ]  |
| Product development | Yes [ ]  No [ ]  |
| Raw material/starting material, specify what for | Yes [ ]  No [ ]  |
| Used as a laboratory control sample, etc. | Yes [ ]  No [ ]  |
| Is identifying analytical data being generated? | Yes [ ]  No [ ]  |
| Other |       |
| FRCBS internal purposes, description |       |

Please note that the availability of blood donor samples or blood components for non-clinical use is limited, and that there are certain preconditions for delivery of blood components for non-clinical use. The Finnish Red Cross Blood Service evaluates and decides about the possibilities to deliver and the specific delivery schedules according to the current blood component stocks and availability levels.

**MATERIALS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Materials** | **ISBT-code** | **Delivery** | **Amount** |
| **A sample from a blood donor** |
| Blood sample, whole blood[ ]  EDTA 2 ml[ ]  EDTA 6 ml[ ]  Citrate 9 ml[ ]  Serum gel 5 ml[ ]  Other\*\*,      Additional information[ ]  blood group[ ]  age[ ]  gender[ ]  dateStowage[ ]  fridge[ ]  room temperature | B0008V00 | [ ]  fridge[ ]  room temperature* The customer delivers the material needed for refrigerated transport to the blood donation office.
* The customer collects the sample from the blood donation office (unless otherwise agreed).
 |       |
| **Intermediate Blood Components** |
| BC 1 unit, non-clinical use (~ 55 ml)\*-delivery earliest after 12:30, the day after donation, blood group according to availability LRS (Leucoreduction System) chamber (leucocyte filter)  | E3818V00A0103V00 | 1 day, afternoon  1 day, afternoon |            |
| **Red Cell Products** |
| PSVS, not for patient use (260 ml)-products that are about to expire-blood group according to availability | A0078V00 | depending on the stock situation and availability |       |
| **Platelet Products** |
| TRVS, not for patient use (190-210 ml)-products that are about to expire-blood group according to availability | A0101V00 | depending on the stock situation and availability |       |
| TRVSPEIPOT, not for patient use (190-210 ml)-only available for internal use at the Finnish Red Cross Blood Service | A0108V00 | limited availability, only available for internal use at the Finnish Red Cross Blood Service |       |
| TRFPANEELI, Platelets, collected by apheresis, Leucocyte-depleted HPA, for panel cells - for laboratory control cells | A0111V00 | The delivery details will be agreed upon more specifically in a separate email. |       |
| **Plasma Components (very limited availability)** |
| FFP 24, not for patient use (250-310 ml)-very limited availability-delivered unfrozen  | A0081V00 | to be evaluated and agreed case-by-case, very limited availability  |       |
|  **Other products** |
| Whole Blood, not for patient use (460 ml)-only available for internal use at the Finnish Red Cross Blood Service | A0001V00 | limited availability, only available for internal use at the Finnish Red Cross Blood Service  |       |
| Whole Blood Product, filtered, not for patient use (460 ml)-products that are about to expire-blood group according to availability | A0109V00 | depending on the stock situation and availability |       |
| **Other, what**      |
| **More information** |
| **Additional charges** |  |
| Processing fee company | 360,50 € | B0006V00 |  |       |
| Processing fee research organization | 103 € | B0007V00 |  |       |

\*BC 1 unit, not for patient use (E3818V00) can be provided for non-clinical purposes only when in excess and according to availability earliest at around 12:30 the day after the donation. Blood group according to availability.

\*\* Delivery of test tubes to Blood Service to be agreed with the order.

**Disclaimer**

The applicant/Sample Service customer confirms to have understood, that the samples and blood components that are delivered from the Finnish Red Cross Blood Service for non-clinical purposes **before** the infection screening results are known. The Finnish Red Cross Blood Service does not check, nor inform the applicant/sample service customer about the infection screening results. The samples and blood components are to be handled and stored as potentially contagious, the applicant/customer is responsible for the safe handling and disposal of samples and blood components in all circumstances. The Finnish Red Cross Blood Service is not responsible for the safety and traceability of the samples and blood components.

The delivered material may not be used for products that are delivered to those subjects to

sanctions to <https://www.sanctionsmap.eu/#/main>.

FRCBS can publishes the Receiving Party company´s name and description of the Project.

**Plan required from the applicant**

A detailed plan must be included with the application, specifying the intended use of the product ordered from the Blood Service. The application must also clearly describe the analyses to be performed on the material and the methodologies to be employed. A comprehensive and precise description is an essential prerequisite for the approval of the permit.

Does the project have license from the ethics committee?

The applicant for a sample/research material license is responsible for the ethical clearance, if the setting requires this.

Additional questions will be answered by the research nurse/coordinator Tuija Ahonen p. 029 300 1563

**Form returns by e-mail** tutkijaluvat@veripalvelu.fi

or

Finnish Red Cross Blood Service

Biobank and sample service

Härkälenkki 13

01730 Vantaa

**MANUFACTURING METHODS OF PRODUCTS SUPPLIED TO CUSTOMERS**

Description of the manufacturing method:

1. **A sample from a blood donor**

**Blood sample, B0008V00**

* The extra blood sample (7-10 ml) remaining in the sample bag during the donation after the screening samples of the blood donor have been taken from the bag. The blood is always mixed with a small amount of citrate solution in the tubing
* The sample is taken into the desired tube
* The sample tube is marked with the following information at most: age, sex, blood group, time, place
1. **Intermediate Products**

**BC, Buffy Coat (the leukocyte-platelet layer of centrifuged blood) 1 unit, not for patient use E3818V00**

* The weight of the contents of the BC is approx. 50-60 g
* The availability of the product depends on the amount of donated blood, the hospitals need for platelets and the Blood Service's stock situation
* delivery in the afternoon on the following day from donation after the daily platelet product need is secured, earliest at 12:30 onwards

**LRS-chamber BC** **A0103V00 (Leukoreduction System, leucocyte filter)**

* The white blood cell removal chamber of the platelet preparation collected with the Trima Accel thrombopheresis device
* The availability of the product depends on the production plan of the Blood Service
1. **Red Cell Products**

 **Red blood cells, leucocyte-depleted, not for patient use A0078V00**

* Red blood cells (SAG-M as storage solution) are filtered to be free of white blood cells immediately after separation
* Storage after filtration +2 to +6 °C
* See more detailed information from the guide to the [use of blood products](https://www.veripalvelu.fi/ammattilaiset/verensiirto/verivalmisteiden-kayton-opas/)
* products are about to be expired
* The availability of the product depends on the Blood Service's stock situation, blood group according to availability
1. **Platelet Products**

**Platelets, leucocyte-depleted, not for patient use A0101V00**

* BCs from four donors of the same ABO blood group have been combined into a single pool and platelet storage solution (PAS-E) has been added to it
* Separation (II) takes place with an automatic separator
* In the separation phase (II), approx. 24 - 28 hours have passed since the blood donation
* See more detailed information from [the guide to the use of blood products](https://www.veripalvelu.fi/ammattilaiset/verensiirto/verivalmisteiden-kayton-opas/)
* products are about to be expired
* The availability of the product depends on the Blood Service's stock situation, blood group according to availability

**TRVSPEIPOT, not for patient use A0108V00**

* limited availability, only for internal purposes within the Finnish Red Cross Blood Service

**TRFPANEELI, Platelets, collected by apheresis, leukocyte-free, HPA, for panel cells, A00111V00**

* The product is collected from a single donor using Plateletpheresis

ACD-A anticoagulant solution is used to prevent clotting. The product contains

approximately 30% plasma and 70% PAS-E Platelet storage solution

* HPA typed, not radiated
1. **Plasma Products (very limited availability)**

**FFP 24, not for patient use A0081V00**

* evaluated and agreed case-by-case, very limited availability
* delivered unfrozen
1. **Other components**

**Whole Blood, not for patient use A0001V00**

* limited availability, only for internal purposes within the Finnish Red Cross Blood Service

**Whole Blood Product, leucocyte-depleted, not for patient use A0109V00**

* Whole blood (CPD as an anticoagulant) is filtered to reduce white blood cells the day after donation
* The filtered whole blood product is stored in a refrigerator at +2 to +6 °C
* Products about to be expired, according to availability