МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

СПЕЦІАЛІЗОВАНА ДЕРЖАВНА УСТАНОВА «УКРАЇНСЬКИЙ ЦЕНТР ТРАНСПЛАНТ-КООРДИНАЦІЇ»

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MINISTRY OF HEALTH OF UKRAINE

SPECIALIZED STATE INSTITUTION "UKRAINIAN TRANSPLANT COORDINATION CENTER"

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10.03.2022 № 19-08/0066

The European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe
Ms. Petra Dörr
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Request for humanitarian aid to the blood system establishments of Ukraine in the context of martial law caused by the military aggression by the Russian Federation

Dear Ms. Dörr,

On behalf of the Specialized State Institution "Ukrainian Transplant Coordination Center" Administration, I would like to express my highest consideration to the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe and address you personally with the following.

The Specialized State Institution "Ukrainian Transplant Coordination Center" (hereafter – SSI "UTCC") is a public healthcare institution coordinating the provision of medical care such as transplantation and transplantation-related activities, as well as blood and blood components donation, blood system establishments' operations and management, circulation of donated blood and blood components, compliance with safety and quality standards of donated blood and blood components, coordination of health care services provision with adequate and timely supply of blood components and transfusion services, coordination of transfusion related activities, and contribution to the implementation of policies in blood donation area. SSI "UTCC" fulfills the functions of the National Transfusion Center.

Since 24 February 2022 Ukraine suffers from the Russian Federation's military aggression and is under martial law. Millions of Ukrainians live under constant shelling, aerial bombardment and rocket attacks. As a result, the national blood system represented by 25 blood system establishments (blood centers) in each region of Ukraine and in Kyiv city coordinated by SSI "UTCC", was transferred in a reinforced functional regime to meet the needs of civilian healthcare facilities and military hospitals in blood components.

To coordinate the activities of blood centers in martial law conditions and establish a clear interaction with military hospitals, and to urgently solve organizational and management problems, a Ministry of Health Operational Headquarters was established by the order of the Ministry of Health of Ukraine dated 28.02.20022 № 386 to coordinate the activity in the area of blood and blood components donation, and functioning of the blood system in martial law.

Due to the coordinated work of the SSI "UTCC" and the Operational Headquarters of the Ministry of Health of Ukraine, and following the timely measures undertaken during the period from 24.02.2022 – 01.03.2022, the national blood system managed to form a supply of blood components sufficient to meet civilian and military needs in accordance with the operational situation associated with resistance to the Russian Federation's military aggression. Currently, the stocks of blood components in the country are maintained at a constant level. At the same time, there is a critical need for emergency supply of consumables and equipment to ensure basic technological processes to the blood centers, which is primarily due to a sharp increase in collection of donor blood and blood components and the use of blood components; increase in the number of civilian and military casualties within the last 5 days, requiring the use of blood components, as well as the aggressor's attempt to destroy the blood centers (for example, rocket attacks targeted twice the blood center in Kharkov, Mariupol blood center destroyed by missile strikes, attack of the Kyiv City blood center by a subversive group, direct location of several blood centers in the epicenter of hostilities – Chernihiv, Sumy, Severodonetsk, Kherson, Mykolaiv).

In view of the above circumstances and taking into account that Ukraine is a co-founding member of the Council of Europe, we kindly ask your assistance in ensuring the blood centers with consumables and equipment and count on a prompt consideration and positive solution to our request.

SSI "UTCC" as the National Transfusion Center coordinating and performing operational management of blood centers in martial law, can act as a recipient of such assistance, and ensure its distribution among blood centers.

Please see attached a brief description of the technology and particularities of the main processes in the blood centers for your acknowledgement (Annex 1).

Taking into account the estimations of the current state of hostilities, the number of civilian and military casualties, and the intensity of blood centers' activity, we are kindly asking you to provide consumable needed for collection of 150,000 whole blood units that would meet the projected need in blood components for 3 months.

We consider the most priority and urgent the provision of the following: Blood Bag Quadruple with Whole Blood Filter CPD / SAGM, Blood Bag Quadruple CPD / SAGM, Blood Bag Triple CPD / SAGM; monoclonal antibodies, consumables for Ortho immunohematological analyzers; refrigeration equipment; thermal containers; backup power supply generators (We consider the supply of other equipment as an option to strengthen the capacity of blood centers and restore technology in blood centers that have been shelled or partially destroyed (Annex 2).

We consider the supply of other equipment as an option to strengthen the capacity of blood centers and restore the technological processes in the blood centers that have been shelled or partially destroyed (Annex 2).

Contact details:

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Sincerely

Director General **Dmytro KOVAL**

Annex 1

BRIEF DESCRIPTION OF THE TECHNOLOGY AND PARTICULARITIES OF THE MAIN PROCESSES IN THE BLOOD CENTERS

Blood and blood components collection, testing, processing, storage and distribution are carried out by 24 regional and Kyiv city blood centers.
The following are the technological features of the blood centers (excluding the apheresis method):

1. Collection of whole blood and blood components

Whole blood is collected directly in blood centers, as well as outside blood centers by organized mobile teams.

1.1. Registration of blood donors and blood components, medical examination, pre-donation laboratory screening

The requirements for donors' medical checkup are identical to the EU requirements
The pre-donation laboratory testing uses the following:

- Portable devices for determining the level of hemoglobin / hematocrit
- Hematological analyzers of different types
- Biochemical analyzers of different types

1.2. Whole blood collection

1.2.1. Collection of whole blood directly in the blood centers
The standard volume of whole blood collected is 450 ml.
The following items are used in the process of whole blood collection in blood centers

- Donor chair for donor blood and blood components collection
- Mixing scales
- Portable dielectric sealers

There is a need for equipment for whole blood collection (Table 1).

1.2.3. Whole blood collection outside blood centers
Whole blood collection outside the blood centers is carried out according to preestablished schedules, for personnel, equipment, consumables and collected blood transportation using non-specialized vehicles.
The following items are used to collect whole blood outside the blood centers

- Mobile donor chairs – at least 2 per blood collection point
- Portable devices for determining the level of hemoglobin / hematocrit
- Mixing scales – at least 2 per blood collection point
- Portable dielectric sealers
- Isothermal containers with a capacity of at least 15 blood units
- Cold elements for isothermal containers
- Loggers for temperature control during blood components transportation

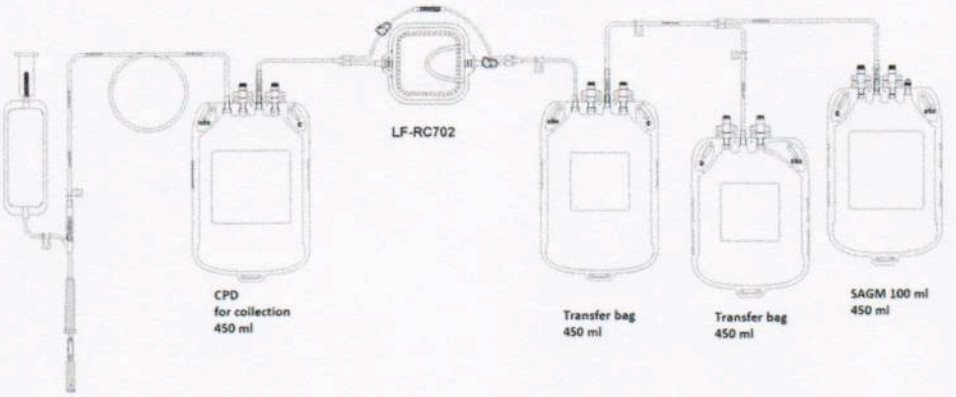
There is a need for equipment to collect whole blood in mobile settings (Table 1).

1.2.3. Types of Blood Bags for blood collection used in Ukraine
Top & Bottom Blood Bags are not used in blood centers because there is no appropriate technological equipment.
The most commonly used modifications are:

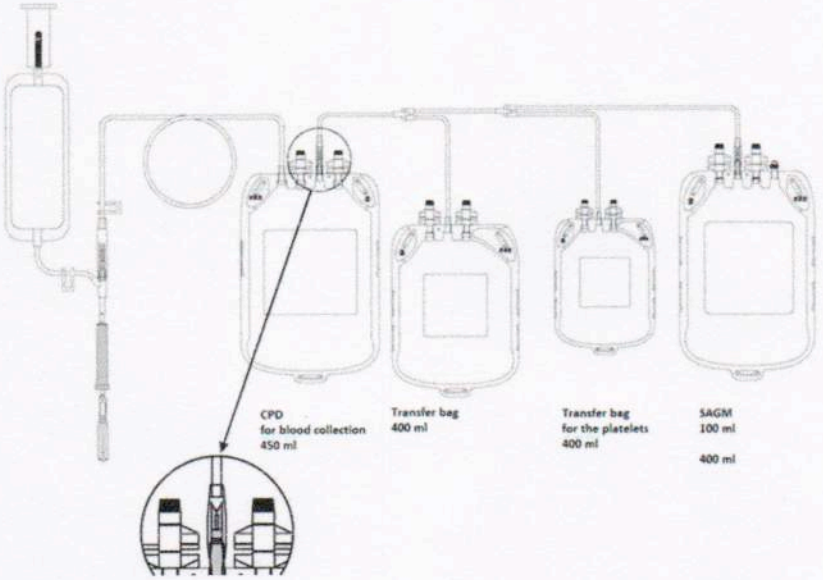
- Blood Bag Quadruple with Whole Blood Filter CPD / SAGM – 70%
- Blood Bag Quadruple CPD / SAGM – 20%

- Blood Bag Triple CPD / SAGM – 10%

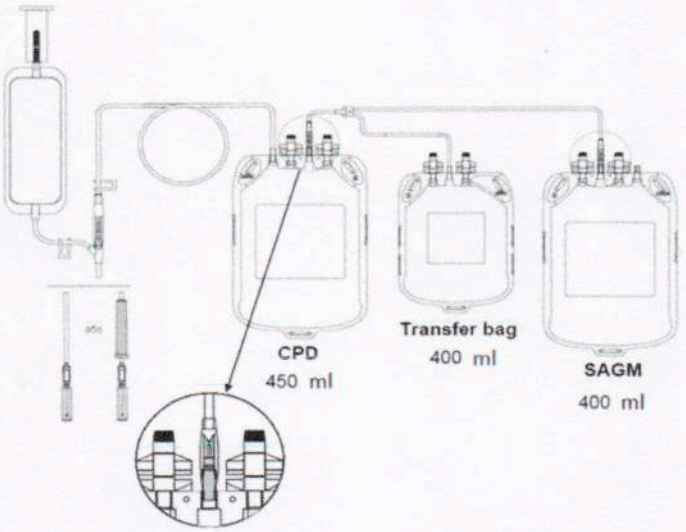
There is a need for Blood Bags for blood collection (Table 1).



Blood Bag Quadruple with Whole Blood Filter CPD / SAGM



Blood Bag Quadruple CPD / SAGM



Blood Bag Triple CPD / SAGM

All needs in the tables are calculated and entered for 25 blood centers (BC).

Needs in Blood Bags based on the following calculation: monthly blood collection volume requirements of 25 blood centers considering the emergency situation + an additional 40% for combat conditions.

Table 1

Needs for donor blood collection

Mobile donor chairs	4 per BC	100
Mixing scales	6 per BC	150
Portable dielectric sealers	4 per BC	100
Isothermal containers with a capacity of at least 15 blood units	See the Table 6	
Cold elements for isothermal containers	See the Table 6	
Loggers for temperature control	See the Table 6	
Blood Bag Quadruple with Whole Blood Filter CPD / SAGM	70%	105 000
Blood Bag Quadruple CPD / SAGM	20%	30 000
Blood Bag Triple CPD / SAGM	10%	15 000

2. Testing

2.1. Screening for transfusion-transmitted infections (HIV 1/2, hepatitis B and C, syphilis) is carried out after blood donation).

Screening for transfusion-transmitted infections is carried out using immunochemiluminescent (ICLA), electrochemiluminescent (ECLA) and NAT methods.

There is currently no need for consumables for screening.

2.2. Immunohematological studies

2.2.1. Pre-donation blood group typing carried out using monoclonal antibodies.

There is a need for the supply of monoclonal antibodies for 3 months of intensive blood collection (Table 2).

Table 2

Need for the supply of monoclonal antibodies for 3 months of intensive blood collection

Consumable material	Bottles
Anti A	1 500
Anti B	1 500
Anti D	1 500
Anti D - D6	1 500
Calculation: Per 150 000 blood donors – 3 month of intensive blood collection regime of 25 blood centers 1 bottle of reagent volume – 10 ml 10 ml of reagent = 100 tests = 100 blood donors 150 000 blood donors = 1500 bottles of reagents	

2.2.2. Post-donation blood group and Rh typing carried out using automatic analyzers:

- ABO typing (cross method)
- Rhesus phenotype (D, C, c, E, e)
- Kell typing
- Anti-RBC antibodies

Equipment used by Blood Centers for immunohematological testing:

- 14 Blood Centers use Diamed semi-automatic equipment set (centrifuge and incubator) (BioRad) – the need for consumables is covered by government procurement;

- 3 Blood Centers use IH-500 automatic analyzer (BioRad) – the need for consumables is covered by government procurement;
- 5 Blood Centers use IH-1000 automatic analyzer (BioRaD) – the need for consumables is covered by government procurement;
- 3 Blood Centers use Ortho VISION automatic analyzer (Ortho) – the need for consumables *is not* covered by government procurement. In this regard, there is a need to support the activities of these blood centers in intensive blood collection mode for 3 months with a total of 18,000 donations.

There is a need for the supply of consumables for immunohematological testing of donor blood for 3 months of operation of 3 blood centers on Ortho VISION automatic analyzer (Ortho) – 18 000 donations (Table 3).

Table 3

Need for consumables for immunohematological testing of donor blood for 3 months of operation of 3 blood centers on Ortho VISION automatic analyzer (Ortho) – 18 000 donations

Consumable material	Packages
Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette), 400 cassettes	3
Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette), 100 cassettes	0
Anti-A/Anti-B/Anti-D Ortho BioVue® System (ABD Confirmation Cassette), 100 cassettes	0
ORTHOTM Sera Anti-D (DVI) Human Monoclonal IgM 5 ml	30
Anti-A/Anti-B/Anti-D/Control/Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette), 400 cassettes	45
Anti-A/Anti-B/Anti-D/Control/Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette), 100 cassettes	0
Anti-IgG, -C3d; polyspecific Ortho BioVue® System, 400 cassettes	22
Anti-IgG, -C3d; polyspecific Ortho BioVue® System, 100 cassettes	2
0.8% Surgiscreen®, 3 x 10 ml	97
Anti-C/Anti-E/Anti-c/Anti-e/Anti-K/Control Ortho BioVue® System (RH/K Cassette), 400 cassettes	45
Anti-C/Anti-E/Anti-c/Anti-e/Anti-K/Control Ortho BioVue® System (RH/K Cassette), 100 cassettes	0
ORTHOTM CONFIDENCE WB (Simulated Whole Blood Controls), 4 x 6,5 ml	9
ORTHO VISION Dilution Tray, 180 x 16 holes	7
ORTHO VISION Evaporation Caps (10mL), 250 pcs.	3
ORTHO 7% BSA, 12 x 5 ml	12
ORTHO 7% BSA, 15 x 12 ml	0
Ortho® BLISS, 3 x 10 ml	0
Ortho® BLISS, 4 x 50 ml	0
0.8% Affirmagen® A1, B, 2 x 10 ML	95

3. Blood processing

3.1. Separation of whole blood into components is carried out according to the recommended methodologies using freezing centrifuges.

Following items used for blood processing:

- Refrigerator centrifuges to separate whole blood into components. Unfortunately, some blood centers have not yet been equipped with modern centrifuges to separate whole blood into components, which slows down the work of such centers and reduces their productivity, in addition, significant wear and tear of such equipment jeopardizes the implementation of the separation process.

There is a need for refrigerated centrifuges for 8 or 12 blood bags filled with blood.

- Refrigerator showcases for the blood service/biological materials (operating temperature range (4±2)°C; the volume not less than 250 liters).
  There is a need for refrigerators for blood service/biological materials
- Portable dielectric sealers
  There is a need for portable dielectric sealers.
- Rollers.
- Dielectric welders.
  There is a need for dielectric welders.
- Plasma shock freezer (operating temperature range: minus 70°C and below; volume: not less than 48 units of plasma).
  There is a need for shock plasma freezers.
- System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 20 doses of platelets (4 shelves)).
  There is a need for systems to store platelets recovered from blood doses and apheresis.

Table 4

Needs for Blood processing

Refrigerated centrifuges for 8 blood bags filled with blood	1 per BC	10
Refrigerated centrifuges for 12 blood bags filled with blood	1 per BC	15
Refrigerator showcases for the blood service/biological materials (operating temperature range (4±2)°C; the volume not less than 250 liters)	1 per BC	25
Portable dielectric sealers	1 per BC	25
Dielectric welders	1 per BC	25
Plasma shock freezer (operating temperature range: minus 70°C and below; volume: not less than 48 units of plasma)	1 per BC	25
System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 20 doses of platelets (4 shelves))	1 per BC	25

4. Storage of blood components

4.1. Quarantine storage of fresh-frozen plasma and long-term storage of fresh-frozen plasma
In accordance with the requirements of the legislation of Ukraine, all collected fresh frozen plasma is subject to quarantine storage for at least 180 days.
Subsequently, the plasma is stored at minus 30°C and below up to 36 months

Due to the increase in the intensity of blood collection in martial law, fresh-frozen plasma began to accumulate intensively, as a result of which there is a need for low-temperature refrigerators for plasma storage (temperature range – minus 30°C and below, useful volume not less than 200 liters).

4.2. Storage of blood components before distribution
In order to store blood components before distribution, the following equipment is used:

- Refrigerators showcases for the blood service/biological materials (operating temperature range (4±2)°C; the volume not less than 250 liters).
- Low-temperature refrigerators for storage of plasma and cryoprecipitate (temperature range – minus 30°C and below, useful volume not less than 250 liters)

- System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 40 doses of platelets (8 shelves)).
  There is a need for all equipment for storing blood components.

Table 5

Needs for blood components storage

Refrigerators showcases for the blood service/biological materials (operating temperature range (4±2)°C; the volume not less than 250 liters)	2 per BC	50
Low-temperature refrigerators for storage of plasma and cryoprecipitate (temperature range – minus 30°C and below, useful volume not less than 250 liters)	7 per BC	175
System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 40 doses of platelets (8 shelves))	1 per BC	25

5. Distribution and transportation of blood components

The distribution and transportation of blood components and transportation is carried out by motor transport of blood centers or by motor transport of health care institutions.
The following items are used for transportation:

- Isothermal containers with a capacity of at least 15 blood units
- Isothermal containers with a capacity of at least 50 blood units
- Isothermal containers with a capacity of at least 100 blood
- Cold elements for isothermal containers
- Loggers to control the blood components transportation temperature

There is a need to provide additional equipment for transportation.

Table 6

Needs for transportation of blood components

Isothermal containers with a capacity of at least 15 blood units	20 per BC	500
Isothermal containers with a capacity of at least 50 blood units	10 per BC	250
Isothermal containers with a capacity of at least 100 blood units	5 per BC	125
Cold elements for isothermal containers	720 per BC	1800
Loggers to control the blood components transportation temperature	35 per BC	875

6. Backup power supply generators

Blood centers are also in urgent need of backup power supply generators (Table 7).

Table 7

Need in backup power supply generators

Backup power supply generator, 10 kW	1
Backup power supply generator, 20 kW	10
Backup power supply generator, 30 kW	1
Backup power supply generator, 50 kW	5
Backup power supply generator, 60 kW	2
Backup power supply generator, 70 kW	2
Backup power supply generator, 76 kW	2
Backup power supply generator, 80 kW	1

Annex 2

PRIORITY AND URGENCYOF SUPPLY

1. The most priority and urgency of supply

1.1. Blood Bags

Blood Bag Quadruple with Whole Blood Filter CPD / SAGM	70%	105 000
Blood Bag Quadruple CPD / SAGM	20%	30 000
Blood Bag Triple CPD / SAGM	10%	15 000

1.2. Monoclonal antibodies

Consumable material	Bottles
Anti A	1 500
Anti B	1 500
Anti D	1 500
Anti D – D6	1 500
Calculation: Per 150 000 blood donors – 3 month of intensive blood collection regime of 25 blood centers 1 bottle of reagent volume – 10 ml 10 ml of reagent = 100 tests = 100 blood donors 150 000 blood donors = 1500 bottles of reagents	

1.3. Consumables for Ortho immunohematological analyzers

The need for consumables for immunohematological testing of donor blood for 3 months of operation of 3 blood centers on Ortho VISION automatic analyzer (Ortho) – 18 000 donations	
Consumable material	Packages
Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette), 400 cassettes	3
Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette), 100 cassettes	0
Anti-A/Anti-B/Anti-D Ortho BioVue® System (ABD Confirmation Cassette), 100 cassettes	0
ORTHOTM Sera Anti-D (DVI) Human Monoclonal IgM 5 ml	30
Anti-A/Anti-B/Anti-D/Control/Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette), 400 cassettes	45
Anti-A/Anti-B/Anti-D/Control/Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette), 100 cassettes	0
Anti-IgG, -C3d; polyspecific Ortho BioVue® System, 400 cassettes	22
Anti-IgG, -C3d; polyspecific Ortho BioVue® System, 100 cassettes	2
0.8% Surgiscreen®, 3 x 10 ml	97
Anti-C/Anti-E/Anti-c/Anti-e/Anti-K/Control Ortho BioVue® System (RH/K Cassette), 400 cassettes	45
Anti-C/Anti-E/Anti-c/Anti-e/Anti-K/Control Ortho BioVue® System (RH/K Cassette), 100 cassettes	0
ORTHOTM CONFIDENCE WB (Simulated Whole Blood Controls), 4 x 6,5 ml	9
ORTHO VISION Dilution Tray, 180 x 16 holes	7
ORTHO VISION Evaporation Caps (10mL), 250 pcs.	3
ORTHO 7% BSA, 12 x 5 ml	12
ORTHO 7% BSA, 15 x 12 ml	0
Ortho® BLISS, 3 x 10 ml	0

Ortho® BLISS, 4 x 50 ml	0
0.8% Affirmagen® A1, B, 2 x 10 ML	95

1.4. Refrigeration equipment

Refrigerator showcases for the blood service/biological materials (operating temperature range (4±2)°C; the volume not less than 250 liters)	3 per BC	75
Low-temperature refrigerators for storage of plasma and cryoprecipitate	7 per BC	175
Plasma shock freezer (operating temperature range: minus 70°C and below; volume – not less than 48 units of plasma)	1 per BC	25

1.5. Thermal containers

Isothermal containers with a capacity of at least 15 blood units	20 per BC	500
Isothermal containers with a capacity of at least 50 blood units	10 per BC	250
Isothermal containers with a capacity of at least 100 blood units	5 per BC	125
Cold elements for isothermal containers	720 per BC	1800
Loggers to control the blood components transportation temperature	35 per BC	875

1.6. Backup power supply generators

Backup power supply generator, 10 kW	1
Backup power supply generator, 20 kW	10
Backup power supply generator, 30 kW	1
Backup power supply generator, 50 kW	5
Backup power supply generator, 60 kW	2
Backup power supply generator, 70 kW	2
Backup power supply generator, 76 kW	2
Backup power supply generator, 80 kW	1

2. The supply of other equipment as an option to strengthen the capacity of blood centers and restore the technological processes in the blood centers that have been shelled or partially destroyed

Mobile donor chairs	4 per BC	100
Mixing scales	6 per BC	150
Portable dielectric sealers	5 per BC	125
Dielectric welders	1 per BC	25
Refrigerated centrifuges for 8 blood bags filled with blood	1 per BC	10
Refrigerated centrifuges for 12 blood bags filled with blood	1 per BC	15
System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 20 doses of platelets (4 shelves))	1 per BC	25
System for storage of platelet blood components (platelets recovered, pooled and platelets apheresis): climatic chamber (operating temperature range (22±2)°C) and shaker (volume of at least 40 doses of platelets (8 shelves))	1 per BC	25