List of diagnostic products, laboratory reagents, consumables used for donor blood testing, and eligibility criteria

1	Test for determining antibodies anti HBs	11328 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for haemotransmissible infections markers. **Properties:** Reaction type – enzyme immunoassay, antiHBs antibodies detection Analytical sensitivity - up to 2 mUI/ml, inclusive. Technical sensitivity - 100%. Specificity - including 99.90% and greater. The duration of incubation in test reaction - up to 150 minutes, inclusive. Incubating the test reaction - shall not include stirring. Spectrophotometric and visual check of the well content colour change at consistent sequencing, according to the instruction manual of the test.
2	Test for determining antibodies anti-HCV	47280 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for haemotransmissible infections markers. **Properties:** Reaction type – enzyme immunoassay, determination of antiHCV human antibodies, with recombinant and/or synthetic antigens in the solid phase, mandatorily representing C, NS3, NS4, NS5 genomic zones in human serum/plasma; Analytical sensitivity - including 99.8% and greater; Technical sensitivity – 100%; Specificity - including 99.8% and greater; The duration of incubation in test reaction - up to 120 minutes, inclusive. Incubating the test reaction - shall not include stirring; Spectrophotometric and visual check of the well content colour change at consistent sequencing, according to the instruction manual of the test.
3	Diagnostic tests to detect human T-pallidum antibodies	48000 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Reaction type –enzyme immunoassay, detection of human antibodies of Treponema Pallidum, type IgM and IgG in human serum/plasma. Analytical sensitivity – including 99.9% and greater. Technical sensitivity – 100%. Specificity - including 99.8% and greater. The duration of incubation in test reaction - up to 120 minutes, inclusive. Incubating the test reaction - shall not include stirring. Spectrophotometric and visual check of the well content colour change at consistent sequencing, according to the instruction manual of the test.
4	Test for the determining the antibodies against HIV-1 and HIV antigen P24	47520 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Reaction type –enzyme immunoassay, simultaneous determination of anti HIV-1 antibodies, group M and O, anti HIV-2, and the HIV-1 P24 antigen in human serum/plasma; Analytical sensitivity in antibodies detection - including 99.9% and greater; Sensitivity in determining P24 antigen – up to 25 pg/ml, inclusive or equivalent in UI/ml; Technical sensitivity - 100%; Specificity - including 99.8% and greater; The duration of incubation in test reaction - up to 120 minutes, inclusive; Incubating the test reaction - shall not include stirring.

			Spectrophotometric and visual check of the well content colour change at consistent sequencing, according to the instruction manual of the test.
5	Set of reagents for inverse transcription, amplification and detection of nucleic acids RNA in HCV infection	4650 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for hemotransmissible infection markers. **Properties:** Compatible • with Real Time technology; • with IQ5 amplifier with excitation/emission filters with the wave length of 485/530, 530/575, 545/585,575/625,630/685; • with biological specimen of blood serum, plasma on EDTA-K3, CPD, CPDA-1; The sensitivity of the reagents in the set shall be smaller or equal to 5000 UI /ml per one sample of donor serum in the pool, or at least 500 UI /ml for the created pool. Primers specificity shall comply with: • common characteristics for the HCV virus genetic variations commonly known as type 1,2,3,4,5,6, inclusively, and for the Eastern Europe region; • at least with 99 %, inclusive
6	Set of reagents for reverse transcription, amplification and detection of nucleic acids RNA in HIV infection	4650 100% - in 4 weeks from PO issuance	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Compatible: • with Real Time technology; • with IQ5 amplifier with excitation/emission filters with the wave length of 485/530, 530/575, 545/585,575/625,630/685; • with biological specimen of blood serum, plasma on EDTA-K3, CPD, CPDA-1. The sensitivity of the reagents in the set shall be smaller or equal to 10000 UI /ml per one sample of donor serum in the pool, or at least 1000 UI /ml for the created pool. Praimers specificity shall comply with: ✓ common characteristics for the HIV virus genetic variations known worldwide, including for the Eastern Europe region; ✓ at least with 99 %, inclusive.
7	Tests for confirmation of the diagnosis of CVH infection	300 100% - in 4 weeks from PO issuance	**Purpose:** to confirm HCV infection in the donor blood. **Reaction type** – immunoblot strips for detection of antibodies to hepatitis C (anti-HCV) in human serum or plasma, qualitative method; Strips captured with antigens coded for Hepatitis C virus. The duration of incubation – up to 4.5 – 5 hours.
8	Plastic container for transfer of blood components 300ml or 400ml	10350 100% - in 4 weeks from PO issuance	**Purpose:** processing human donor blood. **Properties:** Plastic material– PVC; Container for blood components transfer -Volume 300ml or 400ml; ensured with anticoagulant solution. Background and marking labels - tamper and -80° C temperature and high humidity resistant; The tubes of the sampling parts - provided with a clip
9	Closed plastic containers system for blood collection 450/450/400 with integrated leucocyte filter for blood filtering	1750 buc 100% - in 4 weeks from PO issuance	**Purpose:** for collection and processing of the human donor blood with integrated leucocyte filter for whole blood filtering, before separation into blood components. **Properties:** Blood collection container - volume of app. 450 ml provided with anticoagulant solution; Container for the transfer of collected and filtered through the leukocyte blood filter – at least 450 ml volume; Container for the transfer of the blood components - of app. 400 ml volume Integrated soft leucocyte filter ensuring retention of more than 99.9% leucocytes, and no more than $1x10^6$ post-filter leucocytes in one unit; Blood sample collection system in vacuum tube equipped with holder and needle: ✓ Integrated in the closed and sterile system of the collection tubing; ✓ provided with a clip; ✓ located on the harvesting tubing. Hooding system of post-donation needle with safe disposal – a requirement.
10	T-PAS additive solution, 500 ml	500fl	**Purpose:** for partial replacement of plasma during preparation and storing of a leuko-platelet layer derived from the thrombocytes concentrate or apheresis platelet units. **Properties:**

		100% - in 4 weeks from PO issuance	Sterile and non-pyrogenic solution, shall contain sodium citrate, sodium acetate, sodium dihydrogenophosphas dihydricus, disodium phosphas dodecahydricus, potassium chloridum, magnesium hexahydricum chloridum, sodium chloridum. Tubing internal diameter between 3mm-4,5mm
11	Closed plastic containers system for blood collection, type "top-bottom" 450/400/400ml with separation of leuco-thrombocyte layer and blood components and additive solution for erythrocytes	33250 100% - in 4 weeks from PO issuance	**Purpose:** for collection and processing of the human donor blood with preparation of plasma, erythrocytes and leukothrombocytar layer. **Properties:** Blood collection container - volume of app. 450 ml provided with anticoagulant solution; (up to 80ml) Container for the transfer of the blood components, plasma - of app. 400 ml volume; Container for the transfer of the blood components, red cells –app 400 ml volume with additive solution (up to 100 ml); Blood sample collection system in vacuum tube equipped with holder and needle: ✓ Integrated in the closed and sterile system of the collection tubing; ✓ provided with a clip; ✓ located on the harvesting tubing. Hooding system of post-donation needle with safe disposal – a requirement.
12	Set of consumables for double dose collection of thrombocytes, erythrocytes and plasma each in single dose	750 100% - in 4 weeks from PO issuance	**Purpose:** cytopheresis. Collection of double dose of thrombocytes and one dose of plasma by cytopheresis method **Properties of the required components of the set:** • Shall contain containers for collection and storage of platelets • disposable device compatible with the Trima Accel cytopheresis apparatus; • Needle with lateral notch; • The volume of each thrombocytes container shall not be more than 300 ml and the volume of plasma container shall not be less than 600 ml; • Hooding system of post-donation needle with safe disposal – a requirement; • Anticoagulant solution – shall contain sodium citrate, dextrose, sterile, non-pyrogenic, • Samples collection system; • Sterile and non-pyrogenic.