Invitation to Bid

Amendment no. 1

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Ref. no. **ITB17/01466**

Date: **4 April 2017**

Subject: Procurement of Tests and Consumables for Transplant, Transfusion and Immunoprophylaxis Health Programmes for MoH

1. UNDP Moldova is hereby amending the solicitation documents.

2. ITB Data Sheet is hereby amended as follows (changes are marked in red):

DS No.	Cross Ref. to Instructions	Data	Specific Instructions / Requirements
21	C.21.1 D.24	Deadline of Bid Submission	Date and Time: 18 April 2017, 15:00 (Moldova local time)
24	D.23.1 c)	Date, time and venue for opening of Bid	Date and Time: 18 April 2017, 15:00 (Moldova local time) Venue: UN House Conference Room, 131, 31 August 1989 Street, MD-2012 Chisinau, Moldova. Any bidder that intends to participate in the public bid opening shall notify UNDP by address alina.gilca@undp.org at least 24 hours in advance.
26	C.15.1	Required Documents that must be Submitted to Establish Qualification of Bidders (In "Certified True Copy" form only)	☒ Duly filled-in, signed and stamped Sections 4-8. ☒ Original of properly furnished Bid Security (as per DS# 9). Please use template provided in the Section 9. ☒ Copies of required documents to establish conformity of Bidder to the qualifications requirements and products quoted to product standards and requirements as per Section 4 "Criteria for award and checklist of documents required". ☒ All bids must include product catalogue/leaflet, with detailed technical specifications per each item. ☒ Each offered item must include product instruction for use. ☒ Copies of Manufacturer Quality Confirmation Letter describing product properties must be provided for Items 3-16 from Lot 3, and Items 2 and 3 from Lot 6. Manufacturer Quality Confirmation Letter shall be provided in original upon each Item delivery.

31		UNDP will award the contract to:	☒ One or more Bidders, depending on the following factors: Lowest-priced technically responsive offer per: • Lot for Lots 1,2,3,6,9, 10; • Item for Lots 4, 5, 7, 8;
32	F.34	Criteria for the Award and Evaluation of Bid	**Award Criteria** ☒ **1st stage:** Non-Discretionary "Pass/Fail" Qualifying Criteria on the Technical Requirements listed in the Section 4 "Criteria for award and checklist of documents required"; and ☒ **2nd stage:** For the bids, that passed 1st stage evaluation with "Pass" qualifying criteria, products' samples will be required to pass equipment compliance tests. Samples will be required only for Items 3-16 from Lot 3 and Items 2 and 3 from Lot 6. Only samples which demonstrated equipment compliance will be considered for further evaluation. Bids with samples which do not comply with equipment requirements will be disqualified; and ☒ **3rd stage:** Lowest price offer of technically qualified/responsive Bid.
35		Other Information Related to the ITB	Administrative Requirements: Prior to technical evaluation, submitted offers will be reviewed on a "Pass" or "Fail" basis to determine compliance with the below formal criteria/requirements: ☒ Bids must be submitted within the stipulated deadline; ☒ Bids must meet required Bid Validity; ☒ Bids must include original of properly furnished Bid Security (as per DS 9). ☒ Bids have been signed by the proper authority ☒ Full compliance and agreement with UNDP General terms and conditions (see Section 12 below) ☒ Bids must include confirmation of adequate performance of tests for Items 3-16 from Lot 3 and Items 2 and 3 from Lot 6. If required, the awarded supplier must perform calibration of the devices from Transfusion Centers from its own resources. Further information, instructions and/or amendments to the solicitation documents shall be published at the UNDP Moldova tenders website: http://www.undp.md/tenders/index.shtml

3. The Section 3: Schedule of Requirements and Technical Specifications of the ITB is hereby amended and shall read as follows (changes are marked in red):

The Section 3 Schedule of Requirements and Technical Specifications include **Annex 1 Technical Specifications** for former Lot 2, current Lots: 2-9.

2. PRODUCT STANDARDS

Original Version:	**To be replaced with:**
2.1.1. A. In order to be compliant with this criterion bidder will be requested to provide one of the following pre-market approval(s) / market clearance(s)/registration(s): A.1. CE mark (EU), (Directive 93/42 EEC or Directive 98/79 EEC), or A.2. Registration No. issued by the Medicines and Medical Devices Agency of the Republic of Moldova; A.3. SM mark (in accordance with Government Decision no.418 of 05 June 2014 of Republic of Moldova "re Medical Devices" or Government Decision no.435 of 10 June 2014 of Republic of Moldova "re in vitro diagnostic Medical Devices"). 2.1.2. B. Suppliers/manufacturers shall provide at least one certificate of conformity with the following Quality Management System standards: B.1. ISO13485, or B.2. ISO 9001	2.1.1. A. In order to be compliant with this criterion bidder will be requested to provide one of the following pre-market approval(s) / market clearance(s)/registration(s): A.1. CE mark (EU), (Directive 93/42 EEC or Directive 98/79 EEC), or A.2. Registration No. issued by the Medicines and Medical Devices Agency of the Republic of Moldova; **(A.3. is deleted)** 2.1.2. B. Suppliers/manufacturers shall provide at least one certificate of conformity with the following Quality Management System standards: B.1. ISO13485, or B.2. ISO 9001 2.1.3. Manufacturer Quality Confirmation Letter describing product properties must be provided for Items 3-16 from Lot 3, and Items 2 and 3 from Lot 6. Manufacturer Quality Confirmation Letter shall be provided in original upon each Item delivery.

3. PRODUCTS SPECIFICATION:

Lot 1: Tests and consumables for Transplant service list of items remains unchanged.
Lot 2: Tests and consumables for Blood Transfusion service is divided in 8 lots: Lot: 2,3, 4, 5, 6,7,8, 9.

Lot 2 shall include following items:

Item	Medical Product	Presentation	Quantity	Delivery ratio
1	Monoclonal reagent anti -A including: from a single reagent set of monoclonal antibodies from a single batch of hybridoma	kit	18550	100% - by Aug. 1, 2017
2	Monoclonal reagent anti - B - from another single series of reagent monoclonal of another single batch of hybridoma	Piece	18550	100% - by Aug. 1, 2017
3	Monoclonal reagent anti – B - from a single reagent set of monoclonal antibodies from a single batch of hybridoma	Piece	18550	100% - by Aug. 1, 2017
4	Monoclonal reagent anti - D (IgM+IgG)	Piece	18400	100% - by Aug. 1, 2017
5	Monoclonal reagent anti - D IgM	Piece	18700	100% - by Aug. 1, 2017

Item	Medical Product	Presentation	Quantity	Delivery ratio
6	Monoclonal reagent anti – A inclusively: from another single series of reagent monoclonal of another single batch of hybridoma	Piece	18550	100% - by Aug. 1, 2017
7	Monoclonal reagent anti –AB	Piece	18400	100% - by Aug. 1, 2017
8	Monoclonal reagent anti Fya	Piece	825	100% - by Aug. 1, 2017
9	Monoclonal reagent anti Fyb	Piece	825	100% - by Aug. 1, 2017
10	Monoclonal reagent anti Jka	Piece	1650	**100 % urgent – within 4 weeks from PO signature**
11	Monoclonal reagent anti Jkb	Piece	1650	**100 % urgent – within 4 weeks from PO signature**
12	Monoclonal reagent anti k	Piece	825	100% - by Aug. 1, 2017
13	Monoclonal reagent anti S	Piece	825	100% - by Aug. 1, 2017
14	Monoclonal reagent anti s	Piece	825	100% - by Aug. 1, 2017
15	Monoclonal reagent anti-C	Piece	4625	100% - by Aug. 1, 2017
16	Monoclonal reagent anti-c	Piece	3175	100% - by Aug. 1, 2017
17	Monoclonal reagent anti-E	Piece	4625	100% - by Aug. 1, 2017
18	Monoclonal reagent anti-e	Piece	3175	100% - by Aug. 1, 2017
19	Monoclonal reagent anti-Kell	Piece	18700	100% - by Aug. 1, 2017
20	Erythrocyte pool from 10 cells – test	Kit	6	**Monthly delivery, 1 test per each month, as per Annex 1**
21	Erythrocyte Count (RBC) 3-cell panel	Tests	12	**Monthly delivery, 1 test per each month, as per Annex 1**
22	Polyspecific antiglobulin serum	Piece	34000	100% - by Aug. 1, 2017
23	Pool erythrocyte standard test	Piece	12000	100% - by Aug. 1, 2017
24	IgG - covered cells	Piece	18900	**Monthly delivery, 1 test per each month, as per Annex 1**

Lot 3 shall include following items:

Item	Medical Product	Presentation	Quantity	Delivery ratio
1	Normal control material	Piece	18	100% - by Aug. 1, 2017
2	Pathologic control material	Piece	18	100% - by Aug. 1, 2017
3	Reagent ALAT	Piece	17300	100% - by Aug. 1, 2017
4	Set of reagents for reverse transcription, amplification and detection of nucleic acids RNA in HIV infection	Kit	4650	100% - by Aug. 1, 2017
5	Set of reagents for extraction of RNA in HIV infection	Kit	9600	**100 % urgent – within 4 weeks from PO signature**
6	Set of reagents for extraction of RNA in HCV infection	Kit	9600	**100 % urgent – within 4 weeks from PO signature**
7	Set of reagents for inverse transcription, amplification and detection of nucleic acids RNA in HCV infection	Kit	4650	100% - by Aug. 1, 2017
8	Diagnostic tests for HBsAg	Piece	624	100% - by Aug. 1, 2017

Item	Medical Product	Presentation	Quantity	Delivery ratio
9	Confirmatory tests for the diagnosis of HCV infection	Piece	300	100% - by Aug. 1, 2017
10	Diagnostic tests for AgHBs	Piece	50400	100% - by Aug. 1, 2017
11	Test for determining antibodies anti HBcor IgM	Piece	12720	100% - by Aug. 1, 2017
12	Test for determining antibodies anti HBc total	Piece	46800	100% - by Aug. 1, 2017
13	Test for determining antibodies anti HBs	Piece	11280	100% - by Aug. 1, 2017
14	Diagnostic tests to detect human T-palladium antibodies	Piece	48000	100% - by Aug. 1, 2017
15	Test for determining antibodies anti-HCV	Piece	47280	100% - by Aug. 1, 2017
16	Test for the determining the antibodies against HIV-1 and HIV antigen P24	Piece	47520	100% - by Aug. 1, 2017

Bids must include confirmation of adequate performance of tests for Items 3-16 from Lot 3. If required, the awarded supplier must perform calibration of the devices from Transfusion Centers from its own resources.

Lot 4 shall include following items:

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
1	Epindorf tube, type II	Piece	41500	5	100% - by Aug. 1, 2017
2	Big size tampon saturated with alcohol	Piece	169000	20	100% - by Aug. 1, 2017
3	Cone, type I, 100 mcl	Piece	27000	5	100% - by Aug. 1, 2017
4	Cone, type II 200mcl	Piece	48000	5	100% - by Aug. 1, 2017
5	Cone, type III, 10 mcl	Piece	650	5	100% - by Aug. 1, 2017
6	Cone, type V 200mcl	Piece	428750	5	100% - by Aug. 1, 2017
7	Cone, type VI 1000mcl	Piece	46500	5	100% - by Aug. 1, 2017
8	Gloves	Piece	200000	10	100% - by Aug. 1, 2017
9	Plate, type I	Piece	600	5	100% - by Aug. 1, 2017
10	Scarificators	Piece	43900	20	100% - by Aug. 1, 2017
11	Sterile tampon	Piece	44800	20	100% - by Aug. 1, 2017
12	Test tube type III	Piece	41500	5	100% - by Aug. 1, 2017
13	Combs (magnetic)	Piece	75	5	100% - by Aug. 1, 2017
14	Big size tampon saturated with Iodine	Piece	84500	20	100% - by Aug. 1, 2017

Lot 5 shall include following items:

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
1	Plastic container for transfer of blood components 300ml or 400ml	Piece	10350	5	100% - by Aug. 1, 2017

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
2	Closed plastic containers system for blood collection 450/500/400 with integrated leucocyte filter for blood filtering	Piece	1750	5	100% - by Aug. 1, 2017
3	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	Piece	33250	5	100% - by Aug. 1, 2017
4	Additive solution for thrombocytes	Piece	500	5	100% - by Aug. 1, 2017
5	Medical Wafers	Piece	82	1 set	100% - by Aug. 1, 2017
6	Set of consumables for double dose collection of thrombocytes and one dose of plasma	Piece	750	5	100% - by Aug. 1, 2017
7	Set of consumables for plasmapheresis	Kit	3960	5	100% - by Aug. 1, 2017

Lot 6 shall include following items:

Item	Medical Product	Presentation	Quantity	Delivery ratio
1	Sterile cassette	Kit	1200	100% - by Aug. 1, 2017
2	Reagents for examining blood products for presence of anaerobic microbe germs	Piece	1500	100% - by Aug. 1, 2017
3	Reagents for examining blood products for presence of aerobic microbe germs	Piece	1500	100% - by Aug. 1, 2017

Bids must include confirmation of adequate performance of tests for Items 2 and 3 from Lot 6. If required, the awarded supplier must perform calibration of the devices from Transfusion Centers from its own resources.

Lot 7 shall include following items:

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
1	Flasks, type I 5 ml	Piece	20000	10	**100 % urgent – within 4 weeks from PO signature**
2	Pessaries, type IV – flip-off (2120)	Piece	35000	10	**100 % urgent – within 4 weeks from PO signature**
3	Pessaries, type V – flip-off (2134)	Piece	7000	10	**100 % urgent – within 4 weeks from PO signature**

Lot 8 shall include following items:

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
1	Continuous label tape roll	Piece	800	1 roll	**100 % urgent – within 4 weeks**

Item	Medical Product	Presentation	Quantity	No. of Samples to be required	Delivery ratio
					from PO signature
2	Marking barcode stickers	Piece	85000	20	**100 % urgent – within 4 weeks from PO signature**

Lot 9 shall include following items:

Item	Medical Product	Presentation	Quantity	Delivery ratio
1	Ethyl alcohol 96%	dL	250	100% - by Aug. 1, 2017

Lot 3 shall be renamed into LOT 10 Tests and consumables (medicines and disinfectants). The list of items for this lot remains unchanged.

All products must be supplied in complete sets as produced by manufacturer.

Reagents must contain control kits and other components (as per instruction of use) in sufficient quantities according to the required number of tests.

4. DELIVERY TIMEFRAMES

Original Version	To be replaced with:
Shipping documents	
• Commercial invoice – 2 originals. • Packing list – 1 copy. • Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier. • Certificate of Origin, if goods are being imported • Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported. • Registration No. issued by the Medicines and Medical Devices Agency;(if applicable) • SM mark, according to the Government Decision no.418 of 05 June 2014 of Republic of Moldova, re Medical Devices or Government Decision no.435 of 10 June 2014 of Republic of Moldova re in vitro diagnostic Medical Devices (if applicable)	• Commercial invoice – 2 originals. • Packing list – 1 copy. • Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier. • Certificate of Origin, if goods are being imported • Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported. • Registration No. issued by the Medicines and Medical Devices Agency;(if applicable) • Last bullet is deleted

4. All other terms and conditions of the solicitation documents, except as amended herein, shall remain unchanged and shall continue in full force and effect.

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

Nr. d/o	Generic name of the basic specific preparations	The required quantity and delivery time	**Eligibility criteria**
			Technical requirements
1	Monoclonal reagent anti -A including:		
	from a single reagent set of monoclonal antibodies from a single batch of hybridoma	100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity – avidity up to 60 sec with the appropriate antigen; Specificity – according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
	from another single reagent set of monoclonal antibodies from a single batch of hybridoma	18550 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
2	Monoclonal reagent anti -B including:		
	from a single reagent set of monoclonal antibodies from a single batch of hybridoma	18550 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
	from another single reagent set of monoclonal antibodies from a single batch of hybridoma	18550 100% by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class.

			Antibodies titre - not less than 1:32 in the on surface assessment method
3	Monoclonal reagent anti –AB	18400 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
4	Monoclonal reagent anti - D (IgM+IgG)	18400 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
5	Monoclonal reagent anti - D IgM	18700 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
6	Monoclonal reagent anti-Kell	18700 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
7	Monoclonal reagent anti-C	4625 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
8	Monoclonal reagent anti-E	4625 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination.

			Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
9	Monoclonal reagent anti-c	3175 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25 ° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
10	Monoclonal reagent anti-e	3175 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
11	Monoclonal reagent anti k	825 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination. Type of antibodies - IgM class. Antibodies titre - not less than 1:32 in the on surface assessment method
12	Monoclonal reagent anti Fya	825 100% - by Aug. 1, 2017	Purpose: to detect erythrocyte antigens in donors and patients' blood. Properties: Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgG class; Antibodies titre - not less than 1:16 in the on surface assessment method
13	Monoclonal reagent anti Fyb	825 100% - by Aug. 1, 2017	Purpose: to detect erythrocyte antigens in donors and patients' blood. Properties: Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgG class; Antibodies titre - not less than 1:16 in the on surface assessment method
14	Monoclonal reagent anti Jka	1650	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:**

		100 % urgent – within 4 weeks from PO signature	Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgM class; Antibodies titre – not less than 1:16 with reaction intensity 3 plus in slide test and 4 plus in tube test;
15	Monoclonal reagent anti Jkb	1650 100 % urgent – within 4 weeks from PO signature	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgM class; Antibodies titre - not less than 1:32 in the slide test;
16	Monoclonal reagent anti S	825 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgM class; Antibodies titre - not less than 1:16 in slide test, reaction intensity of 3 plus 4 plus in tube test;
17	Monoclonal reagent anti s	825 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in donors and patients' blood. **Properties:** Sensitivity - avidity up to 60 sec with the appropriate antigen; Specificity - according to Ag without immune haemolysis and false agglutination reactions; The reagent use method - agglutination on the surface, tube and the well at 15-25° C room temperature, visual examination; Type of antibodies - IgM class; Antibodies titre not less than 1:16 in slide test, reaction intensity of 3 plus 4 plus in tube test;
18	Polyspecific antiglobulin serum	34000 100% - by Aug. 1, 2017	**Purpose:** to detect erythrocyte antigens in the direct antiglobulin test, agglutination in tube. **Properties:** Necessarily containing antibodies class G and C3d. Reactivity and Specificity: agglutination of antibody-coated red blood cells.
19	Pool erythrocyte standard test	12000 100% - by Aug. 1, 2017	**Purpose:** to detect anti erythrocyte irregular antibodies in screening the donated blood, by in the tube method **Properties:** stabilized solution of group O with minimum required amount of primary antigens: D, C, E, c, e, C^w, K, k, Kp^a, Kpb, Fy^a, Fy^b, Jk^a, Jk^b, M, N, S, s, Le^a, Le^b, P1. Reactivity and Specificity - clear reaction of selected reagents with the appropriate erythrocyte antigens. Aspect - at visual inspection the supernatant liquid has no signs of haemolysis or opalescence.
20	Erythrocyte cells - 3-cell panel	12 sets Monthly delivery: May Iune Iuly	**Purpose:** to detect anti erythrocyte irregular antibodies in screening for compatibility test, by in the tube method **Properties:** stabilized solution of group O with minimum required amount of primary antigens: D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, M, N, S, s, Le^a, Le^b, P1, Lu^a, Kp^a, C^w. Reactivity and Specificity - clear reaction of selected reagents with the appropriate erythrocyte antigens. Aspect - at visual inspection the supernatant liquid has no signs of haemolysis or opalescence.

		August September October November December1st December 24th 2017	
21	Erythrocyte cells pool from 10 cells – test	6 sets Monthly delivery: August September October November December1st December 24th 2017	**Purpose:** to detect anti erythrocyte irregular antibodies in screening for compatibility test, by in the tube method. **Properties:** stabilized solution of group O with minimum required amount of primary antigens: D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, M, N, S, s, Le^a, Le^b, P1, Lua, Kp^a, C^w. Reactivity and Specificity - clear reaction of selected reagents with the appropriate erythrocyte antigens. Aspect - at visual inspection the supernatant liquid has no signs of haemolysis or opalescence.
22	IgG - covered cells	18900 6 sets Monthly delivery: August September October November December1st December 24th 2017	**Purpose:** to confirm and validate antiglobulin test negative results. **Properties:** 1. Positive reaction - antiglobulin test result considered valid. 2. Negative reaction - antiglobulin test result considered invalid.
23	Reagent ALAT	17300 ml 100% - by Aug. 1, 2017	**Purpose:** for biochemical testing of donor blood. **Properties:** Method - photometric fermentative, kinetic; Reagent type – stable, ready to use liquid, bi-reagent; Material - serum, plasma EDTA; The minimum detection limit per set - up to 4 U / L, inclusive.

24	Pathologic control material	18 fl 100% - by Aug. 1, 2017	**Purpose:** quality control of biochemical reagents in the donor blood. **Properties:** to validate the activity of ALAT reagent used in photometric - kinetic method;
25	Normal control material	18fl 100% - by Aug. 1, 2017	**Purpose:** quality control of biochemical reagents in the donor blood. **Properties:** to validate the activity of ALAT reagent used in photometric - kinetic method;
26	Test for determining antibodies anti HBcor IgM	12720 tests 100% - by Aug. 1, 2017	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Reaction type - enzyme immunoassay, determination of anti-HBcor IgM class antibodies in human serum / plasma Analytical sensitivity - up to 50 U/ml, evaluated according to the PEI standards Diagnostic sensitivity - including 98.0% and greater Specificity - including 98.0% 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.
27	Diagnostic tests for AgHBs	50400 100% - by Aug. 1, 2017	**Purpose:** donor blood testing for haemotransmissibile infection markers. **Properties:** Reaction type - enzyme immunoassay, determination of hepatitis B surface antigen in human serum / plasma Analytical sensitivity – up to 0.15 ng/ml, inclusive or its equivalent in IU/ml. Technical sensitivity - 100%. Specificity- including 99.90% 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.
28	Test for determining antibodies anti HBs	11280 100% - by Aug. 1, 2017	**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 99.40% 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.
29	Test for determining antibodies anti HBc total	46800 100% - by Aug. 1, 2017	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:**

			Reaction type –enzyme immunoassay, simultaneous determination of IgG și IgM antibodies, with specificity to the viral hepatitis B core Ag. 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 color change at consistent sequencing, according to the instruction manual of the test.
30	Test for determining antibodies anti-HCV	47280 100% - by Aug. 1, 2017	**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.
31	Diagnostic tests to detect human T-palladium antibodies	48000 100% - by Aug. 1, 2017	**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.
32	Test for the determining the antibodies against HIV-1 and HIV antigen P24	47520 100% - by Aug. 1, 2017	**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.
33	Set of reagents for extraction of RNA in HCV infection	9600 May 2017–1/2 September 2017 1/2	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Compatible: • with MagMax automated extractor; • the extraction method shall be based on paramagnetic microspheres; • final product yield 75% and greater; • extraction protocols for the MagMax automated extractor.
34	Set of reagents for inverse transcription, amplification and detection of nucleic acids RNA in HCV infection	4650 100% - by July. 1, 2017	**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
35	Set of reagents for extraction of RNA in HIV infection	9600 May 2017–1/2 September 2017 1/2	**Purpose:** donor blood testing for haemotransmissible infection markers. **Properties:** Compatible: • with MagMax automated extractor; • the extraction method shall be based on paramagnetic microspheres; • final product yield 75% and greater; • extraction protocols for the MagMax automated extractor. The set shall be required to include all necessary components for the testing reaction, in quantities sufficient for the indicated number of tests, in conformity with the product user manual.
36	Set of reagents for reverse transcription, amplification and detection of nucleic acids RNA in HIV infection	4650 100% - by July. 1, 2017	**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.
37	Confirmatory tests for the diagnosis of HCV infection	300	**Purpose:** to confirm HCV infection in the donor blood.

		100% - by October 1., 2017	**Reaction type** – immunoblot strips for detection of antibodies to hepatitis C (anti-HCV) in human serum or plasma, qualitative method; The duration of incubation – up to 4.5 – 5 hours.
38	Diagnostic tests for HBsAg/ Confirmatory tests for the diagnosis of HBsAg infection	624 100% - by October.1, 2017	**Purpose:** to confirm AgHBs in donor blood. **Properties:** Reaction type – neutralization, corresponding to the basic test in AgHBS screening; **Analytical sensitivity –** up to 0,06 ng/ml, inclusive or equivalent in UI/ml; **Technical sensitivity -** 100% **Specificity -** including 99,90% 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.
39	Plastic container for transfer of blood components 300ml or 400ml	10350 100% - by Aug. 1, 2017	**Purpose:** processing human donor blood. **Properties:** Plastic material– PVC; Container for blood components transfer -Volume 300ml or 400ml; Background and marking labels - tamper and -80° C temperature and high humidity resistant; The tubes of the sampling parts - provided with a clip
40	Closed plastic containers system for blood collection 450/500/400 with integrated leucocyte filter for blood filtering	1750 buc 100% - by Aug. 1, 2017	**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 filter blood – at least 500 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; Anticoagulant solution – shall contain sodium citrate, phosphate, adenine, and dextrose; 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.
41	Additive solution for thrombocytes	500fl 100% - by Aug. 1, 2017	**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:** Sterile and non-pyrogenic solution, shall contain sodium citrate, sodium acetate, sodium dihydrogenophosphas dihydricus, disodium phosphas dodecahydricus, potassium chloridum, magnesium hexahydricum chloridum, sodium chloridum.
42	Closed plastic containers system for blood collection, type "top-bottom" 450/400/400ml with separation of	33250 100% - by Aug. 1, 2017	**Purpose:** for collection and processing of the human donor blood with preparation of plasma, erythrocytes and leukothrombocytar layer. **Properties:**

	leuco-thrombocyte layer and blood components and additive solution for erythrocytes		Blood collection container - volume of app. 450 ml provided with anticoagulant solution; 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; Anticoagulant solution – shall contain sodium citrate, phosphate and dextrose Additive solution – shall contain adenine, glucose or dextrose, mannitol, sodium chloride 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.
43	Set of consumables for double dose collection of thrombocytes and one dose of plasma.	750 100% - by Aug. 1, 2017	**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.
44	Marking barcode stickers	85000 100 % urgent – within 4 weeks from PO signature	**Purpose:** marking blood units/components, samples, etc. Adhesive in moisture and in the spinning process; Resistant to fast freezing and de-freezing; Easily detachable. **Type**: pre-printed; **Dimensions:** 22 mm x 32 mm; **Set:** 12 units for each donated unit.
45	Continuous label tape roll	800 100 % urgent – within 4 weeks from PO signature	**Purpose:** to mark validated blood products; **Properties:** compatible with the barcode printer „Brother P-touch, QL – 650TD"; low temperatures and fast de-freezing resistant Easily detachable
46	Scarificators	43900 100% - by Aug. 1, 2017	**Purpose:** to facilitate collection of blood from finger phalanx, for laboratory tests purpose **Properties:** sterile, steel, disposable; **Dimensions:** length of scarificator 3 cm inclusive and longer, puncture needle base up to 1 mm, inclusive;
47	Plate, type I	600 100% - by Aug. 1, 2017	**Purpose:** for laboratory tests. **Properties:** compatible with the MagMax 96 automatic extractor, **Packaging:** delivered packaged, marked and labelled by the producer, with the ID information (product name, lot/serial number).

48	Sterile tampon	44800 100% - by Aug. 1, 2017	**Purpose:** for dressing the venipuncture site **Properties:** sterile, dry, disposable tampons for medical use Type of material: material with high liquids absorbent capacity Dimensions: tampon length and width of app. 40 mm tampon thickness of app. 6 mm
49	Tampon saturated with Iodine solution	84500 100% - by Aug. 1, 2017	**Purpose:** to ensure prevention of nosocomial infections. **Properties:** sterile, disposable medical use tampon, saturated (impregnated) with disinfectant 10% iodine solution, with 1% iodine concentration for external use. Type of material: material with high liquids retention capacity. Dimensions**:** LARGE type
50	Big size tampon saturated with alcohol	169000 100% - by Aug. 1, 2017	**Purpose:** to ensure prevention of nosocomial infections. **Properties:** sterile, disposable medical use tampon, impregnated with app 70% concentration medical alcohol for external use. Type of material: material with high liquids retention capacity. Dimensions: LARGE type
51	Medical Wafers	82 100% - by Aug. 1, 2017	**Purpose:** for sterile sealing in blood components production; **Properties:** compatible with the PVC – Termo TSCD – II tubs sterile sealing and connection apparatus;
52	Con, tip I, 100 mcl Cone, type I, 100 mcl	27000 100% - by Aug. 1, 2017	**Purpose:** for PCR laboratory tests. **Properties:** plastic, DNA-ses, RNA-ses free, with filter, of app 0.1 ml volume, packed in plastic bags.
53	Cone, type II 200mcl	48000 100% - by Aug. 1, 2017	**Purpose:** for PCR laboratory tests. **Properties:** plastic, DNA-ses, RNA-ses free, with filter, of app 0.2 ml volume, packed in plastic bags.
54	Cone, type III, 10 mcl	650 100% - by Aug. 1, 2017	**Purpose:** for PCR laboratory tests. **Properties:** plastic, DNA-ses, RNA-ses free, with filter, of app 0.01 ml volume, packed in plastic bags.
55	Cone, type V 200mcl	428750 100% - by Aug. 1, 2017	**Purpose:** for laboratory tests. **Properties:** plastic, volume 0-200 mcl.
56	Cone, type VI 1000mcl	46500 100% - by Aug. 1, 2017	**Purpose:** for laboratory tests. **Properties:** plastic, volume 0-1000 mcl.
57	Eppendorf tube, type II	41500 100% - by Aug. 1, 2017	**Purpose:** for storing serum samples in the freezer. **Properties:** plastic, of app 1.5 ml volume, air-tight.
58	Gloves	200000 100% - by Aug. 1, 2017	**Purpose:** to ensure prevention of nosocomial infections **Properties:** latex non-sterile, non-powdered, smooth, ambidextrous, disposable
59	Tube type III	41500	**Purpose:** to collect blood for laboratory tests.

		100% - by Aug. 1, 2017	**Properties:** of app 6 ml volume, with vacuum pressure, with EDTA K3 type preservative, allowing to collect blood through the needle equipped tube holder.
60	Sterile cassette	1200 100% - by Aug. 1, 2017	**Purpose:** to control sterility of the micro flora in the sterile box of MAirT device while producing biomedical blood preparations. Type of material: sterile, colourless plastic boxes.
61	Reagents for examining blood products for presence of anaerobic microbe germs	1500 fl 100% - by Aug. 1, 2017	**Purpose:** testing blood products for presence of anaerobic microbe germs, bottles used for human donor/patient blood untreated with antibiotics. **Properties:** Glass bottles with nutrient medium compatible with the BacT/Alert automated system Composition of the culture medium in the bottle: tripticaza soya broth with supplements for anaerobic organisms, with SPS (anticoagulant) in CO_2 environment in nitrogen; ready to use reagents, with no intermediate preparation steps. With colorimetric sensor.
62	Reagents for examining blood products for presence of aerobic microbe germs	1500 100% - by Aug. 1, 2017	**Purpose:** testing blood products for presence of anaerobic microbe germs, bottles used for human donor/patient blood untreated with antibiotics. **Properties:** Glass bottles with nutrient medium compatible with the BacT/Alert automated system Composition of the culture medium in the bottle: tripticaza soya broth with SPS (anticoagulant) in CO_2 environment in the air. With colorimetric sensor; ready to use reagents, with no intermediate preparation steps.
63	Ethyl alcohol 96%	250 dL, 100% - by Aug. 1, 2017	**Purpose:** for fractioning human plasma protein fractions while producing biomedical blood preparations (albumine, human immunoglobulin, etc.). **Properties:** in conformity with Ph. Eur. Requirements.
64	Flasks , type I 5 ml	20000 100 % urgent – within 4 weeks from PO signature	**Purpose: for packaging** biomedical blood preparations and /or diagnostic blood preparations. **Properties:** resistant to temperatures up to + 180^0C Volume 5 ml. Total no more than 12 ml Basic material – high quality, neutral, colourless medical glass;
65	Pessaries, type IV – flip-off (2134)	7000 100 % urgent – within 4 weeks from PO signature	**Purpose:** for fixing the rubber stoppers on the necks of bottles with biomedical blood preparations, with external diameter of the bottle neck of app 34 mm. **Properties:** Basic material: aluminium, Tip –flip-off (2134) Dimensions: stopper for 34.0 mm diameter vials
66	Pessaries, type IV – flip-off (2120)	35000 100 % urgent – within 4 weeks from PO signature	**Purpose:** for fixing the rubber stoppers on the necks of bottles with biomedical blood preparations, with external diameter of the bottle neck of app 20 mm. **Properties:** Basic material: aluminium, Tip –flip-off (2120) Dimensions: stopper for 20.0 mm diameter vials

67	Magnetic Comb	75 100% - by Aug. 1, 2017	**Purpose:** to protect the magnet against cross-contamination during automatic extraction, at the PCR laboratory examinations stage **Properties:** magnet fixing capacity compatible with the MagMax 96 automated extractor;
68.	Consumables for Plasmapheresis	3960 100% - by Aug. 1, 2017	**Purpose:** for cleaning and processing human donor blood. **Properties:** A compulsory set components: • The single use set compatible with Heamonetics PCS2 device, piping connection for NaCl saline solution and anticoagulant ensured through clips or similar; • 16 G needle tip, • With safe handling system of the needle after use. • Bowl-centrifuge for blood collection equipment compatible with Heamonetics PCS2 advice; • anticoagulant solution - the content of 4% sodium citrate, Sterile, non-pyrogenic, V-250 ml, with plastic container and anchoring system. • With plasma collection container V-1000 ml volume, adapted for fixing to the bowl, with needle for connecting the plastic container to the NaCl saline solution; Labels and marking - resistant at T minus 80 ° C and increased humidity, with possibility of inscription: type and volume o container, lot nr./serial nr., validity terms, and 'STERILE' notification. Form of packaging: each set or component a set will be delivered separately packaged securely, marked and labeled by the manufacturer indicating identification data (name, batch number / number, shelf life, storage conditions) and Presence notifications "OF SINGLE USE "," STERILE ".