

Annex E. Hematology analyzer BK-6190

1. The equipment must be new, not in operation (Bidder must provide a letter of guarantee).
2. The goods offered by the Bidder must be entered into the State Register of medical equipment and medical devices and / or put into circulation in accordance with the legislation in the field of technical regulation and conformity assessment in the manner prescribed by law.

For confirmation, the Bidder must provide copies of the documents below, or a letter of guarantee that one of the following documents will be provided during delivery:

- a) a certified copy of the declaration or a copy of documents confirming the possibility of putting into circulation and / or operation (use) of a medical device based on the results of passing the conformity assessment procedure in accordance with the requirements of technical regulations at the time of submission of proposals or signing a purchase agreement or upon delivery, or*
- b) considering the requirements of the resolutions of the Cabinet of Ministers of Ukraine dated 02.10.2013 № 753 *, №754 **, №755 ***, if the Bidder offers medical devices that have passed state registration, entered in the State Register of Medical Equipment and Medical Devices and allowed for use in the territory of the country and have been put into circulation before the date of mandatory application of technical regulations, it is allowed to offer such products before their expiration date and not more than five years from the date of entry into circulation, without undergoing conformity assessment and labeling national mark of conformity.*

** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013. № 753 "On the consolidated technical regulations of medical viruses".*

*** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No. 754 "On the consolidation of the Technical Regulations of Medical Viruses for In Vitro Diagnostics".*

**** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013. № 755 "On the consolidation of the Technical Regulations for active medical virobivs that implant".*

3. Warranty period for devices and optics - not less than 12 months from the date of commissioning (provide a letter of guarantee from the bidder as part of the tender offer).

4. Availability of instructions in Ukrainian or Russian on the devices (provide the original or a copy of the letter of guarantee from the bidder as part of the tender offer).

5. The ability of the participant to supply the proposed equipment must be confirmed by the original letter of guarantee from the manufacturer (if the participant is not the manufacturer of the goods) or his official representative in Ukraine (such representation must be confirmed by a copy of the corresponding letter, order, authorization, etc. from the manufacturer), which confirms the possibility of the participant supplying the proposed equipment in the required quantity, quality and within the timeframe determined by this tender documentation and the participant's proposal (provide a scanned copy of the original letter of guarantee as part of the tender proposal).

№	Specification	Compliance (yes / no) with reference to the documentation
1	General requirements	
1.1	This analyzer should be suitable for detecting the parameters of white and red blood cells, hemoglobin and differential counting, and 20 parameters and 3 blood histograms can be obtained from the analysis	
1.2	Blood cells must be counted and measured using the electrical impedance method. Hemoglobin is determined by the colorimetric method	
2	Specification	
2.1	Requirements	
	Number of items before the release, 20 pcs.	
	Reading: white blood cells, lymphocytes, medium-sized cells, neutrophils, percentage of lymphocytes, percentage of medium-sized cells, percentage of neutrophils, erythrocytes, hemoglobin concentration, hematocrit, mean corpuscular (erythrocyte) volume, mean cellular hemoglobin of blood cells (erythrocytes) - standard deviation, deviation from the distribution of red blood cells (erythrocytes) - variation coefficient, platelets, average platelet volume, platelet distribution width, platelet volume, cell volume ratio	
	Histograms: histogram of white blood cells, histogram of red blood cells, histogram of platelets	
	Principle of measurement: blood cells are counted and measured by electrical impedance, and the amount of hemoglobin is measured by colorimetry	
2.2	Parameter display range	
	White blood cells: 0.0-99.9x10 ³ / μ	
	Red blood cells: 0.0-9.99x10 ⁶ / μ L	
	Hemoglobin concentration: 0.0-30g / dL	
	Platelets, compliance: 0-3000x10 ³ / μ L	
	Average corpuscular (erythrocyte) volume: 0-250fL	
	Percentage of lymphocytes: 0-100%	
	Percentage of cells of medium size: 0-100%	
	Percentage of neutrophils: 0-100%	
	Lymphocytes: 0-99.9x10 ³ / μ L	
	Cells of medium size: 0-99.9x10 ³ / μ L	
	Neutrophils: 0-99.9x10 ³ / μ L	
	Hematocrit: 0.0-100%	
	Mean cellular erythrocyte hemoglobin: 0.0-999.9pg	
	The average concentration of cellular hemoglobin in the erythrocyte: 0.0-99.9g / dL	

	Deviation from the distribution of red blood cells (erythrocytes) - standard deviation: 0.0-99.9fL	
	Deviation from the distribution of red blood cells (erythrocytes) - variable coefficient: 0.0-99.9%	
	Platelet distribution width: 0.0-30.0%	
	Mean platelet volume: 0.0-30.0fL	
	Platelet volume: 0.0-9.99%	
	The ratio of platelet volume to large cells: 0.0-99.9%	
2.3	Sample volume	
	Venous blood: 10μL	
	Capillary blood: 10μL	
	Pre-diluted blood: 20μL	
2.4	Mode of operation with venous and capillary blood	
	White blood cells, not less than: 1: 285	
	Red blood cells: 1: 21667	
	Hemoglobin: 1: 500	
	Platelets not less than: 1: 43333	
2.5	The size of the cell reading aperture	
	White blood cells: 100μm	
	Red blood cells: 70μm	
	Platelets not less than: 70μm	
2.6	Other specifications	
	Bandwidth: up to 60 samples per hour	
	Operating modes: double reading, independent system of finding hemoglobin	
	Display, not worse than: LCD touch screen	
	Display resolution, not worse than: 800 * 600 mm	
	Language: Ukrainian	
	Indication: power status indication diode	
	Interface: socket, printer port, RS232 / C port, VGA port, 2 USB ports	
	Printer: thermal printer	
	Power supply: 100-240V, 50 / 60Hz	
	Dimensions (L * W * H): 410 * 435 * 472 mm	
	Net weight: 19 kg	
2.7	Recurrence (accuracy)	
	White blood cells: .02.0%	

	Red blood cells: $\leq 1.5\%$	
	Hemoglobin concentration: $\leq 1.5\%$	
	Mean corpuscular (erythrocyte) volume: $\leq 0.4\%$	
	Platelets: $\leq 4.0\%$	
2.8	Linearity range	
	White blood cells: $0 \sim 5.9 \times 10^9 / l$, $6.0 \sim 99.9 \times 10^9 / l$	
	Red blood cells: $0 \sim 0.99 \times 10^{12} / l$, $1.0 \sim 9.99 \times 10^{12} / l$	
	Hemoglobin concentration: $0 \sim 99g / l$, $100 \sim 300g / l$	
	Platelets: $0 \sim 99 \times 10^9 / l$, $100 \sim 999 \times 10^9 / l$	

