

Detalii specifice și standarde tehnice

LOT. 1. “Analizator microbiologic, automatizat”:

I.	Specificatii tehnice solicitate		Specificatii tehnice oferite
	Model		Phoenix M50
	Producator		Becton, Dickinson and Company
	Cod produs		443624
	Description of function and use:		
	Main function:	Set complex pentru identificarea agenților microbieni (bacterii, fungi, etc) și aprecierea sensibilității la antibiotic (<i>Microbiological automated system for fast, accurate Microbial identification (bacteria and yeast) and Antibiotic Susceptibility Testing (AST) designed for healthcare laboratories.</i>)	Set complex pentru identificarea agenților microbieni (bacterii, fungi, etc) și aprecierea sensibilității la antibiotic (<i>Microbiological automated system for fast, accurate Microbial identification (bacteria and yeast) and Antibiotic Susceptibility Testing (AST) designed for healthcare laboratories</i>) - Corespunde
II.	Main specifications		
	Type of the system:	<ul style="list-style-type: none"> - Closed system: no aerosols, splashing or laboratory accidents; - Compact, sealed ID/AST cards. 	<ul style="list-style-type: none"> - Closed system: no aerosols, splashing or laboratory accidents; - Compact, sealed ID/AST cards Corespunde
	Principal of ID method:	<ul style="list-style-type: none"> - Included. Automated. 	<ul style="list-style-type: none"> - Automated - Corespunde
	Principal of AST method:	<ul style="list-style-type: none"> - Included. Automated. - Phenotypic. - Certified by EUCAST (European Committee on Antimicrobial Susceptibility Testing) 	<ul style="list-style-type: none"> - Automated - Phenotypic. - Certified by EUCAST (European Committee on Antimicrobial Susceptibility Testing) Corespunde

	Time of the AST result:	- The final results of the antibiogram (AST) available in max 18-24 hours.	- The final results of the antibiogram (AST) available in max 8 -24 hours.
	Loading capacity, investigations:	- >30 tests per instrument.	- 50 tests per instrument.
	Patient/consumable Identification:	- Bar-codes Identification of patients and consumables.	- Bar-codes Identification of patients and consumables -Yes
	Connectivity to LIM:	- Connect easily to Laboratory Information System (LIS) and bi-directional computer interface.	- Connect easily to Laboratory Information System (LIS) and bi-directional computer interface. - Yes
	Interface:	- User interface: external computer.	- User interface: external computer -Yes
	Memory:	- Store and review QC results and data.	- Store and review QC results and data -Yes
	Print Options:	- Ability to print results and data.	- Ability to print results and data -Yes
III.	Electricity requirements		
	Supply voltage:	- 230 ± 10 V, AC, 50/60 Hz. - Voltage and plugs type adapted to meet the requirement of electrical system in Moldova.	- 230 ± 10 V, AC, 50/60 Hz. - Voltage and plugs type adapted to meet the requirement of electrical system in Moldova. Corespunde
	Power consumption:	- Power consumption 115 VAC 256 W (standby), 640 W average	- Power consumption 90 VAC (standby), 264 VAC average
IV.	Documentation		
	Manufacturer's certificate	- ISO 13485:2016 - Quality Management Systems for Medical Devices – mandatory. - CE Marking - Indicating compliance with European Union regulations and directives related to medical devices.	- ISO 13485:2016 - Quality Management Systems for Medical Devices – mandatory. - CE Marking - Indicating compliance with European Union regulations and directives related to medical devices. Corespunde
	Quality and safety standards	EU Electrical Safety Standards Compliance: - EN 60601-1: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance - IEC 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - EN 55014 - Electromagnetic compatibility.	EU Electrical Safety Standards Compliance: - EN 60601-1: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance - IEC 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control, and

			Laboratory Use EN 55014 - Electromagnetic compatibility. Corespunde
V.	Accessories:		
	Computer	- Computer to ensure data transfer from the automated system, storage, processing and printing of results.	- Computer to ensure data transfer from the automated system, storage, processing and printing of results- Yes
	Printer	- Printer for printing of results.	- Printer for printing of results -Yes
	Software	- Software for microbial identification and antibiotic susceptibility testing adjusted to international standards, with the possibility of periodic updates, and allowing automated interpretation of data with expert result expertise.	- Epicenter Software for microbial identification and antibiotic susceptibility testing adjusted to international standards, with the possibility of periodic updates, and allowing automated interpretation of data with expert result expertise - Yes
VI.	Consumables		
	ID tests Negatives Gram-bacilli (for 200 tests)	Reagents (Cards) for the automatic identification of Negatives Gram-bacilli fermentative and non-fermentative with the highest clinical importance. Compatible with the Equipment purchased.	Reagents (Cards) for the automatic identification of Negatives Gram-bacilli fermentative and non-fermentative with the highest clinical importance. Compatible with the Equipment purchased. Yes, 200 tests included in the offer
	ID tests Gram-positive cocci & bacilli (for 200 tests)	Reagents (Cards) for the automatic identification of Gram-positive cocci & bacilli with the greatest clinical importance. Compatible with the Equipment purchased.	Reagents (Cards) for the automatic identification of Gram-positive cocci & bacilli with the greatest clinical importance. Compatible with the Equipment purchased. Yes, 200 tests included in the offer
	ID tests for Gram-negative cocci, including	Reagents (Cards) for the automatic identification of Gram-negative cocci, including clinical importance of Neisseria &	Reagents (Cards) for the automatic identification of Gram-negative cocci, including clinical

	Neisseria & Hemophilus (for 100 tests)	Hemophilus with the greatest clinical importance. Compatible with the Equipment purchased.	importance of Neisseria & Hemophilus with the greatest clinical importance. Compatible with the Equipment purchased. Yes, 100 tests included in the offer
	ID tests Fungi/Yeast (for 100 tests)	Reagents (Cards) for the automatic identification of Fungi (yeast) with the greatest clinical importance. Compatible with the Equipment purchased.	Reagents (Cards) for the automatic identification of Fungi (yeast) with the greatest clinical importance. Compatible with the Equipment purchased. Yes, 100 tests included in the offer
	AST tests Staphylococci &/or Enterococci (for 100 tests)	Antibiotic susceptibility cards for Staphylococci &/or Enterococci.	Antibiotic susceptibility cards for Staphylococci &/or Enterococci. Yes, 100 tests included in the offer
	AST tests Gram negative Bacilli (for 100 tests)	Antibiotic susceptibility cards for Gram negative Bacilli.	Antibiotic susceptibility cards for Gram negative Bacilli. Yes, 100 tests included in the offer
	AST tests Streptococcus pneumoniae (for 100 tests)	Antibiotic susceptibility cards for <i>Streptococcus pneumoniae</i> .	Antibiotic susceptibility cards for <i>Streptococcus pneumoniae</i> . Yes, 100 tests included in the offer
	AST tests for Fungi/Yeast (for 60 tests)	Antibiotic susceptibility cards for Fungi/Yeast .	Antibiotic susceptibility cards for Fungi/Yeast . Yes, 60 test included in the offer (Fungi Test Ref: # 60780, Bio-Rad Manufacturer)
VII.	Operation, maintenance and installation		
	Operation and maintenance manual	<ul style="list-style-type: none"> - At least one set of operation, maintenance and service manuals for each equipment. The manuals to include instructions for: <ul style="list-style-type: none"> o setting up the equipment o routine cleaning and maintenance o planning for periodic maintenance. 	<ul style="list-style-type: none"> - At least one set of operation, maintenance and service manuals for each equipment. The manuals to include instructions for: <ul style="list-style-type: none"> o setting up the equipment o routine cleaning and maintenance - planning for periodic maintenance.

	Language of documentation	<ul style="list-style-type: none"> - Written in United Nations languages: <ul style="list-style-type: none"> o at least in English and o mandatory in Romanian. 	<ul style="list-style-type: none"> - Written in United Nations languages: <ul style="list-style-type: none"> o at least in English and - mandatory in Romanian. <p>Yes, will be provided at delivery date</p>
	Installation and maintenance	<ul style="list-style-type: none"> - The bidder must arrange for the equipment to be installed by certified or qualified personnel. Any prerequisites for installation will be communicated to the beneficiary in advance, described in detail in written form. - The bidder will provide a comprehensive maintenance plan. The cost of the maintenance plan to be defined and guaranteed over the period of warranty. - The supplier will provide an after-sale service. - The service to have competent staff, adequate infrastructure and sufficient spare parts to be able to respond to any complaints and to repair or replace within 14 days. 	<ul style="list-style-type: none"> - The bidder must arrange for the equipment to be installed by certified or qualified personnel. Any prerequisites for installation will be communicated to the beneficiary in advance, described in detail in written form. - The bidder will provide a comprehensive maintenance plan. The cost of the maintenance plan to be defined and guaranteed over the period of warranty. - The supplier will provide an after-sale service. - The service to have competent staff, adequate infrastructure and sufficient spare parts to be able to respond to any complaints and to repair or replace within 14 days. <p>Yes, all will be covered</p>
	Training	<ul style="list-style-type: none"> - The bidder will provide user training (including how to use and maintain the equipment). 	<ul style="list-style-type: none"> - The bidder will provide user training (including how to use and maintain the equipment) -Yes
	Standard maintenance tools	<ul style="list-style-type: none"> - All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication material, to be included in the offer. <ul style="list-style-type: none"> o Bidders to specify the quantity of every item included in their offer (including items not specified above). 	<ul style="list-style-type: none"> - All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication material, to be included in the offer. - Bidders to specify the quantity of every item included in their offer (including items not specified above) -Yes, all included.
	Spare parts	<ul style="list-style-type: none"> - Each assembled equipment to be accompanied by an authorized list of spare parts. 	<ul style="list-style-type: none"> - Each assembled equipment to be accompanied by an authorized list of spare parts. Yes, will be provided

	Warranty:	- At least 3 years .	3 years, Yes
	Remarks above.	<ul style="list-style-type: none"> - The equipment offered, including its power supply, to be designed and constructed to operate properly and continuously in the conditions of the Republic of Moldova. - The equipment may need to tolerate high humidity (as high as 90% at 35 °C), ambient temperatures of 5–40 °C, fungi, and spikes in the electricity supply. 	<ul style="list-style-type: none"> - The equipment offered, including its power supply, to be designed and constructed to operate properly and continuously in the conditions of the Republic of Moldova. - The equipment may need to tolerate high humidity (as high as 90% at 35 °C), ambient temperatures of 5–40 °C, fungi, and spikes in the electricity supply <p>Corespunde</p>

- **Toate bunurile vor fi testate de beneficiar. Acceptarea bunurilor și semnarea actelor de recepție va avea loc după testarea pozitivă efectuată de beneficiar.**

NUMELE FURNIZORULUI SC IMUNOTEHNOMED SRL

Locul: Chișinău

Data: 24.05.2024

Semnătura și ștampila autorizate _____