

PRODUCT CATALOGUE

**PCR EQUIPMENT
AND KITS**

DNA-Technology

BIOTECHNOLOGICAL SOLUTIONS FOR IN VITRO RESEARCH AND DIAGNOSTICS LABORATORIES

DNA-Technology realizes full production cycle from R&D to manufacture for PCR and NGS applications in scientific and clinical use.

Our goal is to apply the latest scientific findings in the field of molecular biology methods to routine laboratory practice.

We improve the diagnostic quality in order to make the treatment more effective and the prognosis of clinical outcome more precise.

We provide:

- ▶ Turn-key PCR
- ▶ PCR, NGS & LAMP kits
- ▶ Equipment & software
- ▶ Training and support

50+
COUNTRIES
IN DISTRIBUTION
NETWORK

250+
PRODUCT
RANGE

2000+
KITS
PER DAY

30+
YEARS
IN PCR

4500+
DTPRIME DEVICES
IN LABS

500+
QUALIFIED
PERSONNEL

18000+
M² FACTORY
AREA

20+
RT-PCR DEVICE
MODELS

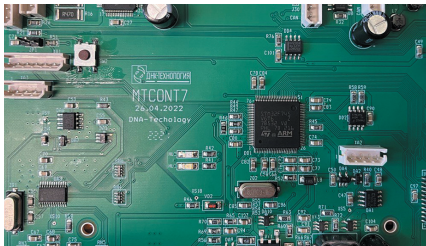
OUR ADVANTAGES



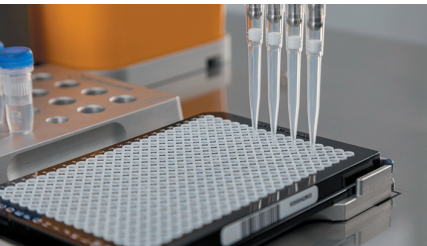
Own unique R&D solutions and scientific projects in cooperation with the leading scientific institutions



Participation in federal programs



Full technological cycle from raw material up to final product



Production from common laboratory devices up to automation solutions for PCR labs



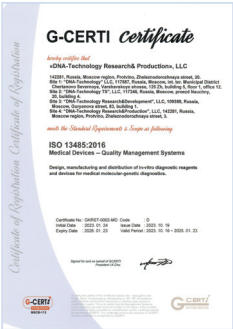
High competences of staff carry out high quality products



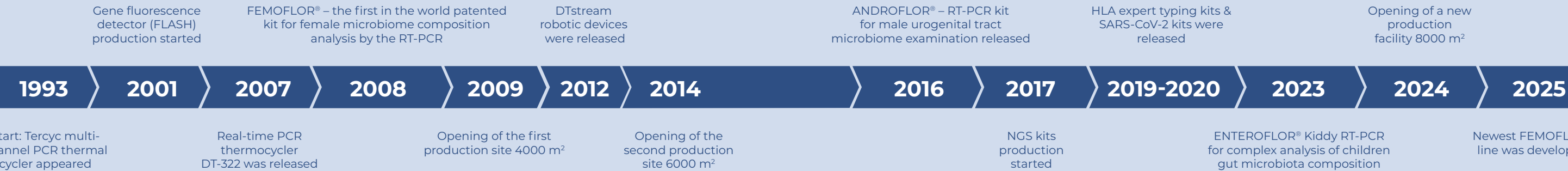
Service support from experts onsite and remotely

CERTIFICATION

- ▶ ISO 13485:2016
- ▶ ISO 9001:2015
- ▶ CE IVD
- ▶ Anvisa
- ▶ GMP class 8



OUR WAY TO SUCCESS



PCR Equipment

DTprime

DTprime Real-Time PCR instruments are available in the following modifications: 4M1, 5M1, 5M3, 5M6, 4X1, 5X1. The first digit stands for a number of detection channels, the letter M or X indicates the thermal unit capacity (M – 96, X – 384 wells), and the following digit reflects the thermal block structure (1 – single-block, 3 or 6 – number of isolated pseudo blocks).

Dimensions (LxWxH), mm	210x538x540
Weight, kg	27
Power supply	50/60 Hz, 550 W, 100-240 V
Warranty period, months	24
Built-in barcode scanner	X only
Thermal unit capacity	96 (M), 384 (X)
Mix volume range, µl	10-100 (M), 5-30 (X)
Optimal mix volume range, µl	10-50 (M), 5-25 (X)
Max/average heating rate, °C/s	3.5/3.3 (M), 2.5/2.1 (X)
Max/average cooling rate, °C/s	2.5/2.1 (M), 1.5/1 (X)
Number of detection channels	4 or 5



DTlite

DTlite is the smallest instrument in its class with a 48-well thermal unit: the optimal solution for low-flow lab. Real-Time PCR instruments are available in the following modifications: 4S1, 5S1. The first digit stands for a number of detection channels.

Dimensions (LxWxH), mm	210x480x310
Weight, kg	17
Power supply	50/60 Hz, 550 W, 100-240 V
Warranty period, months	24
Built-in barcode scanner	no
Thermal unit capacity	48
Mix volume range, µl	10-100
Optimal mix volume range, µl	10-50
Max/average heating rate, °C/s	3.5/3.3
Max/average cooling rate, °C/s	2.5/2.1
Number of detection channels	4 or 5



DTprime II

DTprime II is a new generation of the Real-Time PCR DTprime instruments with 7" touch screen, HRM, FRET assays and other efficient functions. The DTprime II instruments are available in the following modifications: 4M1, 5M1, 5M3, 5M6, 6M1, 6M3, 6M6, 4X1, 5X1, 6X1. The first digit stands for a number of detection channels, the letter M or X indicates the thermal unit capacity (M – 96, X – 384 wells), and the following digit reflects the thermal block structure (1 – single-block, 3 or 6 – number of isolated pseudo blocks).

Dimensions (LxWxH), mm	210x538x540
Weight, kg	28.4
Power supply	50/60 Hz, ≤1100 W, 100-240 V
Warranty period, months	24
Built-in barcode scanner	X only
Thermal unit capacity	96 (M), 384 (X)
Mix volume range, µl	10-100 (M), 5-30 (X)
Optimal mix volume range, µl	10-50 (M), 5-25 (X)
Max/ average heating rate, °C/s	5/4
Max/ average cooling rate, °C/s	3.6/2.5
Number of detection channels	4, 5 or 6



DTclassic

DTclassic is a classic PCR thermal cycler with advanced characteristics. Touch screen display and user-friendly interface combined with reliable performance make DTclassic perfect for molecular biology analysis in medical, research, veterinary and industrial laboratories.

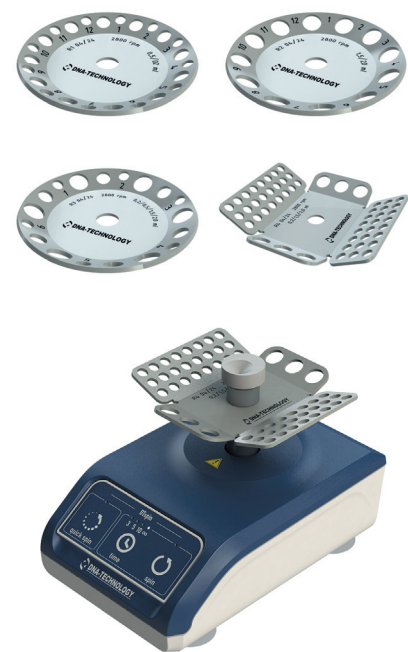
Dimensions (LxWxH), mm	251x451x276
Weight, kg	15
Power supply	50/60 Hz, 100-650 W, 230 V
Warranty period, months	24 months
Thermal unit capacity	96
Mix volume range, µl	10-100
Max/average heating rate, °C/s	3.5/3
Max/average cooling rate, °C/s	3.3/3
Thermal gradient	Vertical, horizontal
Programs in the device memory	1000 files + USB Flash
Touch screen display	7"



DTspin

The efficient, compact and versatile DTspin combines a microcentrifuge and vortexer with an autostop function.

Dimensions (LxWxH), mm	121x179x117
Weight, kg	0.88
Autostop function	yes
Timer, s	3, 5, 10
Tube type	single conical Eppendorf 0.2, 0.5, 1.5, 2 ml & stripped 0.2 ml tubes
Max. speed, rpm	2820
Max. RCF	645 x g
Direction of rotation	Clockwise
Motor and drive	Low-noise drive with roller bearing
Braking time, s	≤2
Number of rotors in the package	4
Maximum power consumption, W	55
Power supply	220-240 V, MAX 50 W, 50/60 Hz



DTtherm programmable thermostat

The programmable solid-state thermostat DTtherm is designed for clinical diagnostic and research laboratories. The thermostat maintains temperature with high accuracy complying to one of the nine preset programs and can fit 1.5 and 0.5 ml Eppendorf-like tubes.

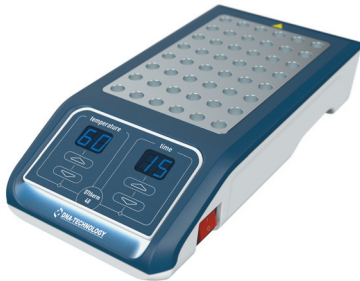
Dimensions (LxWxH), mm	221x188x128
Weight, kg	2.2
Capacity	40x 1.5 ml, 28x 0.5 ml
Temperature range	from ambient temp up to 99 °C
Timer	1 sec – 99 h
Sound signal	yes
Cover lid	yes
Tube type	conical Eppendorf
Number of programs	9
Temperature step	1 °C
Heating rate, °C/min	8
Cooling rate from 90 to 55 °C, min	10
Accuracy (range from 65 to 99 °C)	±0.5 °C
Temperature uniformity	±0.5 °C



DTtherm 48 dry bath

DTtherm 48 is modern and functional instrument is designed for uniform heating and incubation of test samples in tubes for a specified time as an aid in clinical laboratory in vitro diagnostics. The compact size of the instrument allows it to be placed anywhere in the laboratory or in a cabinet alongside other equipment.

Dimensions (LxWxH), mm	292x146x71
Weight, kg	2,52
Capacity	48x 1.5 ml
Power supply	50/60 Hz, 290 W, 230±10 %V
Tube type	conical 1.5 ml Eppendorf
Temperature range, °C	from ambient up to 99±1
Temperature uniformity, °C	±0,5
Heating rate, °C/min	8
Microprocessor control	yes
Sound signal	yes
Timer, min	1-99



Thermit thermostat

Thermit is a solid-state thermostat which is designated for scientific and clinical diagnostic laboratories. The thermostat is designed for 1.5 ml and 0.5 ml Eppendorf tubes. Thermit is the optimal choice in cases where there is no need to change frequently the incubation temperature.

Dimensions (LxWxH), mm	260x130x80
Weight, kg	2
Capacity	40x 1.5 ml, 28x 0.5 ml
Tube type	conical Eppendorf
Temperature range	from ambient temp up to 99 °C
Timer, min	1-99
Temperature step	1 °C
Heating rate, °C/min	8
Temperature uniformity, °C	±0.5
Accuracy, °C	±1



DTmag 16S magnetic rack

The DTmag 16S magnetic rack provides highly efficient sedimentation of magnetic beads at every step of nucleic acid purification: during lysis, concentration and purification of the nucleic acid solution.

Dimensions (LxWxH), mm	179x52x51
Weight, kg	0.4
Tube type	conical 1.5 ml Eppendorf
Capacity	16x 1.5 ml
Numbered wells	yes
Number of magnets	16
MAX tube diameter, mm	11
Rack material	ABS



DTmag 16 magnetic homogenizer

The DTmag 16 presents a new-patented technology for biomaterial homogenization via rotation of a magnetic rod. Advantages of the DTmag 16 homogenizer is high nucleic acid yield and autonomous performance option due to the built-in battery.

Dimensions (LxWxH), mm	90x220x100
Weight, kg	0.74
Tube type	conical 1.5 ml Eppendorf
Capacity	16x 1.5 ml
Numbered wells	yes
Magnetic forceps in the package	yes
Optimal contents volume, µl	500
Rod speed control	yes
Rod speed modulation	yes



Elf power supply

The power supplies Elf-4 and Elf-8 are designed for electrophoresis of nucleic acids and proteins in agarose and polyacrylamide gels. The power supplies operate in the voltage stabilization modes, current stabilization or power stabilization, equipped with a timer that allows to set the shutdown time.

Dimensions (LxWxH), mm	180x120x60
Weight, kg	0,84
Output voltage, V	5-400 (4), 10-800 (8)
Output current, mA	5-400 (4), 3-200 (8)
Output power, W	0,5-80
Programming	manual
Timer	from 1 min to 16 h
Timer step, min	1
Auto-diagnostics of the device status	yes
Automatic shut-off after load circuit fault	yes



DTcleaner device

Well contamination during PCR can lead to unreliable results due to elevated background fluorescence. The DTcleaner is an easy-to-use device that effectively removes parasitic reflected optical signals, helping you obtain accurate and trustworthy PCR data.

Power supply	110-240 V, 50-60 Hz
Weight, kg	0,15
Protection degree	IP20
Continuous operation time, min	20-25
Number of swabs in the package, pcs	25



PCR cabinet

PCR cabinet is applicable for isolation of devices and reagents from the external environment in clinical and scientific laboratories. The cabinet case is made of plated stainless steel and glass, which excludes rusting when surfaces are treated with aggressive detergents.

Dimensions (LxWxH), mm	1205x705x665
Weight (without table), kg	85
Max front panel lift, mm	370
Built-in sockets, units	3
Work surface material	stainless steel
Work chamber lighting	yes
Built-in UV-lamp	yes
UV-lamp durability, hrs	9000
Power supply	50/60 Hz, 30 W, 220 V



DTpack microplate heat sealer

The DTpack microplate sealing device works with various types of microplates and films. Flexible settings and a compact design make DTpack useful and essential during PCR assays using PCR microplates.

Dimensions (LxWxH), mm	190x260x320
Weight, kg	6
Compatible plate formats	48, 96, 384 wells
Power supply	50/60 Hz, 50 (MAX 800) W, 198-253 V
Working surface temperature, °C	100-200
Working surface dimensions (LxW), mm	120x78
Reaching time t 200 °C, min	<6
Operating time, s	0.1-9.9
Clamping force range, N	10-150



DTstream L

DTstream L stations efficiently extract nucleic acids from various types of biomaterial on paramagnetic particles.

Dimensions (WxHxH), mm	715/855/990x650x650
Stand dimensions (WxHxH), mm	930/1100/1160x900x766
Weight (without stand), kg	55/60/70
Max number of plates on the work surface	9/12/15
Pipetting arm	4 airlock channels
Volume of liquids, µl	30-1000
MIN Time of the run, minutes	20
Stand-alone operation without control PC	yes
Preinstalled scripts	yes
LIS integration	yes
Removable adapters	yes



DTstream M

DTstream M stations are designed for assembling the reaction mixture (PCR set-up) in 96- and 384-well formats. The device with 4-channel arm is suitable for fast dosing of large sample flow, the stations with 1-channel arm are designed for medium flow with the possibility of random dosing.

Dimensions (WxHxH), mm	715/855/990x650x650
Stand dimensions (WxHxH), mm	930/1100/1160x900x766
Weight (without stand), kg	55/60/70
Max number of plates on the work surface	9/12/15
Number of dosing channels	4 (M4), 1 (M1)
Target format	384 (M4), 384/ 96 (M1)
Volume of liquids, µl	5-200
MIN Time of the run, minutes	15
Stand-alone operation without control PC	yes
Preinstalled scripts	yes
LIS integration	yes
Removable adapters	yes



PCR AND LAMP KITS

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
SEXUALLY TRANSMITTED DISEASES	Chlamydia trachomatis	<i>Chlamydia trachomatis</i>	Urine, prostate fluid, ejaculate, scrapes of epithelial cells (from urogenital tract, oropharynx, rectum, conjunctiva of the eye)	DT, CFX96, Rotor-Gene Q, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P101-23/9ER R1-P101-S3/9ER R1-P101-UA/9ER
	Ureaplasma complex	<i>Ureaplasma urealyticum/ Ureaplasma parvum without differentiation</i>	Epithelial cell scrapes from the urogenital tract, urine, prostate fluid, ejaculate	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P104-23/9EU R1-P104-S3/9EU
	Ureaplasma urealyticum	<i>Ureaplasma urealyticum</i>	Epithelial cell swabs from the urethra, cervix or posterolateral vaginal wall, urine, prostate fluid, ejaculate	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P106-23/9EU R1-P106-S3/9EU
	Ureaplasma parvum	<i>Ureaplasma parvum</i>	Epithelial cell swabs from the urethra, cervix or posterolateral vaginal wall, urine, prostate fluid, ejaculate	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P105-23/9EU R1-P105-S3/9EU
	Trichomonas vaginalis	<i>Trichomonas vaginalis</i>	Epithelial cell swabs from the genitourinary tract, urine, prostate fluid, ejaculate	DT, iQ, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P107-23/9EU R1-P107-S3/9EU
	Neisseria gonorrhoeae	<i>Neisseria gonorrhoeae</i>	Epithelial cell swabs from the genitourinary tract, urine, prostate fluid, ejaculate	DT, iQ, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P109-23/9EU R1-P109-S3/9EU
	Mycoplasma hominis	<i>Mycoplasma hominis</i>	Epithelial cell swabs from the genitourinary tract, urine, prostate fluid, ejaculate	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P102-23/9EU R1-P102-S3/9EU
	Mycoplasma genitalium	<i>Mycoplasma genitalium</i>	Epithelial cell swabs from the genitourinary tract, urine, prostate fluid, ejaculate	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P103-23/9EU R1-P103-S3/9EU
	Gardnerella vaginalis	<i>Gardnerella vaginalis</i>	Epithelial cell swabs from the genitourinary tract, urine, prostate fluid, ejaculate	DT, iQ, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P108-23/9EU R1-P108-S3/9EU
	T.vaginalis/ N.gonorrhoeae Multiplex	<i>Trichomonas vaginalis Neisseria gonorrhoeae</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P114-23/9EU R1-P114-S3/9EU R1-P114-UA/9EU
	C.trachomatis/ N.gonorrhoeae Multiplex	<i>Chlamydia trachomatis Neisseria gonorrhoeae</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P115-23/9EU R1-P115-S3/9EU R1-P115-UA/9EU
	C.trachomatis/ T.vaginalis Multiplex	<i>Chlamydia trachomatis Trichomonas vaginalis</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P116-23/9EU R1-P116-S3/9EU R1-P116-UA/9EU
	M.hominis/ M.genitalium Multiplex	<i>Mycoplasma hominis Mycoplasma genitalium</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, QuantStudio 5	RUO	+2...+8	96	Tubes Strips Universa	R1-P119-23/9EU R1-P119-S3/9EU R1-P119-UA/9EU
	T.vaginalis/ M.genitalium Multiplex	<i>Trichomonas vaginalis Mycoplasma genitalium</i>	Scrapes of epithelial cells from the urogenital tract	DT, CFX96	RU/IVD	+2...+8	96	Tubes Strips Universa	R1-P126-23/9EU R1-P126-S3/9EU R1-P126-UA/9EU
	UMC Multiplex	<i>Ureaplasma urealyticum/ Ureaplasma parvum Mycoplasma genitalium Chlamydia trachomatis</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT	RU/IVD	+2...+8	96	Tubes Strips	R1-P113-23/9EU R1-P113-S3/9EU
	TNC Multiplex	<i>Trichomonas vaginalis Neisseria gonorrhoeae Chlamydia trachomatis</i>	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P111-23/9ER R1-P111-S3/9ER R1-P111-UA/9ER
	NTCM Multiplex	<i>Neisseria gonorrhoeae Trichomonas vaginalis Chlamydia trachomatis Mycoplasma genitalium</i>	Epithelial cell swabs from the urogenital tract, urine, prostate fluid, ejaculate	DT, CFX96 (5 detection channels)	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P122-23/9ER R1-P122-S3/9ER R1-P122-UA/9ER
CAUSATIVE AGENTS OF MYCOSES	MycosoResista Trichophyton	<i>Trichophyton spp., T. mentagrophytes var. indotineae and determination of genetic resistance to antifungal drugs (6 mutations)</i>	Skin and its appendages (hair and nails)	DT, CFX96	RU/IVD	+2...+8	48	Strips	R1-P038-S3/4ER
	Trichophyton spp./ Microsporum spp. Multiplex	<i>Trichophyton spp. Microsporum spp.</i>	Skin and its appendages (hair and nails)	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P037-23/9ER R1-P037-S3/9ER R1-P037-UA/9ER

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
CAUSATIVE AGENTS OF MYCOSES	MycosoScreen Detection and typing of pathogens causing mycoses	14 indicators	Blood, sputum, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates, catheter and endotracheal tube washings, and fungal cultures	DT	RU/IVD	+2...+8	24	Strips	R1-P023-S3/5EU
	Candida albicans	Candida albicans	Epithelial cell swabs (from the genitourinary tract, oropharynx, rectum, conjunctiva of the eye), urine, prostate fluid, ejaculate	DT, iQ, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P110-23/9EU R1-P110-S3/9EU R1-P110-UA/9INT
HERPES VIRUS INFECTIONS	Herpes simplex virus 1, 2	HSV 1/HSV 2	Epithelial cell swabs (from the genitourinary tract, oropharynx, rectum, conjunctiva of the eye, skin), prostate fluid, ejaculate, urine, blood, liquor	DT, iQ, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P201-23/9EU R1-P201-S3/9EU
	HSV1/HSV2 Multiplex	HSV 1, HSV 2	Urine, prostate fluid, ejaculate, epithelial scrapes from urogenital tract, rectal scrapes, epithelial scrapes from oropharynx	DT, CFX96, Rotor-Gene Q, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P213-23/9ER R1-P213-S3/9ER R1-P213-UA/9ER
	HSV1/HSV2/CMV Multiplex	HSV 1 HSV 2 CMV	Urine, scrapes of epithelial cells from the urogenital tract	DT, CFX96, Rotor-Gene Q, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P211-23/9EU R1-P211-S3/9EU R1-P211-UA/9EU
	EBV	Epstein Barr virus	Blood, synovial fluid, cerebrospinal fluid, amniotic fluid, biopsy material or punctate from lesions of organs and tissues, scrapes from the oropharynx, saliva	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P205-23/9EU R1-P205-S3/9EU
	CMV	Cytomegalovirus	Saliva, urine, prostate fluid, ejaculate, swabs from urethra and conjunctiva of the eye, cervix or posterolateral vaginal wall, breast milk, peripheral blood mononuclear cells, liquor, amniotic fluid, tissue samples	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P204-23/9ER R1-P204-S3/9ER R1-P204-UA/9ER
	HHV6	Human herpesvirus 6	Blood, liquor, bioptate or punctate from foci of organ and tissue lesions, oropharyngeal swabs, saliva	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P202-23/9EU R1-P202-S3/9EU
	HHV8	Human herpesvirus 8	Blood, bioptate or punctate from foci of organ and tissue lesions	DT, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips	R1-P203-23/9EU R1-P203-S3/9EU
	VZV	Varicella zoster virus	Blood, vesicular fluid, epithelial cell swabs from erosive and ulcerative elements, cerebrospinal fluid, conjunctival discharge	DT, Rotor-Gene Q	RU/IVD	+2...+8	48	Tubes Strips	R1-P206-23/4EU R1-P206-S3/4EU
HUMAN PAPILLOMA VIRUS	HPV 6/11 Multiplex	HPV 6 HPV 11	Epithelial cell scrapes from urethra, cervical canal, uterine neck	DT	RUO	+2...+8	96	Tubes Strips	R1-P321-23/9EU R1-P321-S3/9EU
	HPV 16/18 Multiplex	HPV 16 HPV 18	Epithelial cell scrapes from urethra, cervix, uterine neck	DT	RU/IVD	+2...+8	96	Tubes Strips	R1-P320-23/9EU R1-P320-S3/9EU
	HPV SCREEN HR14 (16-18-45)	HPV 16 HPV 18 HPV 45 HPV 31/33/35/39/51/52/56/58/59/66/68	Epithelial swabs/scrapes from the mucous membrane of the cervical canal and the vagina	DT (5 detection channels)	RU/IVD	+2...+8	96	Tubes Strips	R1-P325-23/9EU R1-P325-S3/9EU
	HPV QUANT-4®	HPV 6 HPV 11 HPV 16 HPV 18	Epithelial cell swabs, prostate fluid, ejaculate, urine, biopsy material	DT	RU/IVD	+2...+8	48	Strips	R1-P315-S3/4EU
	HPV-QUANT-15®	HPV 6/11 HPV 16/31/33/35/52/58 HPV 18/39/45/59 HPV 56, HPV 51, HPV 68	Epithelial cell swabs, prostate fluid, ejaculate, urine, biopsy material	DT	RU/IVD	+2...+8	48	Strips	R1-P316-S3/4EU
	HPV-QUANT-21® Specific identification and quantification of low-risk and high-risk HPV	HPV: 6, 11, 16, 18, 26, 31, 33, 35, 39, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82 with differentiation	Epithelial cell swabs, prostate fluid, ejaculate, urine, biopsy material	DT	RU/IVD	+2...+8	24	Strips	R1-P317-S3/5EU

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
INTESTINAL INFECTIONS	Shigella/EIEC and Salmonella spp	<i>Shigella</i> spp./enteroinvasive <i>E.coli</i> (EIEC) <i>Salmonella</i> spp.	Feces, bacterial cultures obtained from feces	DT, CFX96	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P503-23/9EU R1-P503-S3/9EU R1-P503-UA/9EU
	BacScreen AEI 1	<i>Campylobacter coli/jejuni</i> <i>Shigella</i> spp./ <i>E.coli</i> (EIEC) <i>Salmonella</i> spp.	Feces, bacterial cultures obtained from feces	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P502-23/9EU R1-P502-S3/9EU R1-P502-UA/9EU
	BacScreen AEI 2	<i>Campylobacter coli/jejuni</i> <i>Shigella</i> spp./ <i>E.coli</i> (EIEC) <i>Salmonella</i> spp. <i>Yersinia enterocolitica</i>	Feces, bacterial cultures obtained from feces	DT, CFX96 (5 detection channels)	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P507-23/9ER R1-P507-S3/9ER R1-P507-UA/9ER
RESPIRATORY INFECTIONS	Coxiella burnetii	<i>Coxiella burnetii</i>	Nasopharyngeal, oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum, pleural fluid, cerebrospinal fluid, blood, biopsy material, autopsy material	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P013-23/4ER R1-P013-S3/4ER R1-P013-UA/9ER
	C. diphtheriae Tox Multiplex	<i>C. diphtheriae</i> (tox+) <i>C. diphtheriae</i>	Swabs/scrapes from nasopharyngeal, oropharyngeal mucous membrane, swabs from affected skin areas, bacterial cultures from this biomaterial	DT	RU/IVD	+2...+8	48	Tubes Strips	R1-P445-23/4EU R1-P445-S3/4EU
	Influenza A virus (one-step)	<i>Influenza A virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT, CFX96, QuantStudio 5, Rotor-Gene	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P452-23/9EU R3-P452-S3/9EU
	Influenza B virus (one-step)	<i>Influenza B virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT, CFX96, QuantStudio 5, Rotor-Gene	RU/IVD	+2...+8 -18...-22	96	Tubes Strips Universal	R3-P453-23/9EU R3-P453-S3/9EU R3-P453-UA/9EU
	Influenza A/B virus (one-step)	<i>Influenza A virus</i> <i>Influenza B virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT, Rotor-Gene (4 detection channels)	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P449-23/9EU R3-P449-S3/9EU
	Influenza A virus H1N1pdm09	<i>Influenza A(H1N1)pdm09 virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, phlegm	DT, CFX96, QuantStudio 5, Rotor-Gene	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P454-23/9EU R3-P454-S3/9EU
	Influenza A virus (subtype H5N1) (RT reagents included)	<i>Influenza A virus (subtype H5N1)</i>	Nasal and guttur smears, lavage	DT, iCycler iQ	RUO	+2...+8 -18...-22	48	Tubes Strips	R3-P407-23/4EU R3-P407-S3/4EU
	Influenza A virus H1N1pdm09/ H3N2 Multiplex	<i>Influenza A(H1N1)pdm09 virus</i> <i>Influenza A(H3N2) virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, phlegm	DT, CFX96	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P433-23/9EU R3-P433-S3/9EU
	AVRI Panel Multiplex Differential diagnosis of AVRI, including influenza virus and SARS-CoV-2	16 indicators	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT	RU/IVD	+2...+8 -18...-22	24	Strips	R3-P439-S3/5ER
	SARS-CoV-2/SARS-CoV Multiplex	<i>SARS-CoV-like Coronaviruses</i> <i>SARS-CoV-2 coronavirus (E-gene)</i> <i>SARS-CoV-2 coronavirus (N-gene)</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT, CFX96, Rotor-Gene (4 detection channels)	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P436-23/9ER R3-P436-S3/9ER
	SARS-CoV-2/ Influenza Multiplex	<i>Influenza A virus</i> <i>Influenza B virus</i> <i>SARS-CoV-2 coronavirus (E, N-genes)</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT, Rotor-Gene (4 detection channels)	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P440-23/9ER R3-P440-S3/9ER
	SARS-CoV-2 Lite	<i>SARS-CoV-2 (E gene, RdRp gene)</i>	Nasopharyngeal and oropharyngeal swabs	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	96	Strips	R3-P446-S3/9EU
	SARS-CoV-2/RSV/Influenza AB virus Multiplex	<i>SARS-CoV-2 coronavirus (E, N-genes)</i> <i>RSV</i> <i>Influenza A virus/Influenza B virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT	RU/IVD	+2...+8 -18...-22	96	Tubes Strips Universal	R3-P448-23/9EU R3-P448-S3/9EU
	SARS-CoV-2/RSV/ Influenza A virus/ Influenza B virus Multiplex	<i>SARS-CoV-2 coronavirus (E, N-genes)</i> <i>RSV</i> <i>Influenza A virus</i> <i>Influenza B virus</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal, nasopharyngeal aspirate, sputum	DT	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P457-23/9EU R3-P457-S3/9EU

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
RESPIRATORY INFECTIONS	C. pneumoniae/ M. pneumoniae Multiplex	<i>Chlamydomphila pneumoniae</i> <i>Mycoplasma pneumoniae</i>	Sputum, blood, pleural fluid, aspirates, bronchopulmonary lavage, biopsy samples, swabs and washings from nasal cavity and nasopharyngeal cavity	DT, CFX96	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P430-23/4EU R1-P430-S3/4EU R1-P430-UA/9EU
	Legionella pneumophila	<i>Legionella pneumophila</i>	Sputum and bronchoalveolar lavage	DT	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P403-23/4EU R1-P403-S3/4EU R1-P403-UA/9INT
	Streptococcus pneumoniae	<i>Streptococcus pneumoniae</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal and nasopharyngeal aspirate, sputum, pleural fluid	DT, CFX96, Rotor-Gene Q, QuantStudio 5	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P412-23/4ER R1-P412-S3/4ER R1-P412-UA/9ER
	Streptococcus pyogenes	<i>Streptococcus pyogenes</i>	Swabs from urethra, cervix, posterolateral vaginal wall, lesions and mucosa of the amygdales, posterior pharyngeal wall	DT, iCycler iQ	RUO	+2...+8	48	Tubes Strips	R1-P402-23/4EU R1-P402-S3/4EU
	M. tuberculosis – M. bovis complex	<i>Mycobacterium tuberculosis/bovis</i>	Cerebrospinal fluid, biopsy material or punctate from lesions of organs and tissues, bronchoalveolar lavage, sputum, urine, ejaculate	DT	RU/IVD	+2...+8	48	Tubes Strips	R1-P458-23/4INT R1-P458-S3/4INT
	Bordetella holmesii	<i>Bordetella holmesii</i>	Swabs from nasopharyngeal and oropharyngeal mucous membranes, bacterial cultures	DT, CFX96	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P041-23/4ER R1-P041-S3/4ER R1-P041-UA/9ER
	Bordetella Screen	<i>Bordetella pertussis</i> <i>Bordetella parapertussis</i> <i>Bordetella bronchiseptica</i> <i>Bordetella holmesii</i>	Swabs from nasopharyngeal and oropharyngeal mucous membranes, bacterial cultures	DT, CFX96 (5 detection channels)	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P039-23/4ER R1-P039-S3/4ER R1-P039-UA/9ER
	BacScreen Pneumo 1 Detection of bacteria causing respiratory nosocomial and community-acquired infections, including atypical pathogens	11 indicators	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal and nasopharyngeal aspirate, sputum, pleural fluid	DT, CFX96	RU/IVD	+2...+8	24	Strips	R1-P032-S3/5ER
	BacScreen Pneumo 2 Detection of major bacteria causing respiratory nosocomial and community-acquired infections	<i>Streptococcus pneumoniae</i> <i>Chlamydomphila pneumoniae</i> <i>Mycoplasma pneumoniae</i> <i>Haemophilus influenzae</i>	Nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, endotracheal and nasopharyngeal aspirate, phlegm, pleural fluid	DT, CFX96 (5 detection channels)	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P459-23/9ER R1-P459-S3/9ER R1-P459-UA/9ER
OTHER INFECTIONS	Streptococcus agalactiae	<i>Streptococcus agalactiae</i>	Blood, sputum, urine, scrapes from respiratory tract, urogenital and gastrointestinal tracts, faeces or meconium, bioptates, cerebrospinal fluid, washings from catheters and endotracheal tubes and bacterial cultures	DT, Rotor-Gene Q	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P012-23/4EU R1-P012-S3/4EU R1-P012-UA/9EU
	Helicobacter pylori	<i>Helicobacter pylori</i>	Bioptates, faeces	DT, iCycler iQ, Rotor-Gene	RU/IVD	+2...+8	96	Tubes Strips	R1-P501-23/9EU R1-P501-S3/9EU
	Toxoplasma gondii	<i>Toxoplasma gondii</i>	Blood, cerebrospinal fluid, amniotic fluid, biopsy specimens or punctate from lesions of organs and tissues	DT, CFX96, QuantStudio 5, Rotor-Gene Q	RU/IVD	+2...+8	96	Tubes Strips Universal	R1-P031-23/9EU R1-P031-S3/9EU R1-P031-UA/9EU
	Human Parvovirus B19	<i>Human Parvovirus B19</i>	Blood plasma, saliva, biopsy samples from heart valves, amniotic fluid, autopsy samples	DT, iCycler iQ	RUO	+2...+8	48	Tubes Strips	R1-P011-23/4INT R1-P011-S3/4INT
	Listeria monocytogenes	<i>Listeria monocytogenes</i>	Blood, scrapes from mucous membranes, cerebrospinal fluid, amniotic fluid, biopsy specimens or punctate from lesions of organs and tissues, feces or meconium	DT, CFX96, QuantStudio 5, Rotor-Gene Q	RU/IVD	+2...+8	48 48 96	Tubes Strips Universal	R1-P003-23/4EU R1-P003-S3/4EU R1-P003-UA/9EU

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
HEPATITIS VIRUSES AND HIV	Hepatitis B virus qualitative NEW	<i>Hepatitis B virus</i>	Blood plasma, blood serum	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R1-P615-23/9ER R1-P615-S3/9ER
	Hepatitis B virus quantitative NEW	<i>Hepatitis B virus</i>	Blood plasma, blood serum	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	Q1-P614-23/9ER Q1-P614-S3/9ER
	Hepatitis C virus qualitative (one-step)	<i>Hepatitis C virus</i>	Blood plasma, blood serum	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P613-23/9ER R3-P613-S3/9ER
	Hepatitis C virus quantitative (one-step)	<i>Hepatitis C virus</i>	Blood plasma, blood serum	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	Q3-P612-23/9ER Q3-P612-S3/9ER
	Hepatitis C virus genotyping (RT reagents included)	<i>Hepatitis 1a, 1b, 2, 3a/3b</i>	Blood plasma	DT, iCycler iQ	RU/IVD	+2...+8 -18...-22	48	Tubes Strips	R4-P604-23/4EU R4-P604-S3/4EU
	Human immunodeficiency virus qualitative (RT reagents included)	<i>HIV-1</i>	Blood plasma	DT, iCycler iQ, Rotor-Gene	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	R3-P609-23/9EU R3-P609-S3/9EU
	Human immunodeficiency virus quantitative (RT reagents included)	<i>HIV-1</i>	Blood plasma	DT, iCycler iQ, Rotor-Gene	RU/IVD	+2...+8 -18...-22	96	Tubes Strips	Q4-P609-23/9EU Q4-P609-S3/9EU
MICROBIOME COMPOSITION ANALYSIS	FEMOFLO ^R II Detailed assessment of microbiome composition of female urogenital tract, including STI and HPV screening	<i>40 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial swabs from mucous membrane of vagina and cervical canal	DT (5 detection channels)	RU/IVD	+2...+8	12	Strips	R1-P811-S3/6ER
	FEMOFLO ^R AlphaScreen Assessment of microbiome composition with detailed analysis of anaerobes for diagnostics of bacterial vaginosis	<i>18 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial swabs from mucous membrane of vagina and cervical canal	DT (5 detection channels)	RU/IVD	+2...+8	24	Strips	R1-P818-S3/5ER
	FEMOFLO ^R DeltaScreen Complex microbiome assessment for diagnostics of infectious and inflammatory urogenital diseases	<i>24 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial swabs from mucous membrane of vagina and cervical canal	DT (5 detection channels)	RU/IVD	+2...+8	24	Strips	R1-P816-S3/5ER
	Femoflor [®] 16 Assessment of microbiome composition of female urogenital tract	<i>18 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial scrapes from cervix, posterolateral vaginal vault and urethra	DT	CE/IVD	+2...+8	12	Strips	R1-P801-S3/6EU
	Femoflor [®] Screen Assessment of the main indicators of microbiota and STIs of female urogenital tract	<i>14 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial scrapes from cervix, posterolateral vaginal vault and urethra	DT	RU/IVD	+2...+8	24	Strips	R1-P804-S3/5ER
	ENTEROFLO ^R Kiddy Assessment of gut microbiota composition of 0-14 years old children	<i>44 indicators, including: Total bacterial load Human genomic DNA</i>	Faeces, meconium	DT	RU/IVD	+2...+8	12	Strips	R1-P815-S3/6EU
	Androflor [®] Assessment of microbiome structure of male urogenital tract	<i>25 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial scrapes from the balanus and urethra, urine, prostate fluid, ejaculate, biopsy samples from prostatic tissues	DT	RU/IVD	+2...+8	12	Strips	R1-P809-S3/6ER
	Androflor [®] Screen Assessment of the main indicators of microbiota and STIs of male urogenital tract	<i>16 indicators, including: Total bacterial load Human genomic DNA</i>	Epithelial scrapes from the balanus and urethra, urine, prostate fluid, ejaculate, biopsy samples from prostatic tissues	DT	RU/IVD	+2...+8	24	Strips	R1-P810-S3/5ER
	ParodontoScreen Detection of opportunistic microorganisms inhabiting human oral cavity	<i>6 indicators, including: Total Bacterial Genome Count Sample Intake Control</i>	Crevicular fluids, dental plaque	DT	RUO	+2...+8	24	Strips	R1-P808-S3/5EU

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
DETECTION OF ANTIBIOTIC RESISTANCE GENES	BacResista GLA Detection of the genes responsible for resistance to Glycopeptide and Beta-lactam antibiotics in bacteria	15 indicators, including: Total bacterial load	Sputum, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, faeces, aspirates, exudates and bacterial cultures	DT	RU/IVD	+2...+8	24	Strips	R1-P026-S3/5EU
	BacResista GLA Van/Mec	van A\B mec A	Sputum, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, faeces, aspirates, exudates and bacterial cultures	DT	RU/IVD	+2...+8	48	Tubes Strips	R1-P027-23/4EU R1-P027-S3/4EU
	MRS/MRSA Multiplex	Staphylococcus spp. Staphylococcus aureus mec A gene	Urina, sputum, breast milk, cerebrospinal fluid, epithelial cell swabs from urethra, cervix, posterior vaginal vault, oropharyngeal and nasal swabs and washings, tracheae aspirate, faeces, swipes and washings from wound surface	DT	RUO	+2...+8	48	Tubes Strips	R1-P022-23/4EU R1-P022-S3/4EU
NOSOCOMIAL AND COMMUNITY-ACQUIRED INFECTIONS	BacScreen OM Detection of opportunistic bacteria causing nosocomial and community-acquired infections	27 indicators, including: Total bacterial load Sample Intake Control	Sputum, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, faeces, aspirates, exudates and bacterial cultures	DT	RU/IVD	+2...+8	12	Strips	R1-P028-S3/6EU
HLA TYPING	HLA-DRB1	13 alleles and groups of alleles of DRB1 gene	Peripheral blood	DT	RU/IVD	+2...+8	24	Strips	R1-H001-S3/5EU
	HLA-DQB1	12 alleles and groups of alleles of DQB1 gene	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	24	Not pre-aliquoted	R1-H003-N3/5EU
	HLA-DQA1	8 alleles and groups of alleles of DQA1 gene	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	24	Not pre-aliquoted	R1-H002-N3/5EU
	HLA-B27	HLA-B27	Peripheral blood	DT	RU/IVD	+2...+8	48	Strips	R1-H004-S3/4EU
GENETICS Diagnosis of hereditary diseases	Hypertension Susceptibility	ADD1: 1378 G>T, AGT: 704 T>C, AGT: 521 C>T, AGTR1: 1166 A>C, AGTR2: 1675 G>A, CYP11B2: -344 C>T, GNB3: 825 C>T, NOS3: -786 T>C, NOS3: 894 G>T	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H902-N3/4EU
	Hemostasis	F2: 20210 G>A, F5: 1691 G>A, F7: 10976 G>A, F13: G>T, FGB: -455 G>A, ITGA2: 807 C>T, ITGB3: 1565 T>C, SERPINE1 (PAI-1): -675 5G>4G	Whole peripheral blood, dry blood spots, buccal epithelium	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H957-N3/4EU
	Hemostasis F2,F5 mutations	F2: 20210 G>A, F5: 1691 G>A	Whole peripheral blood, dry blood spots, buccal epithelium	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H958-N3/4EU R1-H959-N3/4EU
	Folate Metabolism	MTHFR: 677 C>T, MTHFR: 1298 A>C, MTR: 2756 A>G, MTRR: 66 A>G	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H908-N3/4EU
	Hemochromatosis	HFE: 187 C>G, HFE: 193 A>T, HFE: 845 G>A	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H939-N3/4EU
	Cystic Fibrosis	CFTR: F508del, CFTR: E92K, CFTR: W1282X, CFTR: N1303K, CFTR: 2143delT, CFTR: 1677delTA, CFTR: 3849+10kbC>T, CFTR: dele2,3	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H943-N3/4EU
	Cystic Fibrosis rare CFTR mutations	CFTR: L138ins, CFTR: G542X, CFTR: R117H, CFTR: 604insA, CFTR: 621+1G>T, CFTR: S1196X, CFTR: 3821delT, CFTR: 3667insTCAA, CFTR: R334W, CFTR: 394delTT, CFTR: R553X, CFTR: K598ins, CFTR: 2184insA, CFTR: 2183AA>G, CFTR: 2789+5G>A, CFTR: 3944delGT	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H948-N3/4EU
	Osteoporosis	COL1A1: -1997 C>A, COL1A1: 1546 (6252) G>T, CYP19A1: A>G (rs2414096), CYP19A1: C>T (rs936306), ESR1: -397 T>C, ESR1: -351 G>A, IL6: -174 G>C, LRP5: 1999 G>A, LRP5: 3989 C>T, RANKL: C>T (rs9594738), RANKL: C>T (rs9594759), TNFRSF11B (OPG): 245 A>C, TNFRSF11B (OPG): A>G (rs4355801), TNFRSF11B (OPG): 163 (160) T>C, VDR: 283 A>G (BsmI), VDR: 2 A>G (FokI)	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H944-N3/4EU

	 Kit	 Analyte (except IC)	 Biomaterial	 Equipment	 Certification	 Storage	 Number of tests	 Format	 Ref. No
GENETICS Diagnosis of hereditary diseases	Phenylketonuria Screen	PAH: R261Q, PAH: R408W, PAH: IVS10nt546, PAH: IVS12+1G>A	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H950-N3/4EU
	AZF Microdeletions	sY134, sY242, sY142, sY255, sY615, sY254, sY1125, sY84, sY1197, sY86, sY1206, sY127, sY1291, SRY	Peripheral blood	DT	RU/IVD	+2...+8	24	Strips	R1-H801-S3/5EU
	Familial Mediterranean Fever	MEFV: 1437 C>G, MEFV: 2040 G>C, MEFV: 2076_2078del, MEFV: 2040 G>A, MEFV: 2080 A>G, MEFV: 2082 G>A, MEFV: 2177 T>C, MEFV: 2084 A>G, MEFV: 2230 G>T, MEFV: 2282 G>A, MEFV: 1105 C>T, MEFV: 1223 G>A	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H952-N3/4EU
	SMA Screen	Homozygous and heterozygous deletions of exon 7 of the SMN1 gene	Whole blood	DT	RU/IVD	+2...+8	96	Not pre-aliquoted	R1-H821-N3/9EU
GENETICS Neonatal screening	NeoScreen SMA/TREC/ KREC	KREC TREC SMN1 (exon 7 of the SMN1 gene)	Newborn biological material (whole blood, dried blood spots)	DT	RU/IVD	+2...+8	96	Tubes Strips	R1-H810-23/9EU R1-H810-S3/9EU
GENETICS of metabolism	Lactose Intolerance	MCM6: -13910 T>C	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H941-N3/4EU
	Calcium Metabolism	VDR: 283 A>G (BsmI)	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H913-N3/4EU
PHARMACO- GENETICS	Warfarin Pharmacogenetics	CYP2C9: 430 C>T, CYP2C9: A>C, CYP4F2: C>T, VKORC1: -1639 G>A	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H904-N3/4EU
	Clopidogrel Pharmacogenetics	ABCB1: 3435 C>T, CYP2C19: 681 G>A *2, CYP2C19: 636 G>A *3, CYP2C19: -806 C>T *17	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H953-N3/4EU
ONCO- GENETICS	BRCA mutations	BRCA1: 185delAG, BRCA1: 4153delA, BRCA1: 5382insC, BRCA1: 3819delGTAA, BRCA1: 3875delGTCT, BRCA1: 300 T>G, BRCA1: 2080delA, BRCA2: 6174delT	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H927-N3/4EU
	CHEK2 mutations	CHEK2:1100delC, CHEK2:IVS2+1G>A, CHEK2:470T>C	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H967-N3/4EU
	CHEK2 CONTROL SAMPLES	CHEK2:1100delC, CHEK2:IVS2+1G>A, CHEK2:470T>C	Peripheral blood	DT	RUO	+2...+8 -18...-22	48	Not pre-aliquoted	C-020EU
	EGFR 4	T790M, Del19ex, Ins19ex, L858R, Ins19ex	Formalin-fixed paraffin-embedded (FFPE) non-small-cell lung cancer samples	DT	RU/IVD	+2...+8 -18...-22	48	Strips Universal	R1-H806-S3/4EU R1-H806-UA/4EU
	EGFR 8	T790M, Del19ex, Ins19ex, L858R, G719X, Ins20ex, L861Q, S768I	Formalin-fixed paraffin-embedded (FFPE) non-small-cell lung cancer samples	DT	RU/IVD	+2...+8 -18...-22	48	Strips Universal	R1-H807-S3/4EU R1-H807-UA/4EU
IMMUNO- GENETICS	IL28B	IL28B: rs12979860 C>T, IL28B: rs8099917 T>G	Peripheral blood	DT	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	R1-H930-N3/4EU
SIC	Sample Intake Control	Human genomic DNA	Epithelial cell scrapes from urethra, cervical canal, posterior vaginal vault, posterior nasopharynx wall and other mucosa tissues, cells precipitate from urina, conjunctiva swab, whole blood, etc	DT	RU/IVD	+2...+8	96	Tubes Strips	R1-P805-23/9EU R1-P805-S3/9EU
NON-INVASIVE PRENATAL DIAGNOSIS	Fetal RHD Genotyping	RHD gene, 7 exon RHD gene, 10 exon Sample Intake Control	Peripheral blood (8-10 weeks of pregnancy)	DT	RU/IVD	+2...+8	96	Strips	R1-H802-S3/9EU
	Fetal Gender	Y chromosome fragment Sample Intake Control	Peripheral blood (8-10 weeks of pregnancy)	DT	RU/IVD	+2...+8	96	Strips	R1-H803-S3/9EU
ESPECIALLY DANGEROUS AND FERAL HERD INFECTIONS	Bacillus anthracis	Bacillus anthracis pagA Bacillus anthracis capC	Biological material, washings from environmental objects	DT, iCycler iQ	RUO	+2...+8	48	Tubes Strips	R1-P702-23/4EU R1-P702-S3/4EU
	Yersinia pestis	Yersinia pestis pla Yersinia pestis cafI	Discharge of ulcers, punctate from buboes, sputum, blood, faeces, biopsies; samples from dead and sick animals; ticks, ectoparasites, etc	DT, iCycler iQ	RUO	+2...+8	48	Tubes Strips	R1-P703-23/4EU R1-P703-S3/4EU
	Vibrio cholerae	Toxigenic Vibrio cholera strains	Bacterial cells suspension	DT, iCycler iQ	RUO	+2...+8	48	Tubes Strips	R1-P701-23/4EU R1-P701-S3/4EU
LAMP	GBS LAMP	Streptococcus agalactiae	Urogenital scrape, rectal swab	DT, CFX96, QuantStudio 5	RU/IVD	+2...+8 -18...-22	48	Not pre-aliquoted	L2-P012-N3/4EU

	 Kit	 Biomaterial	 Certification	 Storage	 Number of tests	 Purification	 Ref. No
TRANSPORT MEDIUMS	STOR-F	Scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye	CE/IVDR	+2...+8	100	Tubes Not pre-aliquoted	P-901-1/1EU P-901-N/1EU
	STOR-M	Scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye, including those containing an impurity of mucus	CE/IVDR	+2...+8	100	Tubes (1000 µl) Tubes (500 µl)	P-911-1/1EU P-910-1/1EU
SAMPLE PREPARATION KITS	PREP-FU	Peripheral blood	RU/IVD	-18...-22	50	Pretreatment to obtain lymphocytes	P-006/2EU
	PREP-PK	Formalin-fixed paraffin-embedded (FFPE) tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology	CE/IVDR	+2...+8 -18...-22	50	Proteolysis by proteinase K	P-028-N/2EU P-030-N/2EU
	PREP-L	Faeces	RU/IVD	+2...+8	32	Enzymatic destruction by lysozyme	P-018-N/8EU P-019-N/8EU
DNA EXTRACTION KITS	PREP-RAPID	Saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc. Can be used for sample transportation	CE/IVDR	+2...+8	100	Thermocoagulation of impurities	P-001/1EU
	PREP-OPTIMA	Blood, buccal mucosa, scrapes/swabs from respiratory, gastrointestinal, and urogenital tracts, urine, faeces, biotates, amniotic liquid, ejaculate, cerebrospinal fluid, breast milk, microbial cultures (bacterial, fungal)	CE/IVDR	+2...+8	50	Alkaline cell lysis occurring during thermal incubation	P-016-N/2EU P-016-1/2EU
	PREP-OPTIMA MAX	Blood, buccal mucosa, scrapes/swabs from respiratory, gastrointestinal, and urogenital tracts, urine, faeces, biotates, amniotic liquid, ejaculate, cerebrospinal fluid, breast milk, microbial cultures (bacterial, fungal)	CE/IVDR	+2...+8	50	Alkaline cell lysis occurring during thermal incubation	P-015-N/2EU
	PREP-CM	Fungal, bacterial, cell and blood cultures	RU/IVD	+2...+8	50	Alkaline cell lysis occurring during thermal incubation	P-014-N/2ER
	PREP-CITO DBS	Dried blood spots	CE/IVDR	+2...+8	50	Alkaline cell lysis occurring during thermal incubation	P-029-N/2EU
	PREP-GS	Sputum, saliva, urine, ejaculate, prostate fluid, cerebrospinal fluid, milk serum, minced tissue, epithelial scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, biological samples with PCR inhibitors	CE/IVDR	+2...+8	100	Sorption with extra purification	P-003/1EU
	PREP-GS PLUS	Sputum, saliva, urine, ejaculate, prostate fluid, cerebrospinal fluid, milk serum, minced tissue, epithelial scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, biological samples with PCR inhibitors	CE/IVDR	+2...+8	50	Sorption with extra purification	P-003/2EU
	PREP-GS Genetics	Peripheral blood	CE/IVDR	+2...+8	48	Sorption with extra purification	P-023/4EU
	PREP-RAPID Genetics	Peripheral blood	CE/IVDR	+2...+8	48	Thermocoagulation of impurities	P-021/4EU
	PREP-NA-FET	Peripheral blood of pregnant women	CE/IVDR	+2...+8	50	Precipitation	P-027/2EU
	PREP-DERM	Skin and its appendages: hair and nails	RU/IVD	+2...+25	100	Thermocoagulation of impurities	P-032-1/1ER P-032-N/1ER
	PREP-NA	Blood (plasma, leukocytes), saliva, sputum, milk, urine, ejaculate, prostate secretion, liquor, respiratory scrapes/swabs, oropharyngeal and nasopharyngeal flushes, swabs/scrapes (discharge) from urogenital tract, from gastrointestinal tract, faeces (or meconium) etc.	CE/IVDR	+2...+25	100	Precipitation	P-034-N/1EU
DNA/RNA EXTRACTION KITS	PREP-NA PLUS	Blood (plasma, leukocytes), saliva, sputum, milk, urine, ejaculate, prostate secretion, liquor, respiratory scrapes/swabs, oropharyngeal and nasopharyngeal flushes, swabs/scrapes (discharge) from urogenital tract, from gastrointestinal tract, faeces (or meconium) etc	CE/IVDR	+2...+25	100 50	Precipitation	P-036-N/1EU P-036-N/2EU
	PREP-NA-S	Nasopharyngeal, oropharyngeal smears	CE/IVDR	+2...+8	100	Precipitation	P-007/1EU
	PREP-NA-ULTRA	Blood plasma, blood serum	RU/IVD	+2...+25	100	Precipitation	P-017-N/1ER

	 Kit	 Biomaterial		 Certification	 Storage	 Number of tests	 Purification	 Ref. No
MAGNETIC BEADS NA EXTRACTION KITS	PREP-MB-RAPID II	Urine, scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx		CE/IVDR	+2...+25	96	Sorbtion on magnetic particles	P-122-N/9EU P-122-A/9EU P-124-P/9EU
	PREP-MB MAX	Peripheral blood, scrapes/swabs from urogenital tract and rectum, urine, ejaculate, milk, faeces		CE/IVDR	+2...+8	48	Sorption on magnetic particles	P-103-N/4EU
	PREP-MB-LITE	Blood plasma, blood serum		RU/IVD	+2...+25 -18...-22	96	Sorption on magnetic particles	P-136-N/9ER P-136-P/9ER P-137-P/9ER
	PREP-MB DWP	Nasopharyngeal, oropharyngeal swabs		CE/IVDR	+2...+25	96	Sorption on magnetic particles	P-121-P/9EU
	PREP-MB-DBS DWP	Dried blood spots		CE/IVDR	+2...+25	96	Sorption on magnetic particles	P-128-N/9EU P-128-P/9EU

	 Kit	 Intended use		 Certification	 Storage	 Number of tests	 Format	 Ref. No
VERIFICATION KITS	DTcheck-48	For single-use verification of optical, photometric, and thermal systems in 4- and 5-channel DTlite PCR detection systems		RU/IVD	+2...+8	48	Microplate	DTCHECK/4EU
	DTcheck-96	For single-use verification of optical, photometric, and thermal systems in 4- and 5-channel DTprime/DTprime II PCR detection systems, 96 format		RU/IVD	+2...+8	48	Microplate	DTCHECK/9EU
	DTcheck-384	For single-use verification of optical, photometric, and thermal systems in 4- and 5-channel DTprime/DTprime II PCR detection systems, 384 format		RU/IVD	+2...+8	48	Microplate	DTCHECK/XEU

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Kits



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