DNA-TECHNOLOGY

DT SERIES REAL TIME PCR INSTRUMENTS

DT SERIES REAL TIME PCR INSTRUMENTS

DESCRIPTION:

DT Series Real Time PCR Instruments:

- Reliable and sensitive instruments open for most kits
- Small footprint, low noise-level
- Bi-directional LIS-integration capability
- A wide range of pre-designed PCR assays and panels that allow for automated analysis and interpretation of the test results
- Create your very own protocols using our flexible design algorithms
- Support numerous applications including:
  - Pathogen detection, quantification
  - Quantitative analysis of microbiome
  - HLA typing
  - SNP detection

FEATURES:

- Outstanding thermal uniformity for maximum inter-run and intra-run reproducibility.
- Hot lid:
  - Secure clamping of tube caps, eliminating the possibility of spontaneous opening and contamination
  - Uniform heat distribution over the entire volume of the mixture
  - Prevents formation of condensation on the caps of the tubes
- Horizontal and vertical gradients for R&D: A useful option for optimization of conditions for amplification in order to attain maximum efficiency
- Simultaneous detection of a fluorescent signal in all wells of the heating block ensures uniform detection of fluorescence and fast run times
- Outstanding optical performance and compensation for fluorescence spill over for maximum sensitivity.
- Available in several different configurations of the optical system: 4 or 5 channels
- Narrow band filters minimize fluorescence crosstalk
- Tube height adjustment enables the use of different PCR tube formats.
- Small footprint helps to maximize your laboratory space
- Easy performance verification - the easy-to-use, cost-effective DT Check kit gives you confidence in your PCR results.
- Fleet control – manage multiple instruments from a single PC
- Automated data-analysis & results' interpretation
- The instrument is equipped with its own memory:
  - Stores the last protocol
  - Eliminates the possibility of data loss in case of external problems with their transfer

- Flexible and user-friendly interface of DTmaster software:

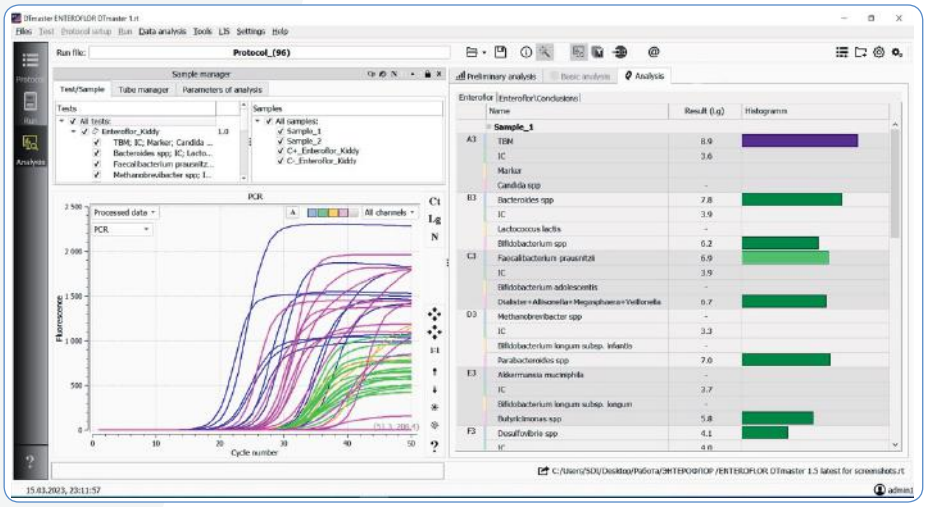
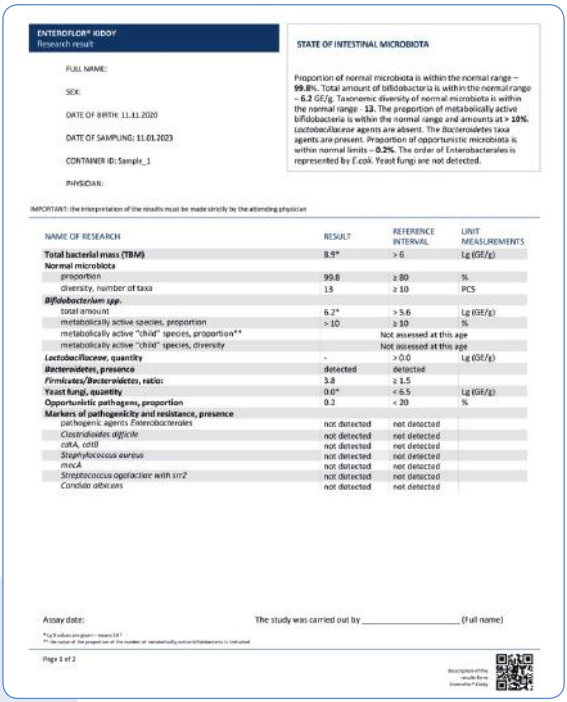


Fig. 1 Test results



ENTEROFLOR® KIDDY
Research result

FULL NAME:

SEX:

DATE OF BIRTH: 11.11.2020

DATE OF SAMPLING: 11.01.2023

CONTAINER ID: Sample_1

PHYSICIAN:

STATE OF INTESTINAL MICROBIOTA

Proportion of normal microbiota is within the normal range – **99.8%**. Total amount of bifidobacteria is within the normal range – **6.2** GE/g. Taxonomic diversity of normal microbiota is within the normal range - **13**. The proportion of metabolically active bifidobacteria is within the normal range and amounts at **> 10%**. *Lactobacillaceae* agents are absent. The *Bacteroidetes* taxa agents are present. Proportion of opportunistic microbiota is within normal limits – **0.2%**. The order of Enterobacterales is represented by *E.coli*. Yeast fungi are not detected.

IMPORTANT: the interpretation of the results must be made strictly by the attending physician

NAME OF RESEARCH	RESULT	REFERENCE INTERVAL	UNIT MEASUREMENTS
Total bacterial mass (TBM)	8.9*	> 6	Lg (GE/g)
Normal microbiota			
proportion	99.8	≥ 80	%
diversity, number of taxa	13	≥ 10	PCS
Bifidobacterium spp.			
total amount	6.2*	> 5.6	Lg (GE/g)
metabolically active species, proportion	> 10	≥ 10	%
metabolically active "child" species, proportion**		Not assessed at this age	
metabolically active "child" species, diversity		Not assessed at this age	
***Lactobacillaceae*, quantity**	-	> 0.0	Lg (GE/g)
***Bacteroidetes*, presence**	detected	detected	
***Firmicutes/Bacteroidetes*, ratio:**	3.8	≥ 1.5	
Yeast fungi, quantity	0.0*	< 6.5	Lg (GE/g)
Opportunistic pathogens, proportion	0.2	< 20	%
Markers of pathogenicity and resistance, presence			
pathogenic agents *Enterobacterales*	not detected	not detected	
Clostridioides difficile	not detected	not detected	
cdtA, cdtB	not detected	not detected	
Staphylococcus aureus	not detected	not detected	
mecA	not detected	not detected	
Streptococcus agalactiae with srr2	not detected	not detected	
Candida albicans	not detected	not detected	

Assay date:

The study was carried out by _____ (Full name)

Page 1 of 2

Fig. 2 Automated interpretation of the test results

CUSTOMIZABLE CONFIGURATIONS TO MATCH THE NEEDS OF YOUR LABORATORY:

DTlite *S1 can analyze up to **48 samples per run**

Suitable for **low throughput laboratories**

DTprime *M** is the perfect choice for a **medium throughput laboratory**

Can analyze up to **96 samples per run**

Instrument models with isolated thermal plate sections available for using multiple kits in a single run

Temperature gradient

DTprime *X1 can analyze up to **384 samples per run**

Ideal for **high throughput laboratories**

* – denotes the number of optical channels
** – denotes the number of sections in the thermal block

COMPARE THE INSTRUMENTS

	DTlite 4S1	DTlite 5S1	DTprime 4M1	DTprime 5M1	DTprime 5M3	DTprime 5M6	DTprime 4X1	DTprime 5X1
Number of optical channels	4	5	4	5			4	5
Sample capacity, wells	48		96				384	
Number of independent sections	1				3	6	1	
2D temperature gradient	—			+	–			
Sample volume, µl	10–100						5–30	
Hot lid, °C	105±1							
Operational range, °C	0–100							
Accuracy, °C	±0,2							
Uniformity, °C	±0,3		±0,15					
Maximum ramp rate heating, °C/sec	3,5						2,5	
Maximum ramp rate cooling, °C/sec	2,5						1,5	
Average ramp rate heating, °C/sec	3,3						2,1	

	DTlite 4S1	DTlite 5S1	DTprime 4M1	DTprime 5M1	DTprime 5M3	DTprime 5M6	DTprime 4X1	DTprime 5X1
Average ramp rate cooling, °C/sec	2,1						1	
Maximum temperature difference (thermal gradient /separate sections of thermal block), °C	—		8				—	
Excitation wavelengths, nm	470 530 580 630	470 530 580 630 687	470 530 580 630	470 530 580 630 687			470 530 580 630	470 530 580 630 687
Emission wavelengths, nm	515 560 620 660	515 560 620 660 731	515 560 620 660	515 560 620 660 731			515 560 620 660	515 560 620 660 731
Number of channels	4	5	4	5			4	5
Dimensions (WxDxH), mm	210x480x310		210x540x540					
Weight, kg	17		27					
Maximum power consumption, watt	550							

129-1 2023.01.31

DNA-TECHNOLOGY

“DNA-Technology”, LLC
www.dna-technology.com
e-mail: info@dna-technology.com
Client support service: +7 (495) 640-17-71
hotline@dna-technology.ru

Certificate of Registration Certificate of Registration

G-CERTI *certificate*

hereby certifies that

«DNA-Technology Research& Production», LLC

142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 20.
Site 1: "DNA-Technology" LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12.
Site 2: "DNA-Technology TS", LLC, 117246, Russia, Moscow, proezd Nauchny, 20, building 4.
Site 3: "DNA-Technology Research&Development", LLC, 109388, Russia, Moscow, Guryanova street, 83, building 1.
Site 4: "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 3.

meets the Standard Requirements & Scope as following

ISO 9001:2015
Quality Management Systems

Design, manufacturing and distribution of in-vitro diagnostic reagents and devices for medical molecular-genetic diagnostics.

Certificate No	: GKRST-0002-QC	Code	: 12, 23
Initial Date	: 2023. 01. 24	Issue Date	: 2023. 10. 19
Expiry Date	: 2026. 01. 23	Valid Period	: 2023. 10. 19 ~ 2025. 01. 23

Signed for and on behalf of GCERTI
President I.K.Choi

<G-CERTI> is accredited by IAS member of IAF for the scope and sub scopes described in this certificate.

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

G CERTI SYSTEM SERVICE

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meets the Standard Requirements & Scope as following

ISO 13485:2016
Medical Devices -- Quality Management Systems

Design, manufacturing and distribution of in-vitro diagnostic reagents and devices for medical molecular-genetic diagnostics.

Certificate No	: GKRST-0002-MD	Code	: D
Initial Date	: 2023. 01. 24	Issue Date	: 2023. 10. 19
Expiry Date	: 2026. 01. 23	Valid Period	: 2023. 10. 19 ~ 2025. 01. 23

Signed for and on behalf of GCERTI
President I.K.Choi

G-CERTi SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

GCERTi SYSTEM SERVICE

117587, Russia, Moscow,
int. ter. Municipal District Chertanovo Severnoye,
Varshavskoye shosse, 125 Zh,
building 5, floor 1, office 12

www.dna-technology.com
info@dna-technology.com

Price list
Equipment and PCR kits

valid from 01.10.2022

Please note that the "DNA Technology" is selling kits with different type of registration:

RU/IVD - kits for *In Vitro* Diagnostic, which are registered in Russia only
CE/IVD - kits for *In Vitro* Diagnostic, which are registered in EU
RUO - kits for Research Use Only

All prices are exclusive of shipping costs (EX-works prices)

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117587, Russia, Moscow,
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building 5, floor 1, office 12

www.dna-technology.com
info@dna-technology.com

Product definition

**-X 000 -α β / μ / EU

**** - part**

R - Real-time detection

Q - Quantitative Real-time detection

P - DNA/RNA extraction Kits

D - DNA extraction Kits

O - equipment

C - reagents

Format	R (Rt)	Q (qRt)
amplification	**R1**	**Q1**
amplification + extraction	**R2**	**Q2**
amplification + reverse transcription	**R3**	**Q3**
amplification + extraction + reverse transcription	**R4**	**Q4**

X - part
P - Obligate and opportunistic pathogens
H - Human genetics

α - stock/pre-aliquoted RCR-Mix
N - stock (not pre-aliquoted)
5 - pre-aliquoted in 0,5 ml tubes
2 - pre-aliquoted in 0,2 ml tubes
S - pre-aliquoted in strips (8 x 0,2)

β - instrument compatibility

3 - DNA-Tecnology DT*prime*, Dtlite
Bio-Rad Lab - iQ5 instruments
(exeption - the kits marked as "Kits adapted only for DT*prime*, DT*lite*")
4 - QIAGEN Rotor-Gene instruments

μ - number of tests
1 - 100 tests
2 - 50 tests
3 - 25 tests
4 - 48 tests
5 - 24 tests
6 - 12 tests
9 - 96 tests

REAL-TIME PCR detection Kits						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
Sexually Transmited Diseases						
Chlamydia trachomatis	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P101-23/9EU
			0.2x8	96		R1-P101-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P101-24/9EU
Mycoplasma hominis	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P102-23/9EU
			0.2x8	96		R1-P102-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P102-24/9EU
Mycoplasma genitalium	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P103-23/9EU
			0.2x8	10		R1-P103-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P103-24/9EU
Ureaplasma complex (U.urealyticum/U.parvum)	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P104-23/9EU
			0.2x8	96		R1-P104-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P104-24/9EU
Ureaplasma parvum	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P105-23/9EU
			0.2x8	96		R1-P105-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P105-24/9EU
Ureaplasma urealyticum	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P106-23/9EU
			0.2x8	96		R1-P106-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P106-24/9EU
Trichomonas vaginalis	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P107-23/9EU
			0.2x8	96		R1-P107-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P107-24/9EU
Gardnerella vaginalis	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P108-23/9EU
			0.2x8	96		R1-P108-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P108-24/9EU
Neisseria gonorrhoeae	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P109-23/9EU
			0.2x8	96		R1-P109-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P109-24/9EU
Herpes Virus Infection						
Herpes symplex virus 1,2	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P201-23/9EU
			0.2x8	96		R1-P201-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P201-24/9EU
Human herpesvirus 6	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P202-23/9EU
			0.2x8	96		R1-P202-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P202-24/9EU
Human herpesvirus 8	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P203-23/9EU
			0.2x8	96		R1-P203-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P203-24/9EU

REAL-TIME PCR detection Kits						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
Herpes Virus Infection						
Cytomegalovirus	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P204-23/9EU
			0.2x8	96		R1-P204-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P204-24/9EU
Epstein Barr virus	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P205-23/9EU
			0.2x8	96		R1-P205-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P205-24/9EU
Varicella zoster virus	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P206-23/4EU
			0.2x8	48		R1-P206-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P206-24/4EU
Multiplex Realtime PCR Kits for Sexually Transmited Diseases, Herpes Virus Infection						
TNC multiplex (T.vaginalis/N.gonorrhoeae/ C.trachomatis)	**RU/IVD**	DT instruments only	0.2	96	12	R1-P111-23/9EU
			0.2x8	96		R1-P111-S3/9EU
UMC multiplex (Ur.urealyticum/M.genitalium/ C.trachomatis)	**RU/IVD**	DT instruments only	0.2	96	12	R1-P113-23/9EU
			0.2x8	96		R1-P113-S3/9EU
Herpes multiplex (HSV1/HSV2/CMV)	**RU/IVD**	DT instruments only	0.2	96	12	R1-P210-23/9EU
			0.2x8	96		R1-P210-S3/9EU
Causative agents of mycoses						
Candida albicans	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P110-23/9EU
			0.2x8	96		R1-P110-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P110-24/9EU
MycosoScreen	**CE/IVD**	DT instruments only	0.2x8	24	12	R1-P023-S3/5EU
Human Papilloma Virus						
HPV QUANT-4 * (HPV 6,11,16,18) Quantitative PCR Kit	**CE/IVD**	DT instruments only	0.2x8	48	12	R1-P315-S3/4EU
HPV QUANT-15* (HPV 6,11,16,18, 31, 33,35,39,45,51,52,56,58,59,68) Quantitative PCR Kit	**CE/IVD**	DT instruments only	0.2x8	48	12	R1-P316-S3/4EU
HPV QUANT-21* (HPV 6,11, 44, 16, 18, 26, 31, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68,73,82) Quantitative PCR Kit	**CE/IVD**	DT instruments only	0.2x8	24	12	R1-P317-S3/5EU
HPV 6/11 multiplex	**RUO**	DT instruments only	0.2	96	12	R1-P321-23/9EU
			0.2x8	96		R1-P321-2S/9EU
HPV 16/18 multiplex	**CE/IVD**	DT instruments only	0.2	96	12	R1-P320-23/9EU
			0.2x8	96		R1-P320-2S/9EU
HPV 16,18 PCR detection Kit	**RU/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	2x96	12	R1-P301-23/9EU
			0.2x8	2x96		R1-P301-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	2x96		R1-P301-24/9EU

Description	Registration	Detection instruments	Tubes(ml)/ Strips	Number of tests	Shelf life, months	Product number
Respiratory infections						
Corynebacterium diphtheriae	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P401-23/4EU
			0.2x8	48		R1-P401-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P401-24/4EU
Bordetella pertussis	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P002-23/4EU
			0.2x8	48		R1-P002-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P002-24/4EU
Legionella pneumophila	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P403-23/4EU
			0.2x8	48		R1-P403-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P403-24/4EU
Chlamydophila pneumoniae	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P406-23/4EU
			0.2x8	48		R1-P406-S3/4EU
Influenza A virus (subtype H5N1) (RT reagents included)	**RUO**	DT instruments only	0.2	48	12	R3-P407-23/4EU
			0.2x8	48		R3-P407-S3/4EU
Influenza A virus (subtype H1N1) (RT reagents included)	**CE/IVD**	DT instruments only	0.2	48	9	R3-P408-23/4EU
			0.2x8	48		R3-P408-S3/4EU
Influenza A virus (RT reagents included)	**CE/IVD**	DT instruments only	0.2	48	12	R3-P409-23/4EU
			0.2x8	48		R3-P409-S3/4EU
Influenza B virus (RT reagents included)	**CE/IVD**	DT instruments only	0.2	48	12	R3-P410-23/4EU
			0.2x8	48		R3-P410-S3/4EU
Mycoplasma pneumoniae	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P411-23/4EU
			0.2x8	48		R1-P411-S3/4EU
Streptococcus pneumoniae	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P412-23/4EU
			0.2x8	48		R1-P412-S3/4EU
Streptococcus pyogenes	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P402-23/4EU
			0.2x8	48		R1-P402-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P402-24/4EU
Multiplex Realtime PCR Kits for Respiratory infections						
AVRI Panel Multiplex REAL-TIME PCR Detection Kit	**CE/IVD**	DT instruments only	0.2x8	24	12	R3-P439-S3/5EU
Viral Pneumonia	**RU/IVD**	DT instruments only	0.2x8	12	12	R3-P428-S3/6EU
SARS-CoV-2/SARS-CoV	**CE/IVD**	DT instruments (DNA-Technology); CFX (Bio-Rad); Rotor-Gene instruments (QIAQEN)	0.2	96	12	R1-P436-23/9EU
			0.2x8	96		R1-P436-S3/9EU
SARS-CoV-2/RSV/Influenza AB	**CE/IVD**	DT instruments (DNA-Technology); CFX (Bio-Rad); Rotor-Gene instruments (QIAQEN)	0.2	96	12	R3-P448-23/9EU
			0.2x8	96		R3-P448-S3/9EU
SARS-CoV-2/Influenza	**CE/IVD**	DT instruments (DNA-Technology); CFX (Bio-Rad); Rotor-Gene instruments (QIAQEN)	0.2	96	12	R3-P440-23/9EU
			0.2x8	96		R3-P440-S3/9EU
SARS-CoV-2 Lite (Direct PCR, without extraction)	**CE/IVD**	DT instruments only	0.2x8	96	12	R3-P446-S3/9EU
SARS-CoV-2/Variants (UK, SA,BR)	**RUO**	DT instruments (DNA-Technology); CFX (Bio-Rad);	0.2x8	96	12	R3-P443-S3/9EU
SARSCoV2/RSV/Influenza AB virus Multiplex	**CE/IVD**	DT instruments	0.2	96	12	R3-P448-23/9EU
			0.2x8			R3-P448-S3/9EU

Description	Registration	Detection instruments	Tubes(ml)/ Strips	Number of tests	Shelf life, months	Product number
Multiplex Realtime PCR Kits for Respiratory infections						
C.pneumoniae, M.pneumoniae Multiplex	**RUO**	DT instruments only	0.2	48	12	R1-P430-23/4EU
			0.2x8	48		R1-P430-S3/4EU
Influenza A virus, Influenza B virus Multiplex	**RU/IVD**	DT instruments only	0.2	48	6	R3-P431-23/4EU
			0.2x8	48		R3-P431-S3/4EU
Mycobacterium complex (M.tuberculosis/M.bovis)	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P404-23/4EU
			0.2x8	48		R1-P404-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P404-24/4EU
Other Infections						
Streptococcus agalactiae	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P012-23/4EU
			0.2x8	48		R1-P012-S3/4EU
Toxoplasma gondii	**RU/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P001-23/9EU
			0.2x8	96		R1-P001-S3/9EU
		Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P001-24/9EU
Listeria monocytogenes	**RU/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P003-23/4EU
			0.2x8	48		R1-P003-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P003-24/4EU
Helicobacter pylori	**CE/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P501-23/4EU
			0.2x8	48		R1-P501-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P501-24/4EU
Human Parvovirus B19	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P011-23/4EU
			0.2x8	48		R1-P011-S3/4EU
MRS/MRSA Multiplex Staphylococcus spp., Staphylococcus aureus,mecA	**RUO**	DT instruments only	0.2	48	12	R1-P022-23/4EU
			0.2x8	48		R1-P022-S3/4EU
Multiplex Real-Time PCR kits for the detection of antibiotic resistance genes						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
BacResista GLA REAL-TIME PCR Detection Kit	**CE/IVD**	DT instruments only	0.2x8	24	12	R1-P026-S3/5EU
BacResista GLA Van/Mec REAL-TIME PCR Detection Kit	**CE/IVD**	DT instruments only	0.2	48	12	R1-P027-23/4EU
			0.2x8	48		R1-P027-S3/4EU
Multiplex Real-Time PCR kits for the detection of nosocomial and community-acquired infections						
BacScreen OM REAL-TIME PCR Detection Kit	**CE/IVD**	DT instruments only	0.2x8	12	12	R1-P028-S3/6EU
Especially dangerous and feral herd infections						
Borrelia burgdorferi	**RU/IVD**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P005-23/4EU
			0.2x8	48		R1-P005-S3/4EU
		Rotor-Gene instruments (QIAQEN)	0.2	48		R1-P005-24/4EU
Vibrio cholerae	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P701-23/4EU
			0.2x8	48		R1-P701-S3/4EU
Bacillus anthracis	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P702-23/4EU
			0.2x8	48		R1-P702-S3/4EU

Quantitative PCR Kits and PCR detection Kits						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
Especially dangerous and feral herd infections						
Yersinia pestis	**RUO**	DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	12	R1-P703-23/4EU
			0.2x8	48		R1-P703-S3/4EU
Hepatitis Viruses and HIV						
Hepatitis C virus genotyping PCR Kit (RT reagents and "PREP-NA" included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	48	9	R4-P604-23/4EU
			0.2x8	48		R4-P604-S3/4EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	48		R4-P604-24/4EU
Hepatitis C virus PCR detection Kit (RT reagents included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	9	R3-P603-23/9EU
			0.2x8	96		R3-P603-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		R3-P603-24/9EU
Hepatitis C virus quantitative PCR Kit (RT reagents and "PREP-NA" included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	9	Q4-P603-23/9EU
			0.2x8	96		Q4-P603-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		Q4-P603-24/9EU
Hepatitis B virus PCR detection Kit	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P602-23/9EU
			0.2x8	96		R1-P602-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P602-24/9EU
Hepatitis B virus quantitative PCR Kit ("PREP-NA" included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	9	Q2-P602-23/9EU
			0.2x8	96		Q2-P602-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		Q2-P602-24/9EU
Hepatitis Viruses and HIV						
Human immunodeficiency virus PCR detection Kit (RT reagents included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	9	R3-P609-23/9EU
			0.2x8	96		R3-P609-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		R3-P609-24/9EU
Human immunodeficiency virus quantitative PCR Kit (RT reagents and "PREP-NA" included)	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	9	Q4-P609-23/9EU
			0.2x8	96		Q4-P609-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		Q4-P609-24/9EU
Sample intake control Kit (SIC)						
SIC	**RU/IVD**	The kit is compatible with DT instruments (DNA-Technology); iQ5, iCycler (Bio-Rad) with 2 or more detection channels	0.2	96	12	R1-P805-23/9EU
			0.2x8	96		R1-P805-S3/9EU
		The kit is compatible with Rotor-Gene instruments (QIAQEN)	0.2	96		R1-P805-24/9EU
Microbiome composition analysis						
Female urogenital microbiome composition analysis*						
Femoflor® 16	**CE/IVD**	DT instruments only	0.2x8	12	12	R1-P801-S3/6EU
Femoflor® Screen	**CE/IVD**	DT instruments only	0.2x8	24	12	R1-P804-S3/5EU
Male urogenital microbiome composition analysis*						
Androflor®	**CE/IVD**	DT instruments only	0.2x8	12	12	R1-P809-S3/6EU
Androflor® Screen	**CE/IVD**	DT instruments only	0.2x8	24	12	R1-P810-S3/5EU

Quantitative PCR Kits and PCR detection Kits						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
Gut microbiome composition analysis**						
ENTEROFLOR Kiddy	**CE/IVD**	DT instruments only	0.2x8	12	12	R1-P815-S3/6EU
Microbiocenosis of the oral cavity analysis						
ParodontoScreen	**RUO**	DT instruments only	0.2x8	24	9	R1-P808-S3/5EU

*** PREP-NA-Plus and PREP-GS-Plus extraction kits must be used for sample preparation**

**** PREP-NA-Plus extraction kits must be used for sample preparation**

SNP genotyping Kits *						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
NeoScreen SMA/TREC/KREC deletion of exon 7 of the SMNI gene	**CE/IVD**	DT instruments only	0.2 0.2x8	96	12	R1-H810-S3/9EU R1-H810-23/9EU
Hypertension Susceptibility (9 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H902-N3/4EU
Thrombophilia Susceptibility (8 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H901-N3/4EU
Hemostasis F2,F5 mutations	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H958-N3/4EU R1-H959-N3/4EU
FOLATE METABOLISM (4 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H908-N3/4EU
LACTOSE INTOLERANCE (1 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H941-N3/4EU
CALCIUM METABOLISM (1 SNP)	**RU/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H913-N3/4EU
WARFARIN Pharmacogenetics (4 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H904-N3/4EU
CLOPIDOGREL Pharmacogenetics (4 SNPs)	**RU/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H953-N3/4
BRCA mutations (8 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H927-N3/4EU
CHEK2 mutations (3 SNPs)	**RUO**	DT instruments only	not pre-aliquoted	48	12	R1-H945-N3/4EU
CHEK2 CONTROL SAMPLES	**RUO**	DT instruments only	not pre-aliquoted	10	12	C-020EU
EGFR mutations (4 SNP)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H806-S3/4EU
EGFR mutations (8 SNP)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H807-S3/4EU
IL 28B (2 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H930-N3/4EU
HEMOCHROMATOSIS (3 SNPs)	**CE/IVD**	DT instruments only	not pre-aliquoted	48	12	R1-H939-N3/4EU
CYSTIC FIBROSIS SCREEN (8 SNPs)	**RUO**	DT instruments only	not pre-aliquoted	48	12	R1-H943-N3/4EU
CYSTIC FIBROSIS - rare CFTR mutations (16 SNPs)	**RUO**	DT instruments only	not pre-aliquoted	48	12	R1-H948-N3/4EU
OSTEOPOROSIS (16 SNPs)	**RUO**	DT instruments only	not pre-aliquoted	48	12	R1-H944-N3/4EU
PHENYLKETONURIA SCREEN (4 SNPs)	**RUO**	DT instruments only	not pre-aliquoted	48	12	R1-H950-N3/4EU
AZF Microdeletions	**CE/IVD**	DT instruments only	strips 0.2x8	24	12	R1-H801-S3/5EU
FMF (12 SNPs)	**CE/IVD**	DT instruments only	strips 0.2x8	48	12	R1-H952-N3/4EU
FMF E148Q	**CE/IVD**	DT instruments only	strips 0.2x8	48	12	R1-H953-N3/4EU

 # PREP-RAPID-GENETICS and PREP-GS-GENETICS extraction kits are recommended for sample preparation

*** PCR-Mix contains an internal control (IC). IC assures there is sufficient DNA in the sample to exclude the possibility of false results. The PCR-Mix for SNP genotyping kits supplyed in stock solution. Tubes or strips must be ordered separately!**

NON-INVASIVE PRENATAL DIAGNOSIS *						
Description	**Registration**	**Detection instruments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
Fetal RHD Genotyping	**CE/IVD**	DT instruments only. PREP-NA-FET extraction kits are recommended for sample preparation.	strips 0.2x8	96	12	R1-H802-S3/9EU
Fetal Gender	**CE/IVD**	DT instruments only. PREP-NA-FET extraction kits are recommended for sample preparation.	strips 0.2x8	96	12	R1-H803-S3/9EU
PREP-NA-FET	**CE/IVD**	NB! additional equipment are necessary: IsoFreeze rack for tubes 1.5 ml; Centrifuge that is compatible with tubes 4.5 ml (RCF at least equal to150g)	not pre-aliquoted	50	12	R-027/2EU

*** PCR-Mix contains an internal control (IC). IC assures there is sufficient DNA in the sample to exclude the possibility of false results. The PCR-Mix for SNP genotyping kits supplyed in stock solution. Tubes or strips must be ordered separately!**

HLA I genotyping PCR Kits for Real Time method						
Description	**Registration**	**Comments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
HLA-B27 alleles genotyping Kit	**CE/IVD**	DT instruments only. PREP-RAPID-GENETICS and PREP-GS-GENETICS extraction kits are recommended for sample preparation	strips 0.2x8	48	12	R1-H004-S3/4EU

HLA II genotyping PCR Kits for Real Time method						
Description	**Registration**	**Comments**	**Tubes(ml)/ Strips**	**Number of tests**	**Shelf life, months**	**Product number**
HLA-DRB1 alleles genotyping Kit	**RU/IVD**	DT instruments only. PREP-RAPID-GENETICS and PREP-GS-GENETICS extraction kits are recommended for sample preparation	strips 0.2x8	24	12	R1-H001-S3/5EU
HLA-DQA1 alleles genotyping Kit	**RU/IVD**	DT instruments only. PREP-RAPID-GENETICS and PREP-GS-GENETICS extraction kits are recommended for sample preparation	**not pre-aliquoted** (tubes should be ordered separately)	24	12	R1-H002-N3/5EU
HLA-DQB1 alleles genotyping Kit	**RU/IVD**	DT instruments only. PREP-RAPID-GENETICS and PREP-GS-GENETICS extraction kits are recommended for sample preparation	**not pre-aliquoted** (tubes should be ordered separately)	24	12	R1-H003-N3/5EU

DNA extraction kits					
Description	**Registration**	**Comments**	**Number of tests**	**Shelf life, months**	**Product number**
PREP-RAPID	**CE/IVD**	DNA extraction from scrapes, smears. Can be used as a transportation media.	100	12	P-001/1EU
PREP-OPTIMA (rapid extraction)	**CE/IVD**	DNA extraction from buccal epithelium; smears/scrapings from respiratory, gastrointestinal, and urogenital tracts; urine; faeces; bioptates; amniotic liquid; ejaculate; cerebrospinal fluid; breast milk, as well as for DNA extraction from microbial cultures (bacterial, fungal)	50	12	P-016-N/2EU P-016-1/2EU
PREP-OPTIMA MAX (rapid extraction)	**CE/IVD**	DNA extraction from blood; buccal epithelium; smears/scrapings from respiratory, gastrointestinal, and urogenital tracts; urine; faeces; bioptates; amniotic liquid; ejaculate; cerebrospinal fluid; breast milk, as well as for DNA extraction from microbial cultures (bacterial, fungal)	50	12	P-015-N/2EU
PREP-CITO DBS	**CE/IVD**	intended for human genomic DNA extraction from dried blood spots (DBS)	50	12	P-016-N/2EU P-016-1/2EU P-015-N/2EU
PREP-GS	**CE/IVD**	DNA extraction from biopsy samples, blood plasma, scrapes, smears, pflegm	100	12	P-003/1EU
PREP-GS plus	**CE/IVD**	DNA extraction kit PREP-GS-Plus with additional buffer	50	12	P-003/2EU
PREP-GS genetics	**CE/IVD**	DNA extraction for genetics studies	48	12	P-023/4EU
PREP-RAPID genetics	**CE/IVD**	Express DNA extraction for genetics studies	48	12	P-021/4EU
PREP-CTAB	**RUO**	DNA extraction for GMO	50	12	P-004/2EU
PREP-FU Cell isolation kit	**RUO**	Ficoll urographin in tubes 1,5ml.	50	6	P-006/2EU
PREP-PK	**CE/IVD**	Set №1 is intended for the preprocessing of FFPE tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology	50	12	P-028-N/2EU
		is a shortened of Set №1 and is intended for the preprocessing of FFPE tissues and cervical swabs taken in fixing transport medium for liquid-based cytology			P-030-N/2EU
PREP-L	**RU/IVD**	is intended for lysozyme pretreatment of human biological material (faeces), as well as bacterial cultures obtained from this biomaterial for further extraction of bacterial DNA	32	12	P-019-N/8INT P-020-N/8INT

DNA/RNA extraction kits					
Description	**Registration**	**Comments**	**Tests number**	**Shelf life, months**	**12**
PREP-NA	**CE/IVD**	DNA/RNA extraction from biopsy samples, blood plasma, scrapes, smears, pflegm, spinal fluid etc.	100	12	P-002/1EU
PREP-NA plus	**CE/IVD**	DNA extraction kit PREP-NA-Plus with additional buffer	50	12	P-002/2EU
PREP-NA-FET	**CE/IVD**	Fetal DNA extraction from mother's blood	50	12	R-027/2EU
PREP-NA-S	**CE/IVD**	DNA/RNA extraction from nasopharyngeal, oropharyngeal swabs	100	12	P-007/1EU
PREP-MB DWP	**CE/IVD**	DNA/RNA extraction from nasopharyngeal, oropharyngeal swabs for automatic nucleic acid extraction in deep-well 96-well trays (KingFisher Flex 96/Allsheng Auto-Pure 96)	96	12	P-119-N/9INT
PREP-MB MAX	**CE/IVD**	is intended for human, bacterial, viral, and fungal DNA extraction from human biological material (whole peripheral blood; smears/scrapings from urogenital tract and rectum; urine; ejaculate; milk; faeces)	48	12	P-103-N/4EU
			32 *(optimal: one run of 32 samples,*		P-103-A/8EU
RNA-IC	**CE/IVD**	Internal control for Sars Cov2 kit	50	12	C-206/EU

Transport medium kits					
Description	**Registration**	**Comments**	**Tests number**	**Shelf life, months**	**Product number**
STOR-F	**CE/IVD**	Transportation and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye)	100	12	P-901-1/1EU P-901-N/1EU
STOR-M	**CE/IVD**	Transportation and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye)	100	12	P-910-1/1EU

Equipment			
Description	**Comments**	**Registration**	**Product number**
RealTime PCR systems			
DTprime 4M1 REAL-TIME Thermal cycler	4 channel, 96x0,2 ml	**CE/IVD**	O-DTPRIME4M1-EU
DTprime 5M1 REAL-TIME Thermal cycler	5 channel, 96x0,2 ml	**CE/IVD**	O-DTPRIME5M1-EU
DTprime 5X1 REAL-TIME Thermal cycler	5 channel, 384x0.045 ml	**CE/IVD**	O-DTPRIME5X1-EU
DTlite 4S1 REAL-TIME Thermal cycler	4 channel, 48x0,2 ml	**CE/IVD**	O-DTLITE4S1-EU
DTlite 5S1 REAL-TIME Thermal cycler	5 channel, 48x0,2 ml	**CE/IVD**	O-DTLITE5S1-EU
DTlite 5L1 REAL-TIME Thermal cycler	5 channel, 192x0.045 ml	**CE/IVD**	O-DTLITE5L1-EU
Devices for electrophoresis detection			
Elf-4 Power supply	400V	**RU/IVD**	O-ELF4-EU
Elf-8 Power supply	800V	**RU/IVD**	O-ELF8-EU
Thermostat			
Gnom Programable thermostat	40x1,5ml and 28x0.5ml	**CE/IVD**	O-TT1-EU
Thermit thermostat	40x1,5 ml,28x0.5ml	**RU/IVD**	O-TT2-EU
DTpack Microplate Heat Sealer		**RUO**	O-DTPACK-EU
PCR cabinet			
UV PCR cabinet	1220x670 mm	**RU/IVD**	O-BOX/01-EU
Racks			
Gene Plus Rack	for 100x0,5 ml tubes	**RUO**	O-GN100/05-EU
Gene Plus Rack	for 200x0,5 ml tubes	**RUO**	O-GN200/05-EU
96x0,2 ml strips Rack	for 0,2 ml tubes	**RUO**	O-ST96/02-EU
200x0,5 ml tubes Rack	for 0,5 ml tubes	**RUO**	O-RA200/05-EU
200x0,2 ml tubes Rack	for 0,2 ml tubes	**RUO**	O-RA200/02-EU
100x0,5 ml tubes Rack	for 0,5 ml tubes	**RUO**	O-RA100/05-EU
50x0,5 ml tubes Rack	for 0,5 ml tubes	**RUO**	O-RA50/05-EU
Rack IsoFreeze	for 0,5 and 1,5-2,0 ul tubes	**IVD**	I-IsoFreeze

SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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EC Certificate IVDD 21 020 0115

Full Quality Assurance System Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV excluding section 4 and section 6

Certificate holder: **"DNA-Technology, Research&Production" LLC**
Zheleznodorozhnaya street 20, Moscow region, Protvino, 142281, Russia

Related audit report: AIVDD 2021NB019 I01

Other Facility(ies):
"DNA-Technology" LLC, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12, int. ter. Municipal District Chertanovo Severnoye, Moscow, 117587, Russia
"DNA-Technology R&D", LLC, Gurianova street, 83, bld.1, Moscow, 109388, Russia
"DNA-Technology TS", LLC, Nauchnyi proyezd, 20, bld.4., 117246, Moscow, Russia
"DNA-Technology, Research&Production", LLC Zheleznodorozhnaya street 3, Moscow region, Protvino, 142281, Russia

The certificate was issued with respect to the following scope:

Chlamydia trachomatis REAL-TIME PCR Detection Kit

This certificate is effective from 09 February 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 09 February 2022.

Certification has been authorized by

Radovan Macaj
Head of Notified body

Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Additional information on certification

Related to certificate number:

IVDD 21 020 0115

Description of product(s) within the certification scope:

The Chlamydia trachomatis REAL-TIME PCR Detection Kit offers an in vitro nucleic acid based test for qualitative pathogen detection. The test uses the Polymerase Chain Reaction (PCR) nucleic acid amplification technique aimed to detect Chlamydia trachomatis in urogenital specimens.

Types/Categories/Models:	R1-P101-S3/9EU, R1-P101-23/9EU, R1-P101-UA/9EU 96 tubes, 12 8-tube strips
Classification:	Device in List B
Validity conditions:	-

This certificate is effective from 09 February 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 09 February 2022.

Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

Declaration of Conformity

Manufacturer: "DNA-Technology Research&Production", LLC

142281, Zheleznodorozhnaya street, 20, Protvino, Moscow region, Russia

Tel/fax: +7(4967) 31-06-70
E-mail: info@dna-technology.com

Sites:

– "DNA-Technology" LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12;

– "DNA-Technology TS", LLC, 117246, Russia, Moscow, proezd Nauchny, 20, building 4;

– "DNA-Technology Research&Development", LLC, 109388, Russia, Moscow, Guryanova street, 83, building 1;

– "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 20;

– "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 3

Authorized Representative: Obelis European Authorized Representative Center (O.E.A.R.C.)

Bd. General Wahis 53, 1030 Brussels, Belgium

Phone: +(32) 2 732-59-54/Fax: +(32) 2 732-60-03

E-mail: mail@obelis.net

Notified Body: bqs. s.r.o.,

Študentská 1641/12 Trenčín, 911 01, Country : Slovakia, Phone : 00421 902 219 853,

Email : radovan.macaj@bqsgroup.eu, Website : www.bqsgroup.eu,

Notified Body number : 2854

Product name: Chlamydia trachomatis REAL-TIME PCR Detection Kit

Catalogue numbers: R1-P101-23/9EU, R1-P101-S3/9EU, R1-P101-UA/9EU

Category: *in vitro* diagnostic device and NAT (Nucleic Acid Test) – pathogen-detection-based product

Indication: For *in vitro* diagnostics

Device classification: Class B

Classification Rule: Annex II of IVDD 98/79/EC Council Directive

Conformity assessment route: According to Directive 98/79/EC Annex IV (excl. 4, 6), Full Quality Assurance System

Standards applied: EN ISO 18113-2:2011, ISO 15223-1:2021, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN ISO 14971:2019, ISO/TR 24971:2020, NCCLS EP12AE, EN ISO 18113-1:2011

"DNA-Technology Research&Production" LLC declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and mentioned applicable standards.

The Technical file to the mentioned product is kept by the manufacturer.

EC certification

EC certificate № IVDD 21 020 0115 issued in 09 February 2022

First issued 09 February 2022

Valid from 09 February 2022 Valid until 26 May 2025

EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

APPROVED BY **Director General: Mr. Dmitrovskiy V.Y.**

SIGNATURE:

PLACE: Moscow

DATE: 09.02.2022

SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 21 019 0118

Full Quality Assurance System Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV excluding section 4 and section 6

Certificate holder: **"DNA-Technology, Research&Production" LLC**
Zheleznodorozhnaya street 20, Moscow region, Protvino, 142281, Russia

Related audit report: AIVDD 2021NB019 I01

Other Facility(ies):
"DNA-Technology" LLC, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12, int. ter. Municipal District Chertanovo Severnoye, Moscow, 117587, Russia
"DNA-Technology R&D", LLC, Gurianova street, 83, bld.1, Moscow, 109388, Russia
"DNA-Technology TS", LLC, Nauchnyi proyezd, 20, bld.4., 117246, Moscow, Russia
"DNA-Technology, Research&Production", LLC Zheleznodorozhnaya street 3, Moscow region, Protvino, 142281, Russia

The certificate was issued with respect to the following scope:

CMV REAL-TIME PCR Detection Kit

This certificate is effective from 28 March 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 28 March 2022.

Certification has been authorized by

Radovan Macaj
Head of Notified body

Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

Additional information on certification

Related to certificate number:

IVDD 21 019 0118

Description of product(s) within the certification scope:

The CMV REAL-TIME PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) for qualitative pathogen detection. The CMV REAL-TIME PCR Detection Kit is designed to detect CMV nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: 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.

Types/Categories/Models:	R1-P204-S3/9EU, R1-P204-23/9EU, R1-P204-UA/9EU 96 tubes, 12 8-tube strips
Classification:	Device in List B
Validity conditions:	-

This certificate is effective from 28 March 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 28 March 2022.

Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

Declaration of Conformity

Manufacturer: "DNA-Technology Research&Production", LLC

142281, Zheleznodorozhnaya street, 20, Protvino, Moscow region, Russia

Tel/fax: +7(4967) 31-06-70
E-mail: info@dna-technology.com

Sites:

– "DNA-Technology" LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12;

– "DNA-Technology TS", LLC, 117246, Russia, Moscow, proezd Nauchny, 20, building 4;

– "DNA-Technology Research&Development", LLC, 109388, Russia, Moscow, Guryanova street, 83, building 1;

– "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 20;

– "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 3

Authorized Representative: Obelis European Authorized Representative Center (O.E.A.R.C.)

Bd. General Wahis 53, 1030 Brussels, Belgium

Phone: +(32) 2 732-59-54/Fax: +(32) 2 732-60-03

E-mail: mail@obelis.net

Notified Body: bqs. s.r.o.,

Študentská 1641/12 Trenčín, 911 01, Country : Slovakia, Phone : 00421 902 219 853,

Email : radovan.macaj@bqsgroup.eu, Website : www.bqsgroup.eu,

Notified Body number : 2854

Product name: CMV REAL-TIME PCR Detection Kit

Catalogue numbers: R1-P204-S3/9EU, R1-P204-23/9EU, R1-P204-UA/9EU

Category: *in vitro* diagnostic device and NAT (Nucleic Acid Test) – pathogen-detection-based product

Indication: For *in vitro* diagnostics

Device classification: Class B

Classification Rule: Annex II of IVDD 98/79/EC Council Directive

Conformity assessment route: According to Directive 98/79/EC Annex IV (excl. 4, 6), Full Quality Assurance System

Standards applied: EN ISO 18113-2:2011, ISO 15223-1:2021, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN ISO 14971:2019, ISO/TR 24971:2020, NCCLS EP12AE, EN ISO 18113-1:2011

"DNA-Technology Research&Production" LLC declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and mentioned applicable standards.

The Technical file to the mentioned product is kept by the manufacturer.

EC certification

EC certificate № IVDD 21 019 0118 issued in 28 March 2022

First issued 28 March 2022

Valid from 28 March 2022 Valid until 26 May 2025

EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

APPROVED BY Director General: Mr. Dmitrovskiy V.Y.

SIGNATURE:

PLACE: Moscow

DATE: 28.03.2022

Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: IO 2045-2013

Order No.: IO 1490-2013

Date: 26/09/2013

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

SEEN by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 02 OCT. 2013

NAME: DNA-TECHNOLOGY, RESEARCH & PRODUCTION, LLC,

ADDRESS: 142281, MOSCOW REGION, PROTVINO, ZHELEZNODOROZHNAYA STR., 20, RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 10/09/2013 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 4 DEVICES)

As of the 11/09/2013, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
G.Elkayam
T: +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Brussels Enterprise
Commerce & Industry
date & stamp

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels I Registered Office Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net

Ref. No.: IO 2045 - 2013
Order No.: IO 1490 - 2013

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/EDMS code***
1	Detecting thermocycler/PCR-Diagnostics	DTprime	neither A nor B according to annex II IVD 98/79/EC	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	Detecting thermocyclers DTprimeXXX is intended use for in-vitro diagnostics of using PCR method.	48031
2	Detecting thermocycler/PCR-Diagnostics	DTlite	neither A nor B according to annex II IVD 98/79/EC	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	Detecting thermocyclers DTliteXXX is intended use for in-vitro diagnostics of using PCR method.	48031
3	Fluorescent detector /PCR-Diagnostics	Gene-4	neither A nor B according to annex II IVD 98/79/EC	O-GENE4-EU	Fluorescent detector of a polymerase chain reaction is a special instrument to evaluate fluorescent radiation of light of a reactionary mixture in test tubes directly after finishing a polymerase chain reaction (PCR).	26.03.10.01
4	Real-time PCR Kit/PCR-Diagnostics	FEMOFLOR	neither A nor B according to annex II IVD 98/79/EC	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	The FEMOFLOR® Real-time PCR Kit aimed to improve the efficiency of current diagnostic tools used for identification of female genital infections.	48208

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under his/her responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Manufacturer's Name «DNA-Technology, Research&Production», LLC — **Signature:** _____ **Date:** 27.05.2013 — **Stamp:**

Obelis S.A. — **Signature:** G.ELKAYAM, C.E.O. — **Date:** 30/9/2013 — **Stamp:**

Signature: _____ **Date:** _____ **Stamp:**

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES

Obelis SA
BRUSSELS EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis SA
SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: JW 2815-2014

Order No.: JW 2504-2014

Date: 27/03/2014

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: DNA-TECHNOLOGY RESEARCH & PRODUCTION", LLC

ADDRESS: 20 ZHELEZNODOROZHNAYA STR., 142281 PROTVINO, MOSCOW REGION, RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical device(s) has been completed by Obelis s.a. (O.E.A.R.C.) on the 27/03/2014 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (2 PAGES, 10 DEVICES)

As of the 28/03/2014, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

G. Elkayam

Mr. G. Elkayam CEO
Obelis sa
date & stamp

SEEN by the Brussels Chamber of Commerce
Brussels, the Elke Teck

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
31-03-2014
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

31 MARS 2014

Brussels Enterprise
Commerce & Industry
date & stamp

EAR ISO9001 ISO13485

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

CE

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net

Ref. No.: JW 2815-2014
Order No.: JW 2504-2014

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/ EDMS code***
1	Gnome Programmable Solid State Thermostat / PCR-Diagnostics	Gnome	neither A nor B according to annex II IVD 98/79/EC	O-TT1-EU	Programmable Solid State Thermostat Gnome is intended use for in-vitro diagnostics of using PCR method. The device operation consists in the maintenance of prescribed temperature (as well as changing of temperature according to prescribed program) of matrix having special holes into which the tubes containing reaction mixture are placed.	36785
2	PCR Kit/PCR-Diagnostics	Mycoplasma hominis	neither A nor B according to annex II IVD 98/79/EC	R1-P102-23/9EU R1-P102-S3/9EU F1-P102-51/1EU F1-P102-52/1EU F1-P102-21/1EU	The Mycoplasma hominis PCR Detection Kit is designed to detect Mycoplasma hominis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
3	PCR Kit/PCR-Diagnostics	Mycoplasma genitalium	neither A nor B according to annex II IVD 98/79/EC	R1-P103-23/9EU R1-P103-S3/9EU F1-P103-51/1EU F1-P103-52/1EU F1-P103-21/1EU	The Mycoplasma genitalium PCR Detection Kit is designed to detect Mycoplasma genitalium nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
4	PCR Kit/PCR-Diagnostics	Ureaplasma urealyticum	neither A nor B according to annex II IVD 98/79/EC	R1-P106-23/9EU R1-P106-S3/9EU F1-P106-51/1EU F1-P106-52/1EU F1-P106-21/1EU	The Ureaplasma urealyticum PCR Detection Kit is designed to detect Ureaplasma urealyticum nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
5	PCR Kit/PCR-Diagnostics	Trichomonas vaginalis	neither A nor B according to annex II IVD 98/79/EC	R1-P107-23/9EU R1-P107-S3/9EU F1-P107-51/1EU F1-P107-52/1EU F1-P107-21/1EU	The Trichomonas vaginalis PCR Detection Kit is designed to detect Trichomonas vaginalis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
6	PCR Kit/PCR-Diagnostics	Gardnerella vaginalis	neither A nor B according to annex II IVD 98/79/EC	R1-P108-23/9EU R1-P108-S3/9EU F1-P108-51/1EU F1-P108-52/1EU F1-P108-21/1EU	The Gardnerella vaginalis PCR Detection Kit is designed to detect Gardnerella vaginalis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
31-03-2014
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

G.ELKAYAM
C.E.O.

OBELIS s.a. Anti-Counterfeiting Law

7	PCR Kit/PCR-Diagnostics	Neisseria gonorrhoeae	neither A nor B according to annex II IVD 98/79/EC	R1-P109-23/9EU R1-P109-S3/9EU F1-P109-51/1EU F1-P109-52/1EU F1-P109-21/1EU	The Neisseria gonorrhoeae PCR Detection Kit is designed to detect Neisseria gonorrhoeae nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
8	PCR Kit/PCR-Diagnostics	Candida albicans	neither A nor B according to annex II IVD 98/79/EC	R1-P110-23/9EU R1-P110-S3/9EU F1-P110-51/1EU F1-P110-52/1EU F1-P110-21/1EU	The Candida albicans PCR Detection Kit is designed to detect Candida albicans nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
9	PCR Kit/PCR-Diagnostics	Ureaplasma complex	neither A nor B according to annex II IVD 98/79/EC	R1-P104-23/9EU R1-P104-S3/9EU F1-P104-51/1EU F1-P104-52/1EU F1-P104-21/1EU	The Ureaplasma complex PCR Detection Kit is designed to detect Ureaplasma urealyticum and Ureaplasma parvum nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208
10	PCR Kit/PCR-Diagnostics	Ureaplasma parvum	neither A nor B according to annex II IVD 98/79/EC	R1-P105-23/9EU R1-P105-S3/9EU F1-P105-51/1EU F1-P105-52/1EU F1-P105-21/1EU	The Ureaplasma parvum PCR Detection Kit is designed to detect Ureaplasma parvum nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	48208

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

Manufacturer's Name	***Obelis S.A.***	***BECI***
«DNA-Technology, Research&Production», LLC		
Signature:	***Signature:***	
Date: 20.12.2013	***Date:*** 28/3/2014	***Date:*** 31-03-2014
Stamp: "Научно-производственное объединение ДНК-Технология"	***Stamp:***	***Stamp:*** CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: MC 5223-2017

Order No.: MC 4840-2016

BELGIUM

Date: 12/01/2017

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: "DNA-TECHNOLOGY, RESEARCH & PRODUCTION", LLC

ADDRESS: 142281, 20 ZHELEZNODOROZHNAYA STREET,
PROTVINO, MOSCOW REGION,
RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostic medical devices, as stipulated here above, are fulfilling the applicable requirements of the Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 14/12/2016 in compliance with the Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (4 PAGES, 12 DEVICES)

As of the 15/12/2016, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the EU and EEA territory.

G.ELKAYAM CEO

Mr. G. Elkayam, CEO,
Obelis sa
date & stamp

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

EAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

CE

Ref. No.: MC 5223-2017
Order No.: MC 4840-2016

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/EDMS code	Class**
1	R1-P205-23/9EU R1-P205-S3/9EU R1-P205-24/9EU F1-P205-51/1EU F1-P205-21/1EU	EBV	PCR Kit/PCR-Diagnostics	The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are intended for research and diagnostic applications. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are designed to detect Epstein Barr virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49653	All others
2	R1-P201-23/9EU R1-P201-S3/9EU R1-P201-24/9EU F1-P201-51/1EU F1-P201-21/1EU	HSV 1, 2	PCR Kit/PCR-Diagnostics	The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are intended for research and diagnostic applications. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are designed to detect Herpes symplex virus 1, 2 nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49539	All others
3	R1-P315-S3/4EU	HPV-QUANT-4	PCR Kit/PCR-Diagnostics	The HPV-QUANT-4 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-4 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-4 quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6,11) and high-risk (HPV 16,18) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49994	All others

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4	R1-P317-S3/5EU	HPV-QUANT-21	PCR Kit/PCR-Diagnostics	The HPV-QUANT-21® quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-21® quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-21® quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6, 11, 44) and high-risk (HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49994	All others
5	R1-P403-23/4EU R1-P403-S3/4EU R1-P403-24/4EU F1-P403-51/2EU F1-P403-21/2EU	Legionella pneumophila	PCR Kit/PCR-Diagnostics	The Legionella pneumophila PCR Detection Kit is intended for research and diagnostic applications. The Legionella pneumophila PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Legionella pneumophila PCR Detection Kit is designed to detect Legionella pneumophila nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	51060	All others
6	R1-P404-23/4EU R1-P404-S3/4EU R1-P404-24/4EU F1-P404-51/2EU F1-P404-21/2EU	M. tuberculosis – M. bovis	PCR Kit/PCR-Diagnostics	The M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit and M. tuberculosis – M. bovis FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection products. The Kits are designed to detect Mycobacterium tuberculosis and Mycobacterium bovis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	51149	All others
7	R1-P206-23/4EU R1-P206-S3/4EU R1-P206-24/4EU F1-P206-51/2EU F1-P206-21/2EU	VZV	PCR Kit/PCR-Diagnostics	The VZV REAL-TIME PCR Detection Kit and VZV FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are	47291	All others

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				an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Kits are designed to detect Varicella zoster virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.		
8	R1-H801-S3/5EU	AZF Microdeletions	PCR Kit/PCR-Diagnostics	The AZF Microdeletions REAL-TIME PCR Genotyping Kit is intended for research and diagnostic applications. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is in vitro Nucleic Acid Test (NAT) – based human genotyping product. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is intended for detection of AZF locus deletions which are the common cause of male infertility defined by loss of spermatozoids motion ability (azoospermia) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90	All others
9	R3-P408-23/4EU R3-P408-S3/4EU	Influenza A virus (subtype H1N1)	PCR Kit/PCR-Diagnostics	The Influenza A virus (subtype H1N1) PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus (subtype H1N1) PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus (subtype H1N1) PCR Detection Kit is designed to detect Influenza A virus (subtype H1N1) nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49165	All others
10	R1-P316-S3/4EU	HPV-QUANT-15	PCR Kit/PCR-Diagnostics	The HPV-QUANT-15 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-15 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-15® quantitative PCR Detection Kit is intended for the the specific identification and quantification of low- and high-risk (in regard to oncogenic properties) human papillomaviruses including: low-risk HPV types 6 and 11 without differentiation high-risk HPV types 16, 31,	49994	All others

				33, 35, 52, 58 without differentiation HPV types 18, 39, 45, 59 without differentiation HPV type 56 HPV type 51 HPV type 68 in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.		
11	R3-P409-23/4EU R3-P409-S3/4EU	Influenza A virus	PCR Kit/PCR-Diagnostics	The Influenza A virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus PCR Detection Kit is designed to detect Influenza A virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49161	All others
12	R3-P410-23/4EU R3-P410-S3/4EU	Influenza B virus	PCR Kit/PCR-Diagnostics	The Influenza B virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza B virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza B virus PCR Detection Kit is designed to detect Influenza B virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49205	All others

* Annex A is part of the Agreement
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Manufacturer's Name ***Obelis S.A.***

«DNA-Technology, Research&Production», LLC

Signature: ***Signature:*** G.ELKAYAM C.E.O.

Date: 15.12.2016 ***Date:*** 16/1/2017

Stamp: ***Stamp:***

"Научно-производственное объединение ДНК-Технология"

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: GR 1922-2021

Order No.: LM 2003-2021

Belgium

Date: 27/07/2021

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name:	DNA-Technology, Research & Production, LLC
Address:	20 Zheleznodorozhnaya Street Protvino, Moscow Region 142281, Russia

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 27/07/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices (6 pages, 10 Devices)

As of the 28/07/2021, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Order No.: GR 1922-2021
Ref No.: LM 2003-2021

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	P-910-1/1EU	STOR-M transport medium	General specimen container IVD, additive/medium	The STOR-M transport medium is intended for transport and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye), including those containing an impurity of mucus, followed by nucleic acids analysis (human and microbial DNA, viral RNA) by polymerase chain reaction method.	63232	neither A or B according II IVD 98/79/EC
2.	P-001/1EU P-021/4EU	PREP-RAPID DNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-RAPID DNA Extraction Kit is intended for DNA extraction from biological materials (saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) for further analysis by polymerase chain reaction (PCR). The PREP-RAPID Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	52521	neither A or B according II IVD 98/79/EC

3.	P-002/1EU P-002/2EU	PREP-NA DNA/RNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits are intended for DNA/RNA extraction from biological materials for further analysis with reverse transcription (RNA) and/or polymerase chain reaction (DNA). In the PREP-NA PLUS DNA/RNA Extraction Kit the total volume of purified DNA/RNA is larger comparing to standard PREP-NA DNA/RNA Extraction Kit (50 µL) for more PCR tests.	52521	neither A or B according II IVD 98/79/EC
4.	P-007-N/1EU	PREP-NA-S DNA/RNA Extraction Kit	Nucleic acid extraction/isolation kit IVD	The ***PREP-NA-S* DNA/RNA Extraction Kit** is intended for fast NA extraction from biological materials for further analysis by RT-PCR (PCR with Reverse Transcription)/PCR (polymerase chain reaction). The ***PREP-NA-S* DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs.	52521	neither A or B according II IVD 98/79/EC
5.	P-003/1EU, P-003/2EU, P-023/4EU	PREP-GS DNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-GS and PREP-GS PLUS DNA Extraction Kits are intended for DNA extraction from biological materials for further analysis by polymerase chain reaction (PCR). In the PREP-GS PLUS DNA Extraction Kit the total volume of purified DNA is larger comparing to standard PREP-GS DNA Extraction Kit for more PCR tests. The PREP-GS Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	52521	neither A or B according II IVD 98/79/EC

	R1-P023-S3/5EU	MycosoScreen REAL-TIME PCR Detection Kit	Multiple fungi/yeast species nucleic acid IVD, kit	The ***MycosoScreen* REAL-TIME PCR Detection Kit** is intended for detection and typing of fungal infectious agents from genus Candida, Malassezia, Saccharomyces and Debaryomyces: Meyerozyma guilliermondii (C. guilliermondii), Candida albicans, Pichia kudriavzevii (C.krusei), Saccharomyces cerevisiae, Candida auris, Candida tropicalis, Clavispora lusitaniae (C.lusitaniae), Debaryomyces hansenii (C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Kluyveromyces marxianus (C.kefyr), Malassezia furfur. Samples are human biological material (blood, phlegm, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates), catheter and endotracheal tube washings, and fungal cultures.	51973	neither A or B according II IVD 98/79/EC

	R1-H004-23/4EU, R1-H004-S3/4EU, R1-H004-N3/4EU	HLA-B27 REAL-TIME PCR Genotyping Kit	HLA-B27 genotyping IVD, kit, nucleic acid technique (NAT)	The HLA-B27 REAL-TIME PCR Genotyping Kit is intended for rapid group-specific detection of HLA-B27 alleles (major histocompatibility complex, class I, B) by Real-Time PCR method. Samples are human biological materials: peripheral blood. These alleles are generally recognized as a genetic marker of multiple disease conditions e.g. rheumatoid arthritis and ankylosing spondylitis (Bekhterev's disease). Indications for the use: - the presence of clinical symptoms of spondyloarthropathies: inflammatory back pain, asymmetric peripheral oligoarthritis, mainly of the lower extremities, enteritis and/or tendosynovitis; - as an additional laboratory indicator for predicting the severity of spondyloarthropathies	65537	neither A or B according II IVD 98/79/EC
	R1-P501-S3/9EU, R1-P501-23/9EU R1-P501-UA/9EU	Helicobacter pylori REAL-TIME PCR Detection Kit	Helicobacter pylori nucleic acid IVD, kit, nucleic acid technique (NAT)	The Helicobacter pylori REAL-TIME PCR Detection Kit is designed to detect Helicobacter pilory DNA in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: bioptates, faeces.	51000	neither A or B according II IVD 98/79/EC

	R1-P028-S3/6EU	BacScreen OM REAL-TIME PCR Detection Kit	Multiple-bacteria-genus IVDs	The ***BacScreen OM* REAL-TIME PCR Detection Kit** is designed for DNA analysis of opportunistic bacteria from classes Bacilli, Betaproteobacteria and Gammaproteobacteria that cause nosocomial and community-acquired infections with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures.	63010	neither A or B according II IVD 98/79/EC
	R1-P026-S3/5EU, R1-P027-S3/4EU, R1-P027-23/4EU	BacResista GLA REAL-TIME PCR Detection Kits	Multiple antimicrobial resistance nucleic acid IVD, kit	The BacResista GLA and BacResista Gla Van/Mec REAL-TIME PCR Detection Kits are designed for DNA analysis of bacteria resistant to glycopeptide (G) and beta-lactam (L) antibiotics (A) in DNA material obtained from biological samples and bacterial cultures with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures. Indications for the use: the need to study a possible antibiotic resistance in bacteria that caused infectious disease.	60673	neither A or B according II IVD 98/79/EC

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature: _____

Date: _____

Stamp:

G. ELKAYAM
C.E.O.

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Obelis GROUP

Registered Office Address
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Registered Adresss
Bd Général Wahis 53
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CERTIFICATE OF IVD NOTIFICATION

Reference No.: LM 0622-2022

Order No.: EU MD 0481-2022

BELGIUM

Date: 13/06/2022

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name: DNA-Technology, Research & Production, LLC

Address: 20 Zheleznodorozhnaya Street
Protvino, Moscow Region
142281, Russia

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the IVD device(s) comply(ies) with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical device(s), as stipulated here above, is/are fulfilling the applicable requirements of the European Council Directive 98/79/EC on the

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (EC REP) on in compliance with the European Council Directive 98/79/EC - article 10 requirements on the 25/05/2022

IN-VITRO DIAGNOSTIC MEDICAL DEVICE(S): Please See Annex A - List of Devices (11 Devices; 3 Pages)

As of the 26/05/2022 , and provided that the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this(ese) device(s);

- Place this(ese) device(s) in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).*

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Mr. G. Elkayam CEO
Obelis sa

Obelis -1988-

EAAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate will become void automatically upon termination of the EAR agreement

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class and Rule under IVDD
1.	R1-P445-S3/4EU R1-P445-23/4EU	C. diphtheriae Tox Multiplex REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	C. diphtheriae Tox Multiplex REALTIME PCR Detection Kit is intended for detection of DNA and differentiation of toxigenic and nontoxigenic strains of C. diphtheriae in human biological material (smears/scrapes from nasopharyngeal, oropharyngeal mucous membrane, smears from affected skin areas) and bacterial cultures from this biomaterial by real-time PCR.	50879	Neither A nor B according II IVD 98/79/EC
2	R1-H952-N3/4EU R1-H964-N3/4EU	FAMILIAL MEDITERRANEAN FEVER REAL-TIME PCR Genotyping Kit	REAL-TIME PCR Detection Kit	Familial Mediterranean Fever REALTIME PCR Genotyping Kit is intended for the identification of MEFV gene mutations (OMIM #134610) with an aid of PCR method.	59478	Neither A nor B according II IVD 98/79/EC
3	R1-P202-S3/9EU R1-P202-23/9EU	HHV6 REALTIME PCR Detection Kit	REAL-TIME Detection Kit	HHV6 REAL-TIME PCR Detection Kit is designed to detect HHV6 nucleic acids in human biological samples with an aid of PCR method.	49743	Neither A nor B according II IVD 98/79/EC
4	R1-P203-S3/9EU R1-P203-23/9EU	HHV8 REALTIME PCR Detection Kit	REAL-TIME Detection Kit	HHV8 REAL-TIME PCR Detection Kit is designed to detect HHV8 nucleic acids in human biological samples with an aid of PCR method.	49809	Neither A nor B according II IVD 98/79/EC
5	R1-P320-23/9EU R1-P320-S3/9EU	HPV 16,18 Multiplex REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	HPV 16,18 Multiplex REAL-TIME PCR Detection Kit is intended for detection and typing of two most oncogenic and persistent high-risk human papilloma virus types (HPV 16, HPV 18) in human biological samples (epithelial cell smears from urethra, cervical canal, cervix) by method of multiplex Real Time PCR.	49997	Neither A nor B according II IVD 98/79/EC

6	R1-P325-S3/9EU R1-P325-23/9EU	HPV SCREEN HR14(16-18-45) REAL-TIME PCR Kit	REAL-TIME PCR Detection Kit	HPV SCREEN HR14(16-18-45) REALTIME PCR Kit is designed to detect HPV nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: epithelial smears/scrapes from the mucous membrane of the cervical canal and the vagina.	49997	Neither A nor B according II IVD 98/79/EC
7	R3-P448-S3/9EU R3-P448-23/9EU R3-P448-N3/9EU R3-P448-VA/XEU	SARS-CoV2/RSV/ Influenza AB virus Multiplex REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	SARSCoV-2/RSV/Influenza AB virus Multiplex REAL-TIME PCR Detection Kit is designed to detect Coronavirus SARS-CoV-2, Human respiratory syncytial virus (RSV), Influenza A virus and Influenza B virus in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	47922	Neither A nor B according II IVD 98/79/EC
8	R1-P804-S3/5EU R1-P804-XA/4EU	Femoflor Screen REALTIME PCR Detection Kit	REAL-TIME PCR Detection Kit	Femoflor Screen REAL-TIME PCR Detection Kit is designed to detect pathogens, opportunistic flora and normal flora in urogenital specimens with an aid of Polymerase Chain Reaction (PCR) method.	50409	B, according II IVD 98/79/EC
9	R1-P809-S3/6EU R1-P809-XA/5EU	Androflor REAL-TIME PCR Detection Kit	REAL-TIME Detection Kit	The Androflor and Androflor Screen REAL-TIME PCR Detection Kits are designed to detect the total bacterial DNA (total bacterial mass), DNA of the opportunistic and true pathogens in men's urogenital tract by multiplex Real Time Polymerase Chain Reaction (PCR) method.	50409	B,according II IVD 98/79/EC
10	R1-P810 - S3/5EU R1-P810 - XA/4EU	Androflor Screen REALTIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The Androflor and Androflor Screen REAL-TIME PCR Detection Kits are designed to detect the total bacterial DNA (total bacterial mass), DNA of the opportunistic and true pathogens in men's urogenital tract by multiplex Real Time Polymerase Chain Reaction (PCR) method.	50409	B, according II IVD 98/79/EC

11	P-122-A/9EU P-122-N/9EU P-122-P/9EU P-123-P/9EU P-124-P/9EU	PREP-MB-RAPID DWP DNA/RNA Extraction Kit	REAL-TIME PCR Detection Kit	PREP-MB-RAPID DWP DNA/RNA Extraction Kit is designed to extract NA from biological materials: scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.	52521	Neither A nor B according II IVD 98/79/EC

*Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility **(IVD 98/79/EC).**

Obelis s.a.

Date: 13/06/2022

Stamp

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EUROPEAN AUTHORIZED REPRESENTATIVE CENTER
Obelis -1988-

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products

No	Code No.	Name
1	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	DTprime
2	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	DTlite
3	O-GENE4-EU	Gene-4
4	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	FEMOFLOR

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).

- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015;
- ISO 13485:2016.

Corporate Contact Information

"DNA-Technology, Research&Production", LLC
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Country: Russia
Phone: +7(495)640-17-71; +7(4967) 31-07-64;
Fax: +7(4967) 31-06-70; +7(495)640-17-71
E-mail: info@dna-technology.com, protvino@dna-technology.ru
Mr. Vladimir Dmitrovskiy
Position: General Director

Signature:

Date 27 July 2019

Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products

No	Code No.	Name
1	O-TT1-EU	**Gnome**
2	R1-P102-23/9EU R1-P102-S3/9EU	**Mycoplasma hominis** REAL-TIME PCR detection Kit
	F1-P102-51/1EU F1-P102-52/1EU F1-P102-21/1EU	**Mycoplasma hominis** FLASH PCR detection Kit
3	R1-P103-23/9EU R1-P103-S3/9EU	**Mycoplasma genitalium** REAL-TIME PCR detection Kit
	F1-P103-51/1EU F1-P103-52/1EU F1-P103-21/1EU	**Mycoplasma genitalium** FLASH PCR detection Kit
4	R1-P106-23/9EU R1-P106-S3/9EU	**Ureaplasma urealyticum** REAL-TIME PCR detection Kit
	F1-P106-51/1EU F1-P106-52/1EU F1-P106-21/1EU	**Ureaplasma urealyticum** FLASH PCR detection Kit
5	R1-P107-23/9EU R1-P107-S3/9EU	**Trichomonas vaginalis** REAL-TIME PCR detection Kit
	F1-P107-51/1EU F1-P107-52/1EU F1-P107-21/1EU	**Trichomonas vaginalis** FLASH PCR detection Kit
6	R1-P108-23/9EU R1-P108-S3/9EU	**Gardnerella vaginalis** REAL-TIME PCR detection Kit
	F1-P108-51/1EU F1-P108-52/1EU F1-P108-21/1EU	**Gardnerella vaginalis** FLASH PCR detection Kit

7	R1-P109-23/9EU R1-P109-S3/9EU	**Neisseria gonorrhoeae** REAL-TIME PCR detection Kit
	F1-P109-51/1EU F1-P109-52/1EU F1-P109-21/1EU	**Neisseria gonorrhoeae** FLASH PCR detection Kit
8	R1-P110-23/9EU R1-P110-S3/9EU	**Candida albicans** REAL-TIME PCR detection Kit
	F1-P110-51/1EU F1-P110-52/1EU F1-P110-21/1EU	**Candida albicans** FLASH PCR detection Kit
9	R1-P104-23/9EU R1-P104-S3/9EU	**Ureaplasma complex** REAL-TIME PCR detection Kit
	F1-P104-51/1EU F1-P104-52/1EU F1-P104-21/1EU	**Ureaplasma complex** FLASH PCR detection Kit
10	R1-P105-23/9EU R1-P105-S3/9EU	**Ureaplasma parvum** REAL-TIME PCR detection Kit
	F1-P105-51/1EU F1-P105-52/1EU F1-P105-21/1EU	**Ureaplasma parvum** FLASH PCR detection Kit

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

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- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).

- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.
Our current Quality System is formatted to international standards:

- ISO 9001:2015;
- ISO 13485:2016.

Corporate Contact Information

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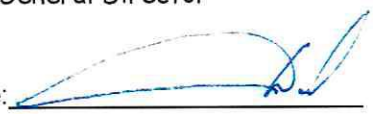
Mr. Vladimir Dmitrovskiy
Position: General Director

Signature: 

Date : 29 July 2019

Stamp

European Authorized Representative:
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Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

- *Please refer to the attached Annex to Declaration of Conformity*

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

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Mr. Vladimir Dmitrovskiy
Position: General Director

Signature: _____

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Representative: Mr. Gideon ELKAYAM (CEO)

Annex to the Declaration of Conformity

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
EBV REAL-TIME PCR Detection Kit	R1-P205-S3/9EU (0.2 ml strips)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are intended for research and diagnostic applications. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are designed to detect Epstein Barr virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P205-23/9EU (0.2 ml tubes)	**96**		
EBV FLASH PCR Detection Kit	F1-P205-21/1EU (0.2 ml tubes)	**100**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P205-51/1EU (0.5 ml tubes)	**100**		
EBV REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P205-24/9EU (0.2 ml tubes)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
HSV 1, 2 REAL-TIME PCR Detection Kit	R1-P201-S3/9EU (0.2 ml strips)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are intended for research and diagnostic applications. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are designed to detect Herpes symplex virus 1, 2 nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P201-23/9EU (0.2 ml tubes)	**96**		
HSV 1, 2 FLASH PCR Detection Kit	F1-P201-21/1EU (0.2 ml tubes)	**100**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P201-51/1EU (0.5 ml tubes)	**100**		
HSV 1, 2 REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P201-24/9EU (0.2 ml tubes)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
HPV-QUANT-4® quantitative Real-Time PCR Detection Kit	R1-P315-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix for HPV 6,11 amplification ▪ Paraffin sealed PCR-mix for	**The HPV-QUANT-4 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-4 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-4 quantitative PCR**

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
			HPV 16,18 amplification ▪ Paraffin sealed PCR-mix for SIC amplification ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6,11) and high-risk (HPV 16,18) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
HPV-QUANT-21® quantitative Real-Time PCR Detection Kit	R1-P317-S3/5EU (0.2 ml strips)	**24**	▪ Paraffin sealed PCR-mix ▪ MAX Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HPV-QUANT-21® quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-21® quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-21® quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6, 11, 44) and high-risk (HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
Legionella pneumophila Real-Time PCR Detection Kit	R1-P403-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The Legionella pneumophila PCR Detection Kit is intended for research and diagnostic applications. The Legionella pneumophila PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Legionella pneumophila PCR Detection Kit is designed to detect Legionella pneumophila nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P403-23/4EU (0.2 ml tubes)	**48**		
Legionella pneumophila FLASH PCR Detection Kit	F1-P403-21/2EU (0.2 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P403-51/2EU (0.5 ml tubes)	**50**		
Legionella pneumophila Real-Time PCR Detection Kit (Rotor-Gene)	R1-P403-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
M. tuberculosis – M. bovis FLASH PCR Detection Kit	F1-P404-51/2EU (0.5 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	**The M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit and M. tuberculosis – M. bovis FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection products. The Kits are designed to detect Mycobacterium tuberculosis and Mycobacterium bovis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	F1-P404-21/2EU (0.2 ml tubes)	**50**		
M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit	R1-P404-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	
	R1-P404-S3/4EU (0.2 ml strips)	**48**		
M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P404-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
VZV REAL-TIME PCR Detection Kit	R1-P206-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The VZV REAL-TIME PCR Detection Kit and VZV FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Kits are designed to detect Varicella zoster virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P206-23/4EU (0.2 ml tubes)	**48**		
VZV FLASH PCR Detection Kit	F1-P206-21/2EU (0.2 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P206-51/2EU (0.5 ml tubes)	**50**		
VZV REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P206-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
AZF Microdeletions REAL-TIME PCR Genotyping Kit	R1-H801-S3/5EU (0.2 ml strips)	**24**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The AZF Microdeletions REAL-TIME PCR Genotyping Kit is intended for research and diagnostic applications. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is in vitro Nucleic Acid Test (NAT) – based human genotyping product. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is intended for**

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
				detection of AZF locus deletions which are the common cause of male infertility defined by loss of spermatozoids motion ability (azoospermia) with an aid of Polymerase Chain Reaction (PCR) method.
Influenza A virus (subtype H1N1) PCR Detection Kit	R3-P408-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza A virus (subtype H1N1) PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus (subtype H1N1) PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus (subtype H1N1) PCR Detection Kit is designed to detect Influenza A virus (subtype H1N1) nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P408-S3/4EU (0.2 ml strips)	**48**		
HPV-QUANT-15® quantitative PCR Detection Kit	R1-P316-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ MAX Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HPV-QUANT-15 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-15 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-15® quantitative PCR Detection Kit is intended for the the specific identification and quantification of low- and high-risk (in regard to oncogenic properties) human papillomaviruses including: low-risk HPV types 6 and 11 without differentiation high-risk HPV types 16, 31, 33, 35, 52, 58 without differentiation HPV types 18, 39, 45, 59 without differentiation HPV type 56 HPV type 51 HPV type 68 in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
Influenza A virus Real-Time PCR Detection Kit	R3-P409-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza A virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus PCR Detection Kit is designed to detect Influenza A virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P409-S3/4EU (0.2 ml strips)	**48**		

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
Influenza B virus Real-Time PCR Detection Kit	R3-P410-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza B virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza B virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza B virus PCR Detection Kit is designed to detect Influenza B virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P410-S3/4EU (0.2 ml strips)	**48**		

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Mr. Vladimir Dmitrovskiy
Position: General Director

Signature: _____

Date: 29 July 2019

Stamp

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Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

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#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	P-910-1/1EU	STOR-M transport medium	The STOR-M transport medium is intended for transport and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye), including those containing an impurity of mucus, followed by nucleic acids analysis (human and microbial DNA, viral RNA) by polymerase chain reaction method.	neither A or B according II IVD 98/79/EC
2.	P-001/1EU P-021/4EU	PREP-RAPID DNA Extraction Kits	The PREP-RAPID DNA Extraction Kit is intended for DNA extraction from biological materials (saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) for further analysis by polymerase chain reaction (PCR). The PREP-RAPID Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	neither A or B according II IVD 98/79/EC
3.	P-002/1EU P-002/2EU	PREP-NA DNA/RNA Extraction Kits	The PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits are intended for DNA/RNA extraction from biological materials for further analysis with reverse transcription (RNA) and/or polymerase chain reaction (DNA). In the PREP-NA PLUS DNA/RNA Extraction Kit the total volume of purified DNA/RNA is larger comparing to standard PREP-NA DNA/RNA Extraction Kit (50 µL) for more PCR tests.	neither A or B according II IVD 98/79/EC
4.	P-007-N/1EU	PREP-NA-S DNA/RNA Extraction Kit	The ***PREP-NA-S* DNA/RNA Extraction Kit** is intended for fast NA extraction from biological materials for further analysis by RT-PCR (PCR with Reverse Transcription)/PCR (polymerase chain reaction). The ***PREP-NA-S* DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs.	neither A or B according II IVD 98/79/EC

5.	P-003/1EU, P-003/2EU, P-023/4EU	PREP-GS DNA Extraction Kits	The PREP-GS and PREP-GS PLUS DNA Extraction Kits are intended for DNA extraction from biological materials for further analysis by polymerase chain reaction (PCR). In the PREP-GS PLUS DNA Extraction Kit the total volume of purified DNA is larger comparing to standard PREP-GS DNA Extraction Kit for more PCR tests. The PREP-GS Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	neither A or B according II IVD 98/79/EC
6.	R1-P023-S3/5EU	MycosoScreen REAL-TIME PCR Detection Kit	The ***MycosoScreen*** **REAL-TIME PCR Detection Kit** is intended for detection and typing of fungal infectious agents from genus Candida, Malassezia, Saccharomyces and Debaryomyces: Meyerozyma guilliermondii (C. guilliermondii), Candida albicans, Pichia kudriavzevii (C.krusei), Saccharomyces cerevisiae, Candida auris, Candida tropicalis, Clavispora lusitaniae (C.lusitaniae), Debaryomyces hansenii (C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Kluyveromyces marxianus (C.kefyr), Malassezia furfur. Samples are human biological material (blood, phlegm, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates), catheter and endotracheal tube washings, and fungal cultures.	neither A or B according II IVD 98/79/EC
7.	R1-H004-23/4EU, R1-H004-S3/4EU, R1-H004-N3/4EU	HLA-B27 REAL-TIME PCR Genotyping Kit	The HLA-B27 REAL-TIME PCR Genotyping Kit is intended for rapid group-specific detection of HLA-B27 alleles (major histocompatibility complex, class I, B) by Real-Time PCR method. Samples are human biological materials: peripheral blood. These alleles are generally recognized as a genetic marker of multiple disease conditions e.g. rheumatoid arthritis and ankylosing spondylitis (Bekhterev's disease). Indications for the use: - the presence of clinical symptoms of spondyloarthropathies: inflammatory back pain, asymmetric peripheral oligoarthritis, mainly of the lower extremities, enteritis and/or tendosynovitis; - as an additional laboratory indicator for predicting the severity of spondyloarthropathies	neither A or B according II IVD 98/79/EC
8.	R1-P501-S3/9EU, R1-P501-23/9EU R1-P501-UA/9EU	Helicobacter pylori REAL-TIME PCR Detection Kit	The Helicobacter pylori REAL-TIME PCR Detection Kit is designed to detect Helicobacter pilory DNA in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: bioptates, faeces.	neither A or B according II IVD 98/79/EC
9.	R1-P028-S3/6EU	BacScreen OM REAL-TIME PCR Detection Kit	The ***BacScreen OM*** **REAL-TIME PCR Detection Kit** is designed for DNA analysis of opportunistic bacteria from classes Bacilli, Betaproteobacteria and Gammaproteobacteria that cause nosocomial and community-acquired infections with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures.	neither A or B according II IVD 98/79/EC
10.	R1-P026-S3/5EU, R1-P027-S3/4EU, R1-P027-23/4EU	BacResista GLA REAL-TIME PCR Detection Kits	The BacResista GLA and BacResista Gla Van/Mec REAL-TIME PCR Detection Kits are designed for DNA analysis of bacteria resistant to glycopeptide (G) and beta-lactam (L) antibiotics (A) in DNA material obtained from biological samples and bacterial cultures with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures. Indications for the use: the need to study a possible antibiotic resistance in bacteria that caused infectious disease.	neither A or B according II IVD 98/79/EC

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Responsible person: Mr. Vladimir Dmitrovskiy
Position: General Director
SIGNATURE :
Date : 22.07.2021
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#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	R1-P445-S3/4EU R1-P445-23/4EU	C. diphtheriae Tox Multiplex REAL-TIME PCR Detection Kit	C. diphtheriae Tox Multiplex REAL-TIME PCR Detection Kit is intended for detection of DNA and differentiation of toxigenic and nontoxigenic strains of C. diphtheriae in human biological material (smears/scrapes from nasopharyngeal, oropharyngeal mucous membrane, smears from affected skin areas) and bacterial cultures from this biomaterial by real-time PCR.	neither A or B according II IVD 98/79/EC
2.	R1-H952-N3/4EU R1-H964-N3/4EU	FAMILIAL MEDITERRANEAN FEVER REAL-TIME PCR Genotyping Kit	Familial Mediterranean Fever REALTIME PCR Genotyping Kit is intended for the identification of MEFV gene mutations (OMIM #134610) with an aid of PCR method.	neither A or B according II IVD 98/79/EC
3.	R1-P202-S3/9EU R1-P202-23/9EU	HHV6 REAL-TIME PCR Detection Kit	HHV6 REAL-TIME PCR Detection Kit is designed to detect HHV6 nucleic acids in human biological samples with an aid of PCR method.	neither A or B according II IVD 98/79/EC
4.	R1-P203-S3/9EU R1-P203-23/9EU	HHV8 REAL-TIME PCR Detection Kit	HHV8 REAL-TIME PCR Detection Kit is designed to detect HHV8 nucleic acids inhuman biological samples with an aid of PCR method.	neither A or B according II IVD 98/79/EC
5.	R1-P320-23/9EU R1-P320-S3/9EU	HPV 16,18 Multiplex REAL-TIME PCR Detection Kit	HPV 16,18 Multiplex REAL-TIME PCR Detection Kit is intended for detection and typing of two most oncogenic and persistent high-risk human papilloma virus types (HPV 16, HPV 18) in human biological samples (epithelial cell smears from urethra, cervical canal, cervix) by method of multiplex Real-Time PCR.	neither A or B according II IVD 98/79/EC

6.	R1-P325-S3/9EU R1-P325-23/9EU	HPV SCREEN HR14(16-18-45) REAL-TIME PCR Kit	HPV SCREEN HR14(16-18-45) REAL-TIME PCR Kit is designed to detect HPV nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: epithelial smears/scrapes from the mucous membrane of the cervical canal and the vagina.	neither A or B according II IVD 98/79/EC
7.	R3-P448-S3/9EU R3-P448-23/9EU R3-P448-N3/9EU R3-P448-VA/XEU	SARS-CoV-2/RSV/Influenza AB virus Multiplex REAL-TIME PCR Detection Kit	SARSCoV-2/RSV/Influenza AB virus Multiplex REAL-TIME PCR Detection Kit is designed to detect Coronavirus SARS-CoV-2, Human respiratory syncytial virus (RSV), Influenza A virus and Influenza B virus in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	neither A or B according II IVD 98/79/EC
8.	P-122-A/9EU P-122-N/9EU P-122-P/9EU P-123-P/9EU P-124-P/9EU	PREP-MB-RAPID DWP DNA/RNA Extraction Kit	PREP-MB-RAPID DWP DNA/RNA Extraction Kit is designed to extract NA from biological materials: scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.	neither A or B according II IVD 98/79/EC

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015
- ISO 13485:2016

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