

1. HUMAN PATHOGEN DETECTION & GENOTYPING

1.1 Hepatitis Viruses

Order number	Product name	Intended use	Legal Status	Tests/Size
BA001	Hepatitis A RNA (HAV) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HAV</i> RNA (quantitative; with or without RNA Extraction)	CE	50, 96
BA401	Hepatitis B DNA (HBV qual) PCR Kit	Real Time PCR test for detection of <i>HBV</i> DNA (qualitative; with or without DNA Extraction)	CE	48
BA002	Hepatitis B DNA (HBV quant) PCR Kit	Real Time PCR test for detection of <i>HBV</i> DNA (quantitative; with or without DNA Extraction)	CE	25, 48, 60, 96, 100, 120
BA402	Hepatitis C RNA (HCV qual) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HCV</i> RNA (qualitative; with or without RNA Extraction)	CE	24, 48
BA003	Hepatitis C RNA (HCV quant) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HCV</i> RNA (quantitative; with or without RNA Extraction)	CE	48, 60, 96, 100, 120
BA004	Hepatitis D RNA (HDV) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HDV</i> RNA (quantitative; with or without RNA Extraction)	CE	50, 60, 96, 100, 120
BA005	Hepatitis E RNA (HEV) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HEV</i> RNA (quantitative; with or without RNA Extraction)	CE	25, 32, 48, 50, 96
BA006	Hepatitis G RNA (HDV) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HGV</i> RNA (qualitative; with or without RNA Extraction)	CE	25, 50
BA011	HBV Genotyping Kit	Real Time PCR test or PCR/reverse Line Blot test for detection of <i>HBV</i> DNA genotypes A-H	CE	20, 50
BA008	HBV/HDV PCR Kit	Multiplex Real Time PCR test for simultaneous detection of <i>HBV</i> and <i>HDV</i>	RUO	100
BA012	HCV Genotyping Kit	Real Time PCR test or PCR/reverse Line Blot test for detection of <i>HCV</i> RNA 1a,1b, 2, 3a, 4, 5a, 6 genotypes	CE	20, 24, 48, 50
BA009	HCV/HBV/HIV PCR Kit	Multiplex Real Time PCR test for simultaneous detection of <i>HBV</i> , <i>HCV</i> and <i>HIV-1</i>	RUO	100
BA010	HCV/HBV/HIV1/HIV2 PCR Kit	Multiplex Real Time PCR test for simultaneous detection of <i>HBV</i> , <i>HCV</i> , <i>HIV-1</i> and <i>HIV-2</i>	RUO	100
BA007	Transfusion-transmitted Virus (TTV) PCR Kit	Real Time PCR test for detection of <i>TTV</i> (synonym: Torque Teno Virus) DNA, often found in patients with liver disease	CE	25

1.2 Human Immunodeficiency Virus

Order number	Product name	Intended use	Legal Status	Tests/Size
BA013	Human Immuno-deficiency Virus (HIV-1) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HIV-1</i> RNA (quantitative; with or without RNA Extraction)	CE	25, 48, 60, 96, 100, 120
BA014	Human Immuno-deficiency Virus (HIV-2) RT-PCR Kit (one-step)	Real Time PCR test for detection of <i>HIV-2</i> RNA (quantitative; with or without RNA Extraction)	RUO	25

HIV-associated diseases

BA015	Pneumocystis PCR Kit	Real Time PCR test for detection and/or quantification of <i>Pneumocystis jirovecii</i> (<i>carinii</i>) DNA	CE	48, 50, 96, 100
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1.3 Human Papilloma Viruses

Order number	Product name	Intended use	Legal Status	Tests/Size
BA403	High Risk HPV Genotyping PCR Kit	Real Time PCR test combined with Multi-Color Melting Curve Analysis to identify the 14 high-risk <i>HPV</i> types, including <i>HPV</i> -16, 18, 31,33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68	CE	48
BA018	Human Papilloma Virus (HPV) Detection and Differentiation PCR Kit	Amplification/Reverse hybridization assay for the differentiation of "high risk" and "low risk" genotypes and the typing of <i>HPV</i> 16, 18, 45, 6, 11, 30s and 50s genotypes	CE	12, 60
BA017	Human Papilloma Virus (HPV) High Risk Screen PCR Kit	Real Time PCR test for quantitative screening of ≥ 12 <i>HPV</i> (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59) in 1 tube; with or without DNA Extraction	CE	25, 60, 100
BA020	Human Papilloma Virus Genotyping PCR Kit	Real Time PCR test or strip test for detection and genotyping of Low & High Risk <i>HPV</i>	CE	20, 48, 96

1.4 Sexually transmitted diseases

Order number	Product name	Intended use	Legal Status	Tests/Size
BA021	Bacterial Vaginosis PCR Kit	Multiplex Real Time PCR test for detection or quantification of <i>G. vaginalis</i> , <i>Atopobium vaginae</i> , <i>Lactobacillus spp.</i> and total bacteria in the vaginal biotope	CE	100
BA022	Candidosis PCR Kits	Real Time PCR test for quantitative detection of <i>C. albicans</i> , <i>C. glabrata</i> , <i>C. krusei</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i> DNA	CE	100
BA023	Chlamydia PCR Kit	Real Time PCR test for detection or quantification of <i>Chlamydia trachomatis</i> DNA	CE	48, 50, 96, 100
BA404	CT/NG PCR Kit	Multiplex Real Time PCR test for detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA	CE	48, 96
BA024	Gardnerella PCR Kit	Real Time PCR test for detection of <i>Gardnerella vaginalis</i>	CE	100
BA405	Mycoplasma genitalium PCR Kit	Real Time PCR test for detection of <i>Mycoplasma genitalium</i> genome by amplification of the B subunit of DNA gyrase gene.	CE	50
BA406	Mycoplasma hominis PCR Kit	Real Time PCR test for the identification of <i>Mycoplasma hominis</i> genome by amplification of the 16S rRNA gene.	CE	50
BA025	Mycoplasma species PCR Kit	Real Time PCR test for detection of <i>Mycoplasma species</i> (<i>M. hominis</i> , <i>M. genitalis</i>) DNA	CE	48, 50, 55, 96, 100, 110
BA026	Neisseria PCR Kit	Real Time PCR test or Amplification/Reverse hybridization assay for detection of <i>Neisseria gonorrhoeae</i> DNA	CE	16, 25, 48, 96, 100
BA407	STD Panel PCR Kit (11 pathogens)	Amplification/Reverse hybridization assay for detection of pathogens related to Sexual Transmitted Diseases, 11 pathogens (<i>T. pallidum</i> , <i>C. trachomatis</i> , <i>N. gonorrhoeae</i> , <i>M. genitalium</i> , <i>T. vaginalis</i> , <i>U. parvum</i> , <i>U. urealyticum</i> , <i>M. hominis</i> , <i>H. simplex I</i> , <i>H. simplex II</i> , <i>L. venereum</i>)	CE	16
BA408	<i>T. vaginalis</i> / <i>N. gonorrhoeae</i> / <i>Chl. Trachomatis</i> PCR Kit	Multiplex Real Time PCR test for detection of <i>T. vaginalis</i> , <i>N. gonorrhoeae</i> and <i>Chl. trachomatis</i> DNA	CE	100
BA028	Treponema PCR Kit	Real Time PCR test for detection of <i>Treponema pallidum</i> DNA	CE	100
BA029	Trichomonas PCR Kit	Real Time PCR test for detection of <i>Trichomonas vaginalis</i> DNA	CE	48, 96, 100
BA030	Ureaplasma species PCR Kit	Real Time PCR test for detection of <i>Ureaplasma species</i> (<i>U. parvum</i> , <i>U. urealyticum</i>) DNA	CE	48, 96, 100
BA409	Urethritis PCR Kit	Multiplex Real Time PCR test for detection of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Mycoplasma genitalium</i> DNA	CE	32
BA410	Vaginal Swab PCR Kit (6 pathogens)	Multiplex Real Time PCR test for detection of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Mycoplasma genitalium</i> , <i>herpes simplex virus 1, 2</i> , <i>Treponema pallidum</i> DNA	CE	32

Combined kits (several combination tests)

BA032	Chlamydia trachomatis/ <i>N. gonorrhoeae</i> PCR Kit	Multiplex Real Time PCR test for detection of <i>Chlamydia trachomatis</i> and <i>N. gonorrhoeae</i> DNA	CE	25, 48, 96 100
BA031	Chlamydia trachomatis/ <i>Ureaplasma</i> / <i>M. hominis</i> PCR Kit	Multiplex Real Time PCR test for detection of <i>Chlamydia trachomatis</i> / <i>Ureaplasma</i> / <i>M. hominis</i> DNA	CE	48, 96 100

1.5 Herpes Virus Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
BA033	Epstein-Barr Virus (EBV) PCR Kit	Real-time PCR test for detection or quantification of <i>EBV</i> DNA in human blood or tissue samples	CE	25, 48, 50, 60, 96, 100, 120
BA034	Human Herpes Virus 6 (HHV6) PCR Kit	Real Time PCR test for detection of <i>Human Herpesvirus type 6</i> DNA	CE	25, 48, 50 96, 100
BA035	Human Herpes Virus 7 (HHV7) PCR Kit	Real Time PCR test for detection and quantification of <i>Human Herpesvirus type 7</i> DNA	CE	48, 96
BA036	Human Herpes Virus 8 (HHV8) PCR Kit	Real Time PCR test for detection and quantification of <i>Human Herpesvirus type 8</i> DNA	CE	25, 48, 96
BA037	Varicella Zoster Virus (VZV) PCR Kit	Real Time PCR test for detection of <i>VZV</i> DNA	CE	25, 48, 50, 96

1.6 Toxoplasma, Rubella, CMV, Herpes Simplex (TORCH) Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
BA038	Herpes Simplex Virus 1 and/or 2 (HSV-1, HSV-2) PCR Kit	Real-time PCR test for detection of <i>HSV-1</i> and/or <i>HSV-2</i> DNA in human samples	CE	25, 48, 60, 96, 100, 120
BA411	HSV 1/2 Typing PCR Kit	Real-time PCR test for detection and typing of <i>HSV</i> DNA	CE	100
BA412	HSV 1+2/VZV PCR Kit	Multiplex Real Time PCR test for detection of <i>Herpes Simplex Virus 1</i> and 2, and <i>Varizella Zoster Virus</i> DNA	CE	96
BA039	Human Cytomegalovirus (HCMV) PCR Kit	Real-time PCR test for detection or quantification of human <i>Cytomegalovirus (HCMV, CMV)</i> DNA in human EDTA plasma or serum samples	CE	25, 48, 50, 60, 96, 100, 120
BA040	Measles Virus RT-PCR Kit	Real Time PCR test for detection of <i>Measles Virus</i> RNA	RUO	150
BA041	Mumps Virus RT-PCR Kit	Real Time PCR test for detection of <i>Mumps Virus</i> RNA	RUO	150
BA042	Parvovirus B19 (PVB19) PCR Kit	Real Time PCR test for detection or quantification of <i>PVB19</i> DNA	CE	25, 48, 50, 60, 96, 120
BA043	Rubella PCR Kit	Real Time PCR test for detection of <i>Rubella</i> DNA	CE	50
BA044	Toxoplasma PCR Kit	Real Time PCR test for detection of <i>Toxoplasma</i> DNA	CE	50

1.7 Respiratory Infections / Tuberculosis

Order number	Product name	Intended use	Legal Status	Tests/Size
Respiratory Infections				
BA413	Atypical CAP PCR test	Multiplex Real-Time PCR test for detection of Atypical Community-Acquired Pneumonia (CAP) including <i>Mycoplasma pneumoniae</i> , <i>Chlamydia pneumoniae</i> , <i>Legionella pneumophila</i> / <i>Legionella longbeachae</i> DNA	CE	32
BA045	Avian Influenza A H5, H7, H9 RT-PCR Kit	Real Time PCR test for detection of H5, H7, H9 subtypes of <i>Influenza A virus</i> RNA	RUO	50
BA046	Avian Influenza A H5N1 RT-PCR Kit	Real Time PCR test for detection or quantification of Avian A virus <i>H5N1</i> subtype RNA	CE	50, 60, 120
BA047	Bordetella PCR Kit	Real Time PCR test for detection and/or typing of <i>Bordetella pertussis</i> / <i>B. paraptussis</i> / <i>B. bronchiseptica</i> / <i>B. holmesii</i> DNA	CE	100
BA414	CAP bacteria PCR Kit	Community Acquired Pneumonia – CAP	CE	12, 60
BA415	hMPV RT-PCR Kit	Real Time PCR test for detection of <i>Human Metapneumovirus A and B</i> RNA	CE	48, 96
BA048	hRSV + hMPV multiplex RT-PCR Kit	Real Time PCR test for qualitative detection of human <i>Respiratory Syncytial virus</i> and human <i>Metapneumovirus</i> RNA from nasal and nasopharyngeal swab specimen	CE	96
BA049	Human Respiratory Syncytial Virus (hRSV) RT-PCR Kit	Real Time PCR test for detection of <i>hRSV</i> RNA	CE	32, 48, 50, 96
BA050	Influenza A H1N1 & H3N2 RT-PCR Kit	Real Time PCR test for detection of <i>H1N1</i> and <i>H3N2</i> types of <i>Influenza A</i> RNA	RUO	50
BA051	Influenza A/B RT-PCR Kit	Multiplex Real Time PCR test for detection and differentiation of influenza viruses (<i>Influenza A</i> , <i>Influenza B</i> and <i>H1N1</i>) from human nasal and throat; detecting the actual circulating <i>avian influenza A (H5N8)</i>	CE	20, 32, 48, 50, 96, 100
BA052	Legionella pneumophila PCR Kit	Real Time PCR test for quantitative detection of <i>Legionella pneumophila</i> DNA	CE	50, 100
BA053	MERS-SARS CoV RT-PCR Kit	Real Time PCR test for detection and differentiation of Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome Coronaviruses RNA	CE	48, 50, 96
BA054	Mycoplasma pneumoniae / Chlamydia. Pneumoniae PCR Kit	Real Time PCR test for detection of <i>Chlamydia pneumoniae</i> and/or <i>Mycoplasma pneumoniae</i> DNA	CE	48, 50, 96
BA416	Mycoplasma pneumoniae PCR Kit	Real Time PCR test for identification of <i>Mycoplasma pneumoniae</i> genome by amplification of the P1 gene.	CE	50
BA055	Parainfluenza (PIV) Virus RT-PCR Kit	Real Time PCR test for detection of <i>Parainfluenza virus</i> RNA (Type 1, 2, 3 & 4)	CE	32, 48, 50, 96, 100
BA056	Pseudomonas aeruginosa PCR Kit	Real Time PCR test for quantitative detection of <i>Pseudomonas aeruginosa</i> DNA	CE	50

1.7 Respiratory Infections / Tuberculosis

Order number	Product name	Intended use	Legal Status	Tests/Size
Respiratory Infections				
BA417	Respiratory Pathogens PCR Kit (21 pathogens)	Multiplex Real-Time PCR test for detection of 21 respiratory pathogens for detection of <i>influenza A</i> , <i>influenza A (H1N1) swl</i> , <i>influenza B</i> , <i>rhinovirus</i> , <i>coronavirus NL63</i> , <i>229E</i> , <i>OC43</i> , <i>HKU1</i> , <i>parainfluenza 1, 2, 3, 4</i> , <i>human metapneumovirus A/B</i> , <i>bocavirus</i> , <i>respiratory syncytial virus A/B</i> , <i>adenovirus</i> , <i>enterovirus</i> , <i>parechovirus</i> , <i>mycoplasma</i>	CE	32
BA057	Respiratory Virus Panel multiplex RT-PCR Kit	Real Time PCR test for detection of the genome of 16 main respiratory viruses	CE	20, 100
BA058	Swine Influenza Virus H1 RT-PCR Kit	Real Time PCR test for detection of <i>Swine Influenza Virus A/H1</i> RNA	RUO	50

Tuberculosis and TB Resistance

BA060	<i>Mycobacterium tuberculosis</i> PCR Kit	Real Time PCR test for detection of <i>Mycobacterium tuberculosis</i> complex strains DNA	CE	48, 50, 60, 96, 100,
BA418	TB Resistance Module 1	Real Time PCR test and Amplification/ Reverse hybridization assay for the modular detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Isoniazid and Rifampicin	CE	12, 48, 60
BA419	TB Resistance Module 2	Real Time PCR test and Amplification/ Real Time PCR test and Amplification/ Reverse hybridization assay for the modular detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Fluoroquinolone antibiotics and Ethambutol	CE	12, 48, 60
BA420	TB Resistance Module 3	Real Time PCR test and Amplification/Reverse hybridization assay for the modular detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances	CE	12, 48, 60
BA421	TB Resistance Module 4	Real Time PCR test for the modular detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Streptomycin	CE	48

1.8 Neurological Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
Enterovirus/Poliovirus				
BA061	Enterovirus RT-PCR Kit	Real Time PCR screening test for detection of <i>Enterovirus (Coxsackie A, Coxsackie B, Echovirus, Enterovirus)</i> RNA	CE	32, 48, 50, 96
BA062	Enterovirus 71 RT-PCR Kit	Real-Time PCR test for qualitative detection of <i>Enterovirus-71 Virus (EV1)</i> RNA	CE	50
BA063	Poliovirus RT-PCR Kit	Real Time PCR test for qualitative detection of <i>Poliovirus / Enterovirus</i> group C (HEV-C) RNA and differentiation of <i>Poliovirus</i> strains Sabin 1, Sabin 2, Sabin 3 RNA	CE	50

Meningitis

BA065	<i>Listeria monocytogenes</i> PCR Kit	Real Time PCR test for detection and quantification of <i>L. monocytogenes</i> DNA	RUO	50, 100
BA422	Neonatal Meningitis PCR Kit	Multiplex Real Time PCR test for detection and quantification of Group B <i>Streptococcus (S. agalactiae)</i> , <i>Listeria monocytogenes</i> , <i>Escherichia coli</i> DNA	CE	32
BA423	Neuro PCR Kit (9 pathogens)	Multiplex Real-Time PCR test for detection of <i>cytomegalovirus</i> , <i>Epstein-Barr virus</i> , <i>adenovirus</i> , <i>herpes simplex virus 1, 2</i> , <i>varicella-zoster virus</i> , <i>enterovirus</i> , <i>parechovirus</i> , <i>human herpes virus 6, 7</i> , <i>parvovirus B19</i>	CE	32
BA064	NHS Meningitidis PCR Kit	Real Time PCR test for detection of <i>N. meningitidis</i> , <i>H. influenzae</i> , <i>St. pneumonia</i> DNA	CE	50
BA424	Viral Meningitis PCR Kit	Multiplex Real Time PCR test for detection of <i>herpes simplex virus 1, 2</i> , <i>varicella-zoster virus</i> , <i>enterovirus</i> , <i>mumps virus</i> , <i>parechovirus</i>	CE	32

1.9 Gastrointestinal Infections / Parasites

Order number	Product name	Intended use	Legal Status	Tests/Size
BA067	A.I.I. (Acute Intestinal Infections) PCR Kit	Real Time PCR test for detection of <i>Shigella Spp.</i> , <i>E.coli</i> , <i>Salmonella spp.</i> , <i>Campylobacter spp.</i> , <i>Adenovirus F</i> , <i>Rotavirus A</i> , <i>Norovirus 2</i> , <i>Astrovirus</i>	CE	50
BA605	Acinetobacter baumannii PCR Kit	Real-time PCR test for detection of <i>Acinetobacter baumannii</i> DNA	RUO	150
BA068	Adenovirus PCR Kit	Real Time PCR test for detection and quantification of <i>Adenovirus</i> DNA species (A, B, C, D, E, and F) or serotypes (HAdV 1-52)	CE	48, 50, 96
BA069	Aerobic complex PCR Kit	Multiplex Real time PCR test for detection of <i>Enterobacteriaceae (E. coli, Klebsiella spp, Proteus spp, Streptococcus spp)</i> DNA	RUO	50
BA070	Bacillus cereus PCR Kit	Real Time PCR test for detection of <i>Bacillus Cereus</i> DNA	CE	100
BA425	Bacterial Gastroenteritis PCR Kit	Multiplex Real-Time PCR test for detection and quantification of Bacterial gastroenteritis including <i>Salmonella spp.</i> , <i>Shigella spp.</i> , <i>Yersinia enterocolitica</i> , <i>Clostridium difficile</i> , <i>Campylobacter coli/jejuni/lari</i> , <i>VTEC</i> DNA	CE	32
BA066	Bacterial Stool Panel PCR Kit	Multiplex Real Time PCR test for detection and differentiation of humanpathogenic <i>Salmonella spp.</i> , <i>Campylobacter spp.</i> and <i>Yersinia enterocolitica</i> in human stool samples	CE	100
BA071	Campylobacter PCR Kit	Real Time PCR test for detection of <i>Campylobacter jejuni</i> DNA	CE	25, 50, 100
BA072	Clostridium difficile PCR Kit	Real Time PCR test for detection of <i>Clostridium difficile</i> Toxin A and B DNA	CE	48, 50, 55, 96, 100
BA073	Clostridium perfringens PCR Kit	Real Time PCR test for detection of <i>Clostridium perfringens</i> DNA	CE	100
BA074	Cronobacter PCR Kit	Real Time PCR test for detection of <i>Cronobacter sakazakii</i> DNA	RUO	50, 100
BA075	E. coli O157 PCR Kit	Real Time PCR test for detection of <i>E. coli</i> O157:H7 DNA	CE	25, 150
BA076	EAEC PCR Kit	Real Time PCR test for detection of Enteroadhesive <i>E coli</i> (EAEC) DNA	CE	100
BA077	EHEC PCR Kit	Real Time PCR test for detection of enterohemorrhagic <i>E. coli</i> (EHEC) DNA	CE	48, 50, 96, 100
BA078	EIEC PCR Kit	Real Time PCR test for detection of Enteroinvasive <i>E. coli</i> (EIEC) DNA	CE	100
BA079	Enterobacter sakazaii PCR Kit	Real Time PCR test for detection of <i>Enterobacter sakazaii</i> DNA	CE	25
BA080	EPEC PCR Kit	Real Time PCR test for detection of Enteropathogenic <i>E. coli</i> (EPEC) DNA	CE	100
BA081	Escherichioses Screen & Differentiation Kit	Real Time PCR test for detection of <i>E.coli</i> (EPEC, ETEC, EIEC, EHEC, and EAgEC) DNA	RUO	50, 100
BA082	ETEC PCR Kit	Real Time PCR test for detection of Enterotoxigenic <i>E. coli</i> (ETEC) DNA	CE	100
BA426	Gut Balance PCR Kit	Real time PCR for the direct qualitative and quantitative detection of Bacteroides and Cluster XIVa DNA from human stool samples to judge symbiotic balance in gut microbiome	CE	100
BA083	Helicobacter pylori PCR Kit	Real Time PCR test for detection of <i>H. pylori</i> DNA e.g. by amplification of the UreC gene	CE	32, 48, 50, 96
BA084	Hospital Stool Panel PCR Kit	Real Time PCR test for detection and differentiation of norovirus (genogroup I and II), rotavirus and <i>Clostridium difficile</i> toxin-genes A (tcdA) and B (tcdB) in human stool samples	CE	100
BA087	Listeria PCR Kit	Real Time PCR test for detection of <i>Listeria monocytogenes</i> DNA	CE	32, 50, 96
BA088	Norovirus RT-PCR Kit	Real Time PCR test for detection of <i>Norovirus</i> (Genogroup I, II and IV) RNA	CE	32, 96
BA427	Rotavirus RT-PCR Kit	Real Time PCR test for detection of <i>Rotavirus</i> RNA	CE	48, 96
BA089	Rotavirus/Norovirus/ Astrovirus RT-PCR Kit	Real Time PCR test for detection of <i>Rotavirus</i> , and/or <i>Norovirus</i> and/or <i>Astrovirus</i> RNA	CE	50, 100
BA428	Salmonella spp. PCR Kit	Real Time PCR test for identification of <i>Salmonella spp</i> genome by amplification of the Nuclease gene	CE	50, 150
BA090	Sapovirus RT-PCR Kit	Real Time PCR test for direct qualitative detection of <i>Sapovirus (Sapporo virus genotypes I-V)</i> RNA in stool	CE	25, 100
BA429	Shigella spp. PCR Kit	Real Time PCR test for identification of <i>Shigella spp</i> genome by amplification of the Yst gene	CE	50

1.9 Gastrointestinal Infections / Parasites

Order number	Product name	Intended use	Legal Status	Tests/Size
BA429	Shigella spp. PCR Kit	Real Time PCR test for identification of Shigella spp genome by amplification of the Yst gene		50
BA091	Shigella/Salmonella/ Campylobacter PCR Kit	Real Time PCR test for detection of Shigella, and/or Salmonella and/ or campylobacter DNA	CE	25, 32, 50, 96
BA092	STEC PCR Kit	Real Time PCR test for detection of Shigella Toxin-Producing E. coli (STEC) DNA	CE	100
BA430	Verotoxin-producing Escherichia coli PCR Kit	Real Time PCR test for detection of Verotoxin-producing E. coli VT1 DNA	RUO	100
BA085	Viral Stool Panel PCR Kit	Real Time PCR test for detection and differentiation of norovirus, rotavirus, adenovirus and astrovirus RNA in human stool samples	CE	100
BA093	Yersinia PCR Kit	Real Time PCR test for detection of Yersinia enterocolitica and/or Y. pseudotuberculosis DNA	CE	32, 50, 96

Parasites / Protozoa

BA431	Cryptosporidium PCR Kit	Real Time PCR Kit for the in vitro quantification of Cryptosporidium (C. parvum, C. hominis [previously C. parvum genotype 1], C. canis, C. felis, C. meleagridis, and C. muris) DNA	RUO	150
BA094	Dientamoeba PCR Kit	Real Time PCR test for detection of Dientamoeba fragilis DNA	CE	100
BA095	Entamoeba PCR Kit	Real Time PCR test for detection of Entamoeba histolytica DNA	CE	100
BA432	Giardia A+B PCR Kit	Real Time PCR Kit for the in vitro quantification of Giardia intestinalis assemblages A and B DNA known to infect humans	RUO	150
BA433	Giardia A-F PCR Kit	Real Time PCR Kit for the in vitro quantification of Giardia intestinalis assemblages A to F DNA	RUO	150
BA121	Leishmania (all species) PCR Kit	Real Time PCR Kit for the in vitro quantification of Leishmania spp DNA via the cytochrome b (cytb) kinetoplast gene	CE	48, 50, 150
BA434	Leishmania infantum & Leishmania donovani PCR Kit	Real Time PCR Kit for the in vitro quantification of Leishmania infantum & Leishmania donovani DNA	RUO	50, 150
BA435	Leishmania major PCR Kit	Real Time PCR Kit for the in vitro quantification of Leishmania major DNA	RUO	50, 150
BA436	Leishmania tropica PCR Kit	Real Time PCR Kit for the in vitro quantification of Leishmania tropica DNA	RUO	50, 150
BA122	Malaria PCR Kit	Real Time PCR test for screening/ detection of Malaria Parasite DNA	CE	50, 96, 150
BA123	Malaria Screening PCR Kit	Qualitative PCR strip test that allows to detect the presence of P. falciparum, P. malariae, P. ovale or P. vivax in DNA extracted from whole blood samples.	CE	48
BA124	Malaria Typing PCR/ Agarose gel electrophoresis	Qualitative PCR strip test that allows to identify the presence of 3 of the 4 Plasmodia that infect humans (P. malariae, P. ovale or P. vivax) in DNA extracted from whole blood samples.	CE	48
BA096	Parasitic Stool Panel PCR Kit	Real Time PCR test for detection of Dientamoeba fragilis, Giardia lamblia (synonym G. intestinalis or G. duodenales), Entamoeba histolytica and Cryptosporidium spp. parasites DNA in stool	CE	100

Parasites / Helminths

BA437	Ascaris lumbricoides/ Ascaris suum PCR Kit	Real Time PCR Kit for identifying the appearance of the roundworms or eggs of Ascaris lumbricoides/ Ascaris suum preferably in feces	RUO	150
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1.10 Further Infectious Diseases

Order number	Product name	Intended use	Legal Status	Tests/Size
BA098	Chlamydomphila pneumonia PCR Kit	Real Time PCR test for detection or quantification of Chlamydomphila pneumoniae DNA	CE	32, 48, 96
BA099	John Cunningham Virus (JCV) PCR Kit	Real Time PCR test for detection and quantification of JC Virus DNA	CE	48, 50, 96
BA100	Polyomavirus BK (BKV) PCR Kit	Real Time PCR test for detection or quantification of PBK virus DNA	CE	25, 48, 50, 96

1.11 Tick Borne Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
BA101	Babesia PCR Kit	Real Time PCR test for detection of Babesia species (<i>Babesia divergens</i> , <i>B. microti</i> and <i>B.sp EU1</i>)	CE	32, 96
BA102	Borrelia burgdorferi PCR Kit	Real Time PCR test for detection of <i>Borrelia burgdorferi</i> DNA	CE	32, 50, 96
BA103	Coxiella burnetii PCR Kit	Real Time Amplification test for detection of <i>Coxiella burnetii</i> DNA	RUO	50
BA104	Ehrlichia PCR Kit	Real Time PCR test for detection of the Ehrlichia species (<i>E. chaffeensis</i> , <i>E. ewingii</i> , <i>Anaplasma phagocytophilum</i> (formerly <i>E. phagocytophilum</i> , <i>E. equi</i>)	CE	32, 96
BA105	Leptospira ssp. PCR Kit	Real Time PCR test for detection of <i>Leptospira</i> DNA	CE	50, 100
BA438	Tick-borne encephalitis (FSME) RT-PCR Kit	Real Time PCR test for detection of <i>Tick-borne encephalitis virus (TBEV)</i> RNA	CE	48, 50
BA106	Vibrio parahaemolyticus PCR Kit	Real Time PCR test for detection of <i>V. parahaemolyticus</i> DNA	CE	96
BA107	Vibrio Vulnificus PCR Kit	Real Time PCR test for detection of <i>V. vulnificus</i> DANN	CE	96

1.12 Fungal and Yeast Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
BA109	Aspergillus fumigates PCR Kit	Real Time PCR test for quantitative detection of <i>Aspergillus fumigates</i> DNA in bronchoalveolar lavage, blood, plasma and serum	CE	50
BA108	Aspergillus ssp. PCR Kit	Real Time PCR test for detection of the most common species <i>A. fumigatus</i> , <i>A. flavus</i> , <i>A. niger</i> , and <i>A. terreus</i> DNA	CE	4x 25
BA606	Candida ssp. PCR Kit	Multiplex Real Time PCR test for detection of <i>Candida albicans</i> , <i>C. glabrata</i> and <i>C. krusei</i> DNA	RUO	100
BA110	Cryptococcus neoformans PCR Kit	Real Time PCR test for detection of <i>Cryptococcus neoformans</i> DNA in bronchoalveolar lavage, blood, plasma, serum, and cerebrospinal fluid	CE	50, 100
BA439	Dermatophytes PCR Kit 1	Multiplex PCR amplification/lateral flow detection kit for diagnosis of the pathogens <i>T. rubrum</i> , <i>Dermatophyton spp. (TME)</i> , <i>Scopulariopsis brevicaulis</i> and <i>Candida spp.</i>	CE	10, 50
BA440	Dermatophytes PCR Kit 2	Multiplex PCR amplification/lateral flow detection kit for diagnosis of the pathogens <i>T. interdigitale</i> / <i>A. vanbreuseghemii</i> ; <i>T. mentagrophytes</i> , <i>T. tonsurans</i> , <i>T. violaceum</i> , <i>A. benhamiae</i> / <i>T. erinacei</i> and <i>T.verrucosus</i>	CE	10, 50
BA441	Dermatophytes PCR Kit 3	Multiplex PCR amplification/lateral flow detection kit for diagnosis of the Microspores <i>M. audouinii</i> , <i>M. gypseum</i> , <i>M. canis</i> , as well as Epidermophyte <i>E. floccosum</i> on species level	CE	10, 50
BA442	Dermatophytes, yeasts, mould or mixed infections PCR Kit	Multiplex Real Time PCR test for detection of <i>Trichophyton mentagrophytes complex</i> , <i>Trichophyton tonsurans</i> , <i>Trichophyton violaceum</i> , <i>Trichophyton rubrum complex</i> , <i>Microsporum canis</i> , <i>Microsporum audouinii</i> , <i>Microsporum ferrugineum</i> DNA from skin scale specimens, plucked hair, nails, culture and swabs of human origin.	CE	10, 32, 50, 64

1.13 Emerging Diseases

Order number	Product name	Intended use	Legal Status	Tests/Size
Viral diseases, hemorrhagic fevers				
BA603	Tropical fever core, 7 pathogens RT-PCR Kit	Multiplex Real-Time PCR Kit for detection of <i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> , <i>Hantaan virus/Seoul virus</i> , <i>Leishmania spp.</i> and <i>Japanese Encephalitis virus</i>	CE	32, 64
BA604	Tropical fever Asia, 4 pathogens RT-PCR Kit	Multiplex Real-time PCR Kit for detection of <i>dengue virus</i> , <i>chikungunya virus</i> , <i>Salmonella spp.</i> , <i>West Nile virus</i> , <i>Plasmodium spp.</i> , <i>Rickettsia spp.</i> , <i>Leptospira spp.</i>	CE	32, 64
BA111	Chikungunya Virus (Chik) RT-PCR Kit	Real Time PCR test for detection of <i>Chikungunya Virus</i> RNA	CE	96, 150
BA443	Chikungunya / Dengue PCR Kit	Multiplex Real Time PCR kit for detection of <i>Chikungunya</i> and <i>Dengue</i> RNA	CE	48, 96
BA112	Crimean-Congo hemorrhagic fever (CCHF) RT-PCR Kit	Real Time PCR test for detection of <i>CCHF RNA</i>	CE	50, 60, 96, 120
BA444	Dengue Genotype RT-PCT Kit	Real Time PCR kit for detection and differentiation of <i>Dengue</i> 1, 2, 3, 4 RNA	CE	50
BA113	Dengue RT-PCR Kit	Real Time PCR kit for detection and/or differentiation of <i>Dengue</i> 1, 2, 3, 4 RNA	CE	50, 60, 96, 120
BA114	Ebola hemorrhagic fever Virus (Sudan, SEBOV) RT-PCR Kit	Real Time PCR test for detection of <i>SEBOV</i> RNA from human samples	RUO	60, 120

1.13 Emerging Diseases

Order number	Product name	Intended use	Legal Status	Tests/Size
Viral diseases, hemorrhagic fevers				
BA115	Ebola hemorrhagic fever Virus (Zaire, ZEBOV) RT-PCR Kit	Real Time PCR test for detection of <i>ZEBOV</i> RNA from human samples	RUO	60, 96, 120
BA445	Filovirus Genotype RT-PCR Kit	Real Time PCR kit for detection of Human pathogenic <i>filoviruses</i> and species differentiation	CE	96
BA446	Filovirus Screen RT-PCR Kit	Real Time PCR kit for detection of Human pathogenic <i>filovirus</i> species RNA	CE	96
BA116	Lassa Virus (LV) RT-PCR Kit	Real Time PCR test for detection of <i>Lassa Virus</i> (LV) RNA	RUO	25
BA117	Marburg Virus (MARV) RT-PCR Kit	Real Time PCR test for detection of <i>MARV</i> RNA from human samples	RUO	120
BA118	Nipah Virus RT-PCR Kit	Real Time PCR test for detection of <i>Nipah Virus</i> (Niv) RNA	CE	25
BA447	Plasmodium spp. PCR Kit	Real-time PCR test for detection of all <i>Plasmodium</i> species, 150 tests	RUO	150
BA119	Rift Valley Fever (RVF) Virus RT-PCR Kit	Real Time PCR test for detection of <i>Rift Valley Fever</i> (RVF) RNA	RUO	60, 96, 120
BA120	West Nile Virus (WNV) RT-PCR Kit	Real Time PCR test for detection of <i>WNV</i> RNA	CE	25, 32, 50, 64, 96
BA448	BA448	Real Time PCR test for detection of <i>Zika Virus</i> RNA	CE	24, 48, 96, 150

Parasites

BA122	Malaria PCR Kit	Real Time PCR test for screening/ detection of <i>Malaria</i> Parasite DNA	CE	96, 150
BA123	Malaria Screening PCR/Agarose gel electrophoresis	Qualitative PCR strip test that allows to detect the presence of <i>P. falciparum</i> , <i>P. malariae</i> , <i>P. ovale</i> or <i>P. vivax</i> in DNA extracted from whole blood samples.	CE	48
BA124	Malaria Typing PCR/ Agarose gel electrophoresis	Qualitative PCR strip test that allows to identify the presence of 3 of the 4 <i>Plasmodia</i> that infect humans (<i>P. malariae</i> , <i>P. ovale</i> or <i>P. vivax</i>) in DNA extracted from whole blood samples.	CE	48

1.14 Bacteriology / Sepsis / Pyogenic Infections

Order number	Product name	Intended use	Legal Status	Tests/Size
BA449	Bartonella henselae PCR Kit	Real Time PCR test for the identification of the <i>Bartonella henselae</i> genome by amplification of the ribC gene	CE	50
BA450	Neonatal Sepsis PCR Kit (7 Pathogens)	Multiplex Real Time PCR test for detection and quantification of <i>cytomegalovirus</i> , <i>Group B Streptococcus</i> (<i>S. agalactiae</i>), <i>Listeria monocytogenes</i> , <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> , <i>Chlamydia trachomatis</i> , <i>Ureaplasma urealyticum/ parvum</i> DNA	CE	32
BA125	Pseudomonas aeruginosa PCR Kit	Real Time PCR test for quantitative detection of <i>Pseudomonas aeruginosa</i> DNA	CE	50
BA451	Rickettsia spp. PCR Kit	Real Time PCR test for the identification of <i>Rickettsia</i> spp. genome by amplification of <i>gltA</i> gene	CE	50
BA126	Streptococcus B PCR Kit	Real Time PCR test for quantitative detection of <i>Streptococcus B</i> DNA	CE	100
BA127	Streptococcus group A and pyogenic group C and G PCR Kit	Real Time PCR test for the qualitative detection and differentiation of group A streptococcal and pyogenic group C and G streptococcal nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as a sore throat.	CE	96
BA128	Streptococcus pyogenes PCR Kit	Real Time PCR test for quantitative detection of <i>Streptococcus pyogenes</i> DNA	RUO	100

1.15 Bacterial Drug Resistance

Order number	Product name	Intended use	Legal Status	Tests/Size
BA129	Carbapenems resistance PCR Kit	Real Time PCR test for detection of <i>Enterobacteriaceae</i> and <i>Pseudomonas</i> resistance against carbapenems, genes VIM, NDM, OXA-48, KPC	RUO	60
BA130	Cephalosporins resistance PCR Kit	Real Time PCR test for detection of <i>Enterobacteriaceae</i> resistance against cephalosporins, genes CTX-M, or <i>S. aureus</i> resistance against cephalosporins, genes MecA	RUO	60
BA131	Glycopeptides resistance PCR Kit	Real Time PCR test for detection of <i>Enterococcus faecalis</i> and <i>E. faecium</i> resistance to Vancomycin and Teicoplanin, genes VanA and VanB	RUO	60

1.15 Bacterial Drug Resistance

Order number	Product name	Intended use	Legal Status	Tests/Size
BA452	H. pylori clarithromycin resistance PCR Kit	Real Time PCR test for detecting <i>Helicobacter pylori</i> A2142C, A2142G and A2143G point mutations in <i>H. pylori</i> genomic DNA, conferring clarithromycin resistance to the bacterium	CE	50
BA132	Macrolides resistance PCR Kit	Real Time PCR test for detection of <i>Streptococcus spp.</i> and <i>Staphylococcus spp</i> resistance to macrolides, lincosamides, streptogramins; genes ErmB and Mef	RUO	60
BA133	MDR KPC / OXA PCR Kit	Real Time PCR kit for detection of the genes KPC, OXA-48 and OXA-162 in <i>Enterobacteriaceae</i> and NFGNB	CE	100
BA134	MDR MBL (VIM, IMP, NDM) PCR Kit	Real Time PCR test for detection of the genes VIM, IMP and NDM in <i>Enterobacteriaceae</i> and NFGNB	CE	100
BA135	MRSA PCR Kit	Real Time PCR test for detection or quantification of Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) DNA	CE	25, 32, 50, 96, 100
BA136	Penicillins resistance PCR Kit	Real Time PCR test for detection of <i>Enterobacteriaceae</i> and <i>Pseudomonas</i> resistance to penicillins and first-generation cephalosporins, genes TEM	RUO	60
BA137	PVL PCR Kit	Real Time PCR test for detection of PVL (Panton-Valentine-Leukozidin)-positive <i>S. aureus</i> DNA as an aid in diagnosis of (skin- / soft tissue-) infections caused by PVL	CE	100
BA453	Q-MRSA Detection PCR Kit	Multiplex Real Time PCR test for simultaneous detection of the 3 MRSA markers <i>nuc</i> , <i>mecA</i> and <i>orfX-SCCmec</i>	RUO	10, 20
BA138	VRSA PCR Kit	Real Time PCR test for detection of Vancomycin-resistant <i>Staphylococcus aureus</i> VRSA DNA	CE	25

1.16 Periodontitis

Order number	Product name	Intended use	Legal Status	Tests/Size
BA139	Periodontitis Screening PCR Kit	Real Time PCR test for detection of <i>Porphyromonas endodontalis</i> , <i>Porphyromonas gingivalis</i> , <i>Aggregatibacter ctinomycetemcomitans</i> , <i>Treponema denticola</i> , <i>Fusobacterium nucleatum</i> , <i>Prevotella intermedia</i> , <i>Tannerella forsythia</i> in periodontal samples	RUO	50

1.17 Biothreat Agents

Order number	Product name	Intended use	Legal Status	Tests/Size
BA140	Anthrax PCR Kit	Real Time PCR test for detection of <i>Bacillus anthracis</i> DNA	CE	50, 96
BA141	Botulinus PCR Kit	Real Time PCR test for detection of <i>Botulinus</i> (Types A/B/E/F) DNA	CE	25
BA142	Brucella PCR Kit	Real Time PCR test for detection of <i>Brucella</i> DNA i.e. by amplification of the <i>bcsp31</i> gene	CE	50, 100
BA143	Set of PCR Kits for detection and quantification of Biothreat high risk pathogen DANN	Real Time PCR kits to detect <i>Bacillus anthracis</i> , <i>Burkholderia spp.</i> (<i>B. mallei</i> , <i>B. pseudomallei</i>), <i>Brucella spp.</i> (<i>B. melitensis</i> , <i>B. suis</i> , <i>B. abortus</i> , <i>B. ovis</i> , <i>B. canis</i>), <i>Francisella tularensis</i> , <i>Salmonella enterica</i> , <i>Yersinia pestis</i> .	RUO	50
BA144	Vibrio cholerae PCR Kit	Real Time PCR test for detection of <i>Vibrio cholerae</i> strains iCtxA, <i>tcpA</i> and/or O139 DNA	CE	25, 50, 96
BA145	Yersinia pestis PCR Kit	Real Time Amplification test for detection of <i>Yersinia pestis</i> DNA	RUO	50

2. ONCOLOGY

2.1 Oncogene Expression Quantification / Minimal Residual Disease (MRD)

Order number	Product name	Intended use	Legal Status	Tests/Size
Chronic Myelogenous Leukaemia				
BA454	BCR-ABL P210/P190 PCR Kit	Multiplex Reverse Transcription Real-time PCR test for in vitro quantification of both the <i>BCR-ABL</i> fusion transcripts P210/P190 in one tube	CE	24
BA146	M-BCR/t(9;22) PCR Kit	Real-time PCR test for in vitro quantification of <i>BCR-ABL</i> fusion transcripts comprising the (Ph+) translocation t(9;22) major breakpoint cluster regions (M-BCR) b2a2 and b3a2) in CML	CE	25, 48, 50, 96, 120
BA147	mi-BCR/t(9;22) PCR Kit	Real-time PCR test for in vitro quantification of <i>BCR-ABL</i> fusion transcripts comprising the (Ph+) translocation t(9;22) minor breakpoint cluster region (M-BCR) e1a2 in CML	CE	48, 96, 120