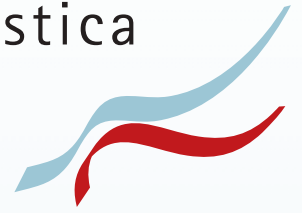


bioactiva diagnostica

The Partner That Cares



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Molecular Diagnostics
Rev. 3/2022



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3. HUMAN GENETIC DISEASES AND GENETIC PREDISPOSITIONS

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1. HUMAN PATHOGEN DETECTION & GENOTYPING

1.1 Hepatitis Viruses

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0001	Hepatitis A RNA (HAV) PCR Kit	Qualitative detection of HAV RNA	RT	CE	50, 96
BA0401	Hepatitis B DNA (HBV qual) PCR Kit	Qualitative detection of HBV DNA	RT	CE	48
BA0002	Hepatitis B DNA (HBV quant) PCR Kit	Quantitative detection of HBV DNA	RT	CE	25, 48, 60, 96, 100, 120
BA0402	Hepatitis C RNA (HCV qual) PCR Kit	Qualitative detection of HCV RNA	RT	CE	24, 48
BA0003	Hepatitis C RNA (HCV quant) PCR Kit	Quantitative detection of HCV RNA	RT	CE	25, 48, 60, 96, 100, 120
BA0004	Hepatitis D RNA (HDV) PCR Kit	Quantitative detection of HDV RNA	RT	CE	50, 60, 96, 100, 120
BA0005	Hepatitis E RNA (HEV) PCR Kit	Quantitative detection of HEV RNA	RT	CE	25, 32, 48, 50, 96
BA0006	Hepatitis G RNA (HGV) RT-PCR Kit	Qualitative detection of HGV RNA	RT	CE	25, 50
BA0007	Transfusion-transmitted Virus (TTV) PCR Kit	Detection of TTV (synonym: Torque Teno Virus) DNA, often found in patients with liver disease	RT	CE	25
BA0009	HCV/HBV/HIV PCR Kit	Multiplex detection of HBV, HCV and HIV-1	RT	RUO	48, 100
BA0010	HCV/HBV/HIV1/HIV2 PCR Kit	Multiplex detection of HBV, HCV, HIV-1 and HIV-2	RT	RUO	100
BA0008	HBV/HDV PCR Kit	Multiplex detection of HBV and HDV	RT	RUO	100

Genotyping

BA0608	HBV Genotyping Kit I	Detection of HBV DNA genotypes A-D	RT	RUO	50
BA0011	HBV Genotyping Kit II	Reverse Line Blot Detection of HBV DNA genotypes A-H	HYB	CE	20, 50
BA0012	HCV Genotyping Kit I	Detection of HCV RNA 1a, 1b, 2, 3a, 4, 5a, 6 genotypes	RT	RUO	48, 50
BA0609	HCV Genotyping Kit II	Detection of HCV RNA 1-7 genotypes and subtypes	HYB	CE	20, 24

1.2 Human Immunodeficiency Virus

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0013	Human Immunodeficiency Virus (HIV-1) PCR Kit (one-step)	Detection of HIV-1 RNA (quantitative; with or without RNA Extraction)	RT	CE	25, 48, 50, 60, 96, 100, 120, 150
BA0014	Human Immunodeficiency Virus (HIV-2) PCR Kit (one-step)	Detection of HIV-2 RNA (quantitative; with or without RNA Extraction)	RT	RUO	25, 150
BA0730	HTLV-1/HTLV-2 PCR Kit	Detection of the proviral DNA HTLV-1 and HTLV-2	RT	CE	24, 48, 96
BA0731	Human T-lymphotropic virus Type 1 (HTLV-1) PCR Kit	Detection of HTLV-1 RNA	RT	RUO	150
BA0732	Human T-lymphotropic virus Type 2 (HTLV-2) PCR Kit	Detection of HTLV-2 RNA	RT	RUO	150

1.2 Human Immunodeficiency Virus

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0015	Pneumocystis PCR Kit	Real Time PCR test for detection and/or quantification of <i>Pneumocystis jirovecii</i> (carinii) DNA	RT	CE	48, 50, 96, 100

HIV-Associated Diseases

1.3 Human Papilloma Viruses

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0017	Human Papilloma Virus (HPV) High Risk Screen PCR Kit	Quantitative screening of ≥ 12 HPV (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59) in 1 tube; with or without DNA Extraction	RT	CE	25, 60, 100
BA0018	PCR Kit for Detection and Differentiation of HPV	Differentiation of "high risk" and "low risk" genotypes and the typing of HPV16, 18, 45, 6, 11, 30s and 50s genotypes	RT HYB	CE	12, 16, 60

Genotyping

BA0020	Human Papilloma Virus Genotyping PCR Kit	Detection and genotyping of Low & High Risk HPV	RT ELPHO HYB	CE	20, 24, 48, 55, 96
BA0403	High Risk HPV Genotyping PCR Kit	Identification of the 14 high-risk HPV types, including HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 combined with Multi-Color Melting Curve Analysis.	RT	CE	48, 100

1.4 Sexually transmitted diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0407	STD Panel PCR Kit (11 pathogens)	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>)	HYB	CE	16
BA0610	STI Mycoplasma Panel PCR Kit	Detection of <i>Mycoplasma hominis</i> , <i>Mycoplasma genitalium</i> and <i>Ureaplasma urealyticum/parvum</i> from human genital swabs and urine	RT	CE	100
BA0409	Urethritis PCR Kit I	Multiplex detection of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Mycoplasma genitalium</i> DNA	RT	CE	32, 64
BA0611	Urethritis PCR Kit II	Multiplex detection of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Mycoplasma genitalium</i> , <i>T.vaginalis</i> DNA	RT	CE	100
BA0410	Vaginal Swab PCR Kit (6 pathogens)	Multiplex 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> DANN	RT	CE	32, 64
BA0021	Bacterial Vaginosis PCR Kit	Multiplex detection or quantification of <i>G. vaginalis</i> , <i>Atopobium vaginae</i> , <i>Lactobacillus spp.</i> and total bacteria in the vaginal biotope	RT	CE	100
BA0408	T. vaginalis/ N. gonorrhoeae/ Chl. Trachomatis PCR Kit	Multiplex detection of <i>T. vaginalis</i> , <i>N. gonorrhoeae</i> and <i>Chl. trachomatis</i> DNA	RT	CE	100
BA0022	Candidosis PCR Kits	Quantitative detection of <i>C. albicans</i> , <i>C. glabrata</i> , <i>C. krusei</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i> DNA	RT	CE	100
BA0023	Chlamydia PCR Kit	Detection or quantification of <i>Chlamydia trachomatis</i> DNA	RT HYB	CE	16, 48, 50, 96, 100
BA0612	CT/NG/MG PCR Kit	Multiplex detection of <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> , and <i>Mycobacterium genitalium</i> DNA	HYB	CE	16
BA0024	Gardnerella PCR Kit	Detection of <i>Gardnerella vaginalis</i>	RT	RUO	100
BA0025	Mycoplasma species PCR Kit	Detection of Mycoplasma species (<i>M. hominis</i> , <i>M. genitalis</i>) DNA	RT	CE	48, 50, 55, 96, 100, 110
BA0613	Mycoplasma cell culture PCR Kit	Detection of all known mollicute strains, i.e. <i>mycoplasma</i> , <i>ureaplasma</i> , <i>mesoplasma</i> , <i>spiroplasma</i> , and <i>acholeplasma</i> , for cell culture testing	ELPHO RT	RUO	50
BA0405	Mycoplasma genitalium PCR Kit	Detection of <i>Mycoplasma genitalium</i> genome by amplification of the B subunit of DNA gyrase gene.	RT	CE	50, 100
BA0406	Mycoplasma hominis PCR Kit	Detection of <i>Mycoplasma hominis</i> genome by amplification of the 16S rRNA gene.	RT	CE	50

1.4 Sexually transmitted diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0026	Neisseria PCR Kit	Detection of <i>Neisseria gonorrhoeae</i> DNA	RT HYB	CE	16, 25, 48, 50, 96, 100
BA0028	Treponema PCR Kit	Detection of <i>Treponema pallidum</i> DNA	RT	CE	50, 100
BA0029	Trichomonas PCR Kit	Detection of <i>Trichomonas vaginalis</i> DNA	RT	CE	48, 96, 100
BA0030	Ureaplasma species PCR Kit	Detection of <i>Ureaplasma species (U. parvum, U. urealyticum)</i> DNA	RT	CE	48, 96, 100
BA0031	Chlamydia trachomatis/ Ureaplasma/M. hominis PCR Kit	Multiplex detection of <i>Chlamydia trachomatis/ Ureaplasma/M. hominis</i> DNA	RT	CE	48, 96, 100
BA0032	Chlamydia trachomatis/ N. gonorrhoeae PCR Kit	Multiplex detection of <i>Chlamydia trachomatis and N. gonorrhoeae</i> DNA	RT	CE	25, 48, 96 100
BA0614	N.gonorrhoeae/C.trachomatis/M.genitalium/T.vaginalis PCR Kit	Multiplex detection of <i>N.gonorrhoeae, C.trachomatis, M.genitalium, T.vaginalis</i> DNA	RT	CE	100

1.5 Herpes Virus Infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0033	Epstein-Barr Virus (EBV) PCR Kit	Detection or quantification of <i>EBV</i> DNA in human blood or tissue samples	RT	CE	25, 48, 50, 60, 96, 100, 120
BA0034	Human Herpes Virus 6 (HHV-6) PCR Kit	Detection of <i>Human Herpesvirus type 6</i> DNA	RT	CE	25, 48, 50 96, 100
BA0615	Human Herpes Virus 6A (HHV-6A) PCR Kit	Detection of <i>Human Herpesvirus type 6A</i> DNA	RT	RUO	50
BA0616	Human Herpes Virus 6B (HHV-6B) PCR Kit	Detection of <i>Human Herpesvirus type 6B</i> DNA	RT	RUO	50
BA0617	Human Herpes Virus 6A,B (HHV-6A,B) PCR Kit	Detection of <i>Human Herpesvirus type 6A+B</i> DNA	RT	RUO	50
BA0035	Human Herpes Virus 7 (HHV-7) PCR Kit	Detection and/or quantification of <i>Human Herpesvirus type 7</i> DNA	RT	CE	48, 50, 96
BA0036	Human Herpes Virus 8 (HHV-8) PCR Kit	Detection and/or quantification of <i>Human Herpesvirus type 8</i> DNA	RT	CE	25, 48, 50, 96
BA0037	Varicella Zoster Virus (VZV) PCR Kit	Detection of <i>VZV</i> DNA	RT	CE	25, 48, 50, 96

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

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0038	Herpes Simplex Virus 1 and/or 2 (HSV-1, HSV-2) PCR Kit	Detection of <i>HSV-1 and/or HSV-2</i> DNA in human samples	RT	CE	25, 48, 50, 60, 96, 100, 120
BA0411	HSV 1/2 Typing PCR Kit	Detection and typing of <i>HSV</i> DNA	RT	CE	100
BA0412	HSV 1+2/VZV PCR Kit	Multiplex detection of <i>Herpes Simplex Virus 1 and 2, and Varizella Zoster Virus</i> DNA	RT	CE	96
BA0039	Human Cytomegalovirus (HCMV) PCR Kit	Detection or quantification of human <i>Cytomegalovirus (HCMV, CMV)</i> DNA in human EDTA plasma or serum samples	RT	CE	25, 48, 50, 60, 96, 100, 120
BA0042	Parvovirus B19 (PVB19) PCR Kit	Detection and/or quantification of <i>PVB19</i> DNA	RT	CE	25, 48, 50, 60, 96, 120
BA0040	Measles Virus RT-PCR Kit	Detection of <i>Measles Virus</i> RNA	RT	RUO	150
BA0041	Mumps Virus RT-PCR Kit	Detection of <i>Mumps Virus</i> RNA	RT	RUO	150

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

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0043	Rubella PCR Kit	Detection of <i>Rubella</i> DNA	RT	CE	50
BA0044	Toxoplasma PCR Kit	Detection of <i>Toxoplasma</i> DNA	RT	CE	50

1.7 Respiratory Infections / Tuberculosis

Order number	Product name	Intended use	Method	Legal status	Tests/Size
Respiratory Infections					
BA0413	Atypical CAP PCR test	Multiplex 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	RT	CE	32, 64
BA0045	Avian Influenza A H5, H7, H9 RT-PCR Kit	Detection of H5, H7, H9 subtypes of <i>Influenza A virus</i> RNA	RT	RUO	50
BA0046	Avian Influenza A H5N1 RT-PCR Kit	Detection or quantification of <i>Avian A virus H5N1</i> subtype RNA	RT	CE	50, 60, 120
BA0047	Bordetella PCR Kit	Detection and/or typing of <i>Bordetella pertussis</i> / <i>B. parapertussis</i> / <i>B. bronchiseptica</i> / <i>B. holmesii</i> DNA	RT	CE	32, 48, 50, 64, 96, 100
BA0414	CAP bacteria PCR Kit	Real Time PCR test for detection of Community Acquired Pneumonia – CAP	RT	CE	12, 60
BA0415	hMPV RT-PCR Kit	Detection of Human Metapneumovirus A and B RNA	RT	CE	48, 96
BA0048	hRSV + hMPV RT-PCR Kit	Multiplex detection of human <i>Respiratory Syncytial virus</i> and human <i>Metapneumovirus</i> RNA from nasal and nasopharyngeal swab specimen	RT	CE	96
BA0049	Human Respiratory Syncytial virus (hRSV) RT-PCR Kit	Detection of <i>hRSVA</i> and B RNA	RT	CE	32, 48, 50, 96
BA0050	Influenza A H1N1 & H3N2 RT-PCR Kit	Detection of <i>H1N1</i> and <i>H3N2</i> types of <i>Influenza A</i> RNA	RT	RUO	50
BA0618	Influenza A RT-PCR Kit	Detection of <i>Influenza A</i> RNA	RT	CE	50
BA0619	Influenza B RT-PCR Kit	Detection of <i>Influenza B</i> RNA	RT	CE	50
BA0051	Influenza A/B RT-PCR Kit	Multiplex detection and differentiation of influenza viruses (<i>Influenza A</i> , <i>Influenza B</i> and <i>H1N1</i>) from human nasal and throat; including avian influenza A (H5N8)	RT	CE	20, 32, 48, 50, 96, 100
BA0620	Influenza H7N9 RT-PCR Kit	Detection of <i>influenza H7N9</i> RNA	RT	CE	48, 96
BA0052	Legionella pneumophila PCR Kit	Quantitative detection of <i>Legionella pneumophila</i> DNA	RT	CE	50, 100
BA0053	MERS-SARS CoV RT-PCR Kit	Detection and differentiation of Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome <i>Coronaviruses</i> RNA	RT	CE	48, 50, 96, 100
BA0621	Human Coronavirus alpha PCR Kit	Detection of <i>Human Coronavirus alpha</i> RNA	RT	RUO	50
BA0622	Human Coronavirus beta PCR Kit	Detection of <i>Human Coronavirus beta</i> RNA	RT	RUO	50
BA0623	Parechovirus PCR Kit	Detection of <i>Parechovirus</i> RNA	RT	RUO	50
BA0624	Rhinovirus (A,B,C) PCR Kit	Detection of <i>Rhinovirus</i> (A,B,C) RNA	RT	CE	50
BA0054	<i>Mycoplasma pneumoniae</i> / <i>Chlamydia Pneumoniae</i> PCR Kit	Detection of <i>Chlamydia pneumoniae</i> and/or <i>Mycoplasma pneumoniae</i> DNA	RT	CE	48, 50, 96
BA0416	<i>Mycoplasma pneumoniae</i> PCR Kit	Identification of <i>Mycoplasma pneumoniae</i> genome by amplification of the P1 gene.	RT	CE	50
BA0625	<i>Streptococcus pneumoniae</i> PCR Kit	Detection of <i>S. pneumoniae</i> DNA	RT	CE	50

1.7 Respiratory Infections / Tuberculosis

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0055	Parainfluenza (PIV) Virus RT-PCR Kit	Detection of <i>Parainfluenza virus</i> RNA (Type 1, 2, 3 Et 4)	RT	CE	32, 48, 50, 96, 100
BA0056	<i>Pseudomonas aeruginosa</i> PCR Kit	Quantitative detection of <i>Pseudomonas aeruginosa</i> DNA	RT	CE	50
BA0626	Metapneumovirus PCR Kit	Detection of <i>Metapneumovirus (HMPV)</i> RNA	RT	CE	50
BA0417	Respiratory Pathogens PCR Kit (21 pathogens)	Multiplex detection of 21 respiratory pathogens for detection of influenza A, influenza A (H1N1) swl, influenza B, rhinovirus, coronavirus NL63, 229E, OC43, HKU1, parainfluenza 1, 2, 3, 4, human metapneumovirus A/B, bocavirus, respiratory syncytial virus A/B, adenovirus, enterovirus, parechovirus, mycoplasma	RT	CE	32, 64
BA0627	Respiratory Pathogens Plus PCR Kit (33 pathogens)	Multiplex detection of 25 respiratory pathogens for detection of influenza A, influenza B, influenza C; influenza A (H1N1) swl, parainfluenza viruses 1, 2, 3 and 4; coronaviruses NL63, 229E, OC43 and HKU1; human metapneumoviruses A and B; rhinovirus; respiratory syncytial viruses A and B; adenovirus; enterovirus; parechovirus; bocavirus; Pneumocystis jirovecii; Mycoplasma pneumoniae; Chlamydia pneumoniae; Streptococcus pneumoniae; Haemophilus influenzae type B; Staphylococcus aureus; Moraxella catarrhalis; Bordetella spp.; Klebsiella pneumoniae; Legionella pneumophila/Legionella longbeachae; Salmonella species and Haemophilus influenzae	RT	CE	32, 64
BA0057	Respiratory Virus Panel RT-PCR Kit (16 pathogens)	Multiplex detection of the genome of 16 main respiratory viruses	RT	CE	20, 100
BA0628	Respiratory Virus Panel RT-PCR Kit (8 pathogens)	Multiplex detection and identification of human of Acute Respiratory viral infections, including parainfluenza virus-1-4 (hPiv); OC43, E229, NL63, and HKU1 human coronavirus (hCov); human rhinovirus (hRv); human B, C, and E adenovirus (hAdv) and human bocavirus (hBov)	RT	CE	100
BA0058	Swine Influenza Virus H1 RT-PCR Kit	Detection of <i>Swine Influenza Virus A/H1</i> RNA	RT	RUO	50

Tuberculosis and TB resistance

BA0060	<i>Mycobacterium tuberculosis</i> PCR Kit	Detection of <i>Mycobacterium tuberculosis</i> complex strains DNA	RT	CE	48, 50, 60, 96, 100, 120
BA0418	TB Resistance Module 1	Detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Isoniazid and Rifampicin	RT HYB	CE	48, 50, 60, 96, 100, 120
BA0419	TB Resistance Module 2	Detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Fluoroquinolone antibiotics and Ethambutol	RT HYB	CE	12, 48, 60
BA0420	TB Resistance Module 3	Detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Aminoglykoside antibiotics	HYB	CE	12, 48, 61
BA0421	TB Resistance Module 4	Detection of <i>Mycobacteria</i> of the <i>Mycobacterium tuberculosis</i> complex and its resistances to Streptomycin	RT	CE	48

1.8 Neurological Infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
Enterovirus/Poliovirus					
BA0061	Enterovirus RT-PCR Kit	Detection of Enterovirus (<i>Coxsackie A</i> , <i>Coxsackie B</i> , <i>Echovirus</i> , <i>Enterovirus</i>) RNA	RT	CE	32, 48, 50, 96
BA0062	Enterovirus 71 RT-PCR Kit	Detection of Enterovirus-71 Virus (EV1) RNA	RT	CE	50
BA0063	Poliovirus RT-PCR Kit	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	RT	CE	50
Meningitis					
BA0065	Listeria PCR Kit	Detection of <i>Listeria monocytogenes</i> DNA	RT	CE	32, 50, 96, 100
BA0629	CSF PCR Kit (7 pathogens)	Isothermal multiplex detection of <i>HSV-1</i> , <i>HSV-2</i> , <i>VZV</i> , <i>N. meningitides</i> , <i>S. pneumoniae</i> , <i>S. agalactiae</i> , <i>L. monocytogenes</i> in cerebrospinal fluid; for use with Genie II Mk2 instruments	RT	CE	12
BA0423	Neuro PCR Kit (9 pathogens)	Multiplex 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>	RT	CE	32

1.8 Neurological Infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0422	Neonatal Meningitis PCR Kit	Multiplex detection and quantification of Group B Streptococcus (<i>S. agalactiae</i>), <i>Listeria monocytogenes</i> , <i>Escherichia coli</i> DNA	RT	CE	32
BA0064	NHS Meningitidis PCR Kit	Detection of <i>N. meningitidis</i> , <i>H. influenzae</i> , <i>St. pneumonia</i> DNA	RT	CE	50
BA0630	Neisseria meningitides PCR Kit	Detection of <i>N. meningitides</i> DNA	RT	CE	50
BA0424	Viral Meningitis PCR Kit	Multiplex detection of <i>herpes simplex virus 1, 2</i> , <i>varicella-zoster virus</i> , <i>enterovirus</i> , <i>mumps virus</i> , <i>parechovirus</i>	RT	CE	32

1.9 Gastrointestinal Infections / Parasites

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0066	Bacterial Stool Panel PCR Kit	Multiplex detection and differentiation of humanpathogenic <i>Salmonella spp.</i> , <i>Campylobacter spp.</i> and <i>Yersinia enterocolitica</i> in human stool samples	RT	CE	100
BA0426	Gut Balance PCR Kit	Quantitative detection of Bacteroides and Cluster XIVa DNA from human stool samples to judge symbiotic balance in gut microbiome	RT	CE	100
BA0067	A.I.I. (Acute Intestinal Infections) PCR Kit	Multiplex 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>	RT	CE	50
BA0425	Bacterial Gastroenteritis PCR Kit	Multiplex 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	RT	CE	32
BA0605	Acinetobacter baumannii PCR Kit	Detection of <i>Acinetobacter baumannii</i> DNA	RT	RUO	150
BA0068	Adenovirus PCR Kit	Detection and quantification of <i>Adenovirus</i> DNA species (A, B, C, D, E, and F) or serotypes (HAdV 1-52)	RT	CE	48, 50, 96
BA0069	Aerobic complex PCR Kit	Multiplex detection of Enterobacteriaceae (<i>E. coli</i> , <i>Klebsiella spp.</i> , <i>Proteus spp.</i> , <i>Streptococcus spp.</i>) DNA	RT	RUO	50
BA0070	Bacillus cereus PCR Kit	Detection of <i>Bacillus Cereus</i> DNA	RT	CE	100
BA0071	Campylobacter PCR Kit	Detection of <i>Campylobacter jejuni</i> DNA	RT	CE	25, 50, 100
BA0631	Clostridium difficile PCR Kit I	Isothermal multiplex detection of detection of <i>C. difficile</i> incl. Inhibition Control, to detect the parameters <i>GDH</i> , <i>Toxin A</i> , <i>Toxin B</i> , and Binary Toxin; for use with Genie II Mk2 instruments	RT	CE	24
BA0072	Clostridium difficile PCR Kit II	Detection of <i>Clostridium difficile</i> Toxin A and B DNA	RT	CE	32, 48, 50, 55, 64, 96, 100
BA0073	Clostridium perfringens PCR Kit	Detection of <i>Clostridium perfringens</i> DNA	RT	CE	50, 100
BA0074	Cronobacter PCR Kit	Detection of <i>Cronobacter sakazakii</i> DNA	RT	RUO	50, 100
BA0075	E. coli O157 PCR Kit	Detection of <i>E. coli O157 : H7</i> DNA	RT	CE	25, 150
BA0076	EAEC PCR Kit	Detection of <i>Enteroadhesive E coli</i> (EAEC) DNA	RT	CE	100
BA0077	EHEC PCR Kit	Detection of <i>enterohemorrhagic E. coli</i> (EHEC) DNA	RT	CE	48, 50, 96, 100
BA0078	EIEC PCR Kit	Detection of Enteroinvasive <i>E. coli</i> (EIEC) DNA	RT	CE	100
BA0079	Enterobacter sakazaii PCR Kit	Detection of <i>Enterobacter sakazaii</i> DNA	RT	CE	25
BA0080	EPEC PCR Kit	Detection of Enteropathogenic <i>E. coli</i> (EPEC) DNA	RT	CE	100
BA081	Escherichioses Screen & Differentiation Kit	Detection of <i>E.coli</i> (EPEC, ETEC, EIEC, EHEC, and EAEC) DNA	RT	RUO	50, 100

1.9 Gastrointestinal Infections / Parasites

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0082	ETEC PCR Kit	Real Time PCR test for detection of Enterotoxigenic <i>E. coli</i> (ETEC) DNA	RT	CE	100
BA0632	<i>E. coli</i> (STEC) Typing PCR Kit	Detection and typing of <i>E. coli</i> STEC via the stx1 & stx2 genes	RT	RUO	50, 100
BA0633	<i>E. coli</i> (EHEC, EPEC) Typing PCR Kit	Detection and typing of <i>E. coli</i> EHEC, EPEC via the eae & ehxA genes	RT	RUO	50, 100
BA0634	<i>E. coli</i> (EHEC or EPEC) Typing PCR Kit	Detection and typing of <i>E. coli</i> EHEC, EPEC via the eae gene	RT	RUO	50, 100
BA0635	<i>E. coli</i> (EHEC) Typing PCR Kit	Real Time PCR test for detection and typing of <i>E. coli</i> EHEC, EPEC via the ehxA gene	RT	RUO	50, 100
BA0430	Verotoxin-producing <i>Escherichia coli</i> PCR Kit	Detection of Verotoxin-producing <i>E. coli</i> VT1 DNA	RT	RUO	100
BA0083	<i>Helicobacter pylori</i> PCR Kit	Detection of <i>H. pylori</i> DNA e.g. by amplification of the UreC gene	RT	CE	32, 48, 50, 96
BA0636	<i>H. pylori</i> / clarithromycin resistance PCR Kit	Detection of <i>H. pylori</i> DNA and its resistance to clarithromycin from human native tissue biopsy material	RT	CE	100
BA0084	Hospital Stool Panel PCR Kit	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	RT	CE	100
BA0085	Viral Stool Panel PCR Kit	Multiplex detection and differentiation of norovirus, rotavirus, adenovirus and astrovirus RNA in human stool samples	RT	CE	50, 100
BA0088	Norovirus RT-PCR Kit	Detection and/or differentiation of Norovirus (Genogroup I, II and IV) RNA	RT	CE	32, 48, 50, 96
BA0427	Rotavirus RT-PCR Kit	Detection of Rotavirus genotype A, most strains of genotype B and C, and some strains of the other genotypes D, E, F and G RNA	RT	CE	48, 50, 96
BA0089	Rotavirus/Norovirus/ Astrovirus RT-PCR Kit	Detection of Rotavirus, and/or Norovirus and/or Astrovirus RNA	RT	CE	50, 100
BA0090	Sapovirus RT-PCR Kit	Detection of Sapovirus (<i>Sapporo virus</i> genotypes I-V) RNA in stool	RT	CE	25, 100
BA0428	<i>Salmonella</i> spp. PCR Kit	Identification of <i>Salmonella</i> spp genome by amplification of the Nuclease gene	RT	CE	50, 150
BA0429	<i>Shigella</i> spp. PCR Kit	Identification of <i>Shigella</i> spp genome by amplification of the Yst gene	RT	CE	50
BA0091	<i>Shigella</i> / <i>Salmonella</i> / <i>Campylobacter</i> PCR Kit	Detection of <i>Shigella</i> , and/or <i>Salmonella</i> and/or <i>campylobacter</i> DNA	RT	CE	25, 32, 50, 96
BA0637	<i>Shigella</i> / EIEC / <i>Salmonella</i> / EHEC / <i>Campylobacter</i> PCR Kit	Multiplex detection of <i>Shigella</i> spp, Enteroinvasive <i>E. coli</i> (EIEC), <i>Salmonella</i> spp, EHEC and <i>Campylobacter</i> spp DNA	RT	CE	50
BA0092	STEC PCR Kit	Detection of Shigella Toxin-Producing <i>E. coli</i> (STEC) DNA	RT	CE	100
BA0093	<i>Yersinia</i> PCR Kit	Detection of <i>Yersinia enterocolitica</i> and/or <i>Y. pseudotuberculosis</i> DNA	RT	CE	32, 50, 96
Parasites/Protozoa					
BA0094	Dientamoeba PCR Kit	Detection of <i>Dientamoeba fragilis</i> DNA	RT	CE	100
BA0095	Entamoeba PCR Kit	Detection of <i>Entamoeba histolytica</i> DNA	RT	CE	100
BA0638	Acanthamoeba PCR Kit	Detection of <i>Acanthamoeba</i> DNA	RT	CE	50
BA0096	Parasitic Stool Panel PCR Kit	Detection of <i>Dientamoeba fragilis</i> , <i>Giardia lamblia</i> (synonym <i>G. intestinalis</i> or <i>G. duodenales</i>), <i>Entamoeba histolytica</i> and <i>Cryptosporidium</i> spp. parasites DNA in stool	RT	CE	100
BA0639	Crypto-Giardia-Entamoeba PCR Kit	Detection of <i>Cryptosporidium</i> spp., <i>Giardia lamblia</i> and <i>Entamoeba histolytica</i> parasites DNA	HYB	CE	20
BA0431	<i>Cryptosporidium</i> PCR Kit	Quantification of <i>Cryptosporidium</i> (<i>C. parvum</i> , <i>C. hominis</i> [previously <i>C. parvum</i> genotype 1], <i>C. canis</i> , <i>C. felis</i> , <i>C. meleagridis</i> , and <i>C. muris</i>) DNA	RT	RUO	150

1.9 Gastrointestinal Infections / Parasites

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0432	Giardia A+B PCR Kit	Quantification of <i>Giardia intestinalis</i> assemblages A and B DNA known to infect humans	RT	RUO	150
BA0640	Cryptosporidium parvum PCR Kit	Detection of Kit Cryptosporidium parvum DNA	RT	RUO	100
BA0433	Giardia A-F PCR Kit	Quantification of <i>Giardia intestinalis</i> assemblages A to F DNA	RT	RUO	150
BA0121	Leishmania (all species), PCR Kit	Quantification of <i>Leishmania spp</i> DNA via the cytochrome b (cytb) kinetoplast gene	RT	CE	48, 150
BA0434	Leishmania infantum & Leishmania donovani PCR Kit	Quantification of <i>Leishmania infantum</i> & <i>Leishmania donovani</i> DNA	RT	RUO	150
BA0435	Leishmania major PCR Kit	Quantification of <i>Leishmania major</i> DNA	RT	RUO	150
BA0436	Leishmania tropica PCR Kit	Quantification of <i>Leishmania tropica</i> DNA	RT	RUO	150

Parasites/Helminths

BA0437	Ascaris lumbricoides/ Ascaris suum PCR Kit	Identifying the appearance of the roundworms or eggs of <i>Ascaris lumbricoides/ Ascaris suum</i> preferably in feces	RT	RUO	150
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1.10 Other infectious diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0098	Chlamydomphila pneumonia PCR Kit	Detection or quantification of <i>Chlamydomphila pneumoniae</i> DNA	RT	CE	32, 48, 50, 96
BA0099	John Cunningham virus (JCV) PCR Kit	Detection or quantification of <i>JC Virus</i> DNA	RT	CE	48, 50, 96
BA0100	Polyomavirus BK (BKV) PCR Kit	Detection or quantification of <i>BKV virus</i> DNA	RT	CE	25, 48, 50, 96
BA0641	JCV/BKV PCR Kit	Detection and/or quantification of <i>JCV</i> and <i>BKV</i> DNA	RT	CE	50

1.11 Tick borne infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0102	Borrelia burgdorferi PCR Kit	Detection of <i>Borrelia burgdorferi</i> DNA	RT	CE	32, 50, 96
BA0642	Borrelia miyatomoi PCR Kit	Detection of <i>Borrelia miyatomoi</i> DNA	RT	CE	50
BA0103	Coxiella burnetii PCR Kit	Detection of <i>Coxiella burnetii</i> DNA	RT	RUO	50
BA0104	Ehrlichia PCR Kit	Detection of the Ehrlichia species (<i>E. chaffeensis</i> , <i>E. ewengii</i> , <i>Anaplasma phagocytophilum</i> (formerly <i>E. phagocytophilum</i> , <i>E. equi</i>))	RT	CE	32, 96
BA0105	Leptospira ssp. PCR Kit	Detection of <i>Leptospira</i> DNA	RT	CE	50, 100
BA0438	Tick-borne encephalitis (FSME) RT-PCR Kit	Detection of <i>Tick-borne encephalitis virus (TBEV)</i> RNA	RT	CE	12, 32, 48, 50, 60, 96
BA0106	Vibrio parahaemolyticus PCR Kit	Detection of <i>V. parahaemolyticus</i> DNA	RT	CE	100
BA0107	Vibrio Vulnificus PCR Kit	Detection of <i>V. vulnificus</i> DNA	RT	CE	100

1.12 Fungal and yeast infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0108	Aspergillus ssp. PCR Kit	Detection of the most common species <i>A. fumigatus</i> , <i>A. flavus</i> , <i>A. niger</i> , and <i>A. terreus</i> DNA	RT	CE	100
BA0109	Aspergillus fumigates PCR Kit	Quantitative detection of <i>Aspergillus fumigates</i> DNA in bronchoalveolar lavage, blood, plasma and serum	RT	CE	25, 50
BA0606	Candida ssp. PCR Kit	Multiplex detection of <i>Candida albicans</i> , <i>C. glabrata</i> and <i>C. krusei</i> DNA	RT	RUO	100
BA0110	Cryptococcus neoformans PCR Kit	Detection of <i>Cryptococcus neoformans</i> DNA in bronchoalveolar lavage, blood, plasma, serum, and cerebrospinal fluid	RT	CE	50, 100
BA0442	Dermatophytes, yeasts, mould or mixed infections PCR Kit	Multiplex detection of Trichophyton mentagrophytes complex, Trichophyton tonsurans, Trichophyton violaceum, Trichophyton rubrum complex, Microsporum canis, Microsporum audouinii, Microsporum ferrugineum DNA from skin scale specimens, plucked hair, nails, culture and swabs of human origin.	RT HYB	CE	10, 32, 50, 64
BA0439	Dermatophytes PCR Kit 1	Multiplex detection of the pathogens <i>T. rubrum</i> , Dermatophyton spp. (TME), Scopulariopsis brevicaulis and <i>Candida</i> spp.	HYB	CE	10, 50
BA0440	Dermatophytes PCR Kit 2	Multiplex detection 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. verrucosum</i> .	HYB	CE	10, 50
BA0441	Dermatophytes PCR Kit 3	Multiplex detection 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	HYB	CE	10, 50

1.13 Emerging diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0603	Tropical fever core, 7 pathogens RT-PCR Kit	Multiplex detection of <i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> , <i>Hantaan virus/Seoul virus</i> , <i>Leishmania</i> spp. and <i>Japanese Encephalitis virus</i>	RT	CE	32, 64
BA0604	Tropical fever Asia, 4 pathogens RT-PCR Kit	Multiplex detection of <i>dengue virus</i> , <i>chikungunya virus</i> , <i>Salmonella</i> spp., <i>West Nile virus</i> , <i>Plasmodium</i> spp., <i>Rickettsia</i> spp., <i>Leptospira</i> spp.	RT	CE	32, 64
BA0111	Chikungunya Virus (Chik) RT-PCR Kit	Detection of <i>Chikungunya Virus</i> RNA	RT	CE	96, 150
BA0443	Chikungunya/Dengue PCR Kit	Multiplex detection of <i>Chikungunya</i> and <i>Dengue</i> virus RNA	RT	CE	24, 48, 96
BA0112	Crimean–Congo hemorrhagic fever (CCHF) RT-PCR Kit	Detection of <i>CCHF</i> RNA	RT	CE	50, 60, 96, 120
BA0444	Dengue Genotype RT-PCT Kit	Detection and differentiation of <i>Dengue</i> 1, 2, 3, 4 RNA	RT	CE	50
BA0113	Dengue RT-PCR Kit	Detection of <i>Dengue</i> 1, 2, 3, 4 RNA	RT	CE	50, 60, 96, 120
BA0114	Ebola hemorrhagic fever Virus (Sudan, SEBOV) RT-PCR Kit	Detection of <i>SEBOV</i> RNA from human samples	RT	RUO	60, 120
BA0115	Ebola hemorrhagic fever Virus (Zaire, ZEBOV) RT-PCR Kit	Detection of <i>ZEBOV</i> RNA from human samples	RT	RUO	60, 96, 120
BA0445	Filovirus Genotype RT-PCR Kit	Detection of Human pathogenic <i>filoviruses</i> and species differentiation	RT	CE	96
BA0446	Filovirus Screen RT-PCR Kit	Detection of Human <i>pathogenic filovirus</i> species RNA	RT	CE	96

Viral diseases, hemorrhagic fevers

1.13 Emerging diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0116	Lassa Virus (LV) RT-PCR Kit	Detection of <i>Lassa Virus (LV)</i> RNA	RT	RUO	25
BA0117	Marburg Virus (MARV) RT-PCR Kit	Detection of <i>MARV</i> RNA	RT	RUO	120
BA0643	Ebola Zaire/Ebola Sudan, Marburg virus RT-PCR Kit	Multiplex detection of <i>ZEBOV</i> , <i>EBOV</i> and <i>MARV</i> RNA	RT	CE	50
BA0644	Yellow Fever Virus (YFV) RT-PCR Kit	Detection of <i>Yellow Fever Virus (YFV)</i> RNA	RT	CE	50
BA0118	Nipah Virus RT-PCR Kit	Detection of <i>Nipah Virus (NiV)</i> RNA	RT	CE	25
BA0447	Plasmodium spp. PCR Kit	Detection of all <i>Plasmodium</i> species	RT	RUO	150
BA0119	Rift Valley Fever (RVF) Virus RT-PCR Kit	Detection of <i>Rift Valley Fever (RVF)</i> RNA	RT	CE	60, 96, 120
BA0120	West Nile Virus (WNV) RT-PCR Kit	Detection of <i>WNV</i> RNA	RT	CE	25, 32, 50, 64, 96
BA0645	Japane Encephalitis (JEV) PCR Kit	Quantitative detection of <i>JEV</i> RNA, genotypes I, II, III, IV, and V	RT	RUO	150
BA0448	Zika Virus RT-PCR Kit (one-step)	Detection of <i>Zika Virus</i> RNA	RT	CE	24, 48, 50, 96, 150

Parasites

BA0122	Malaria PCR Kit	Screening/ detection of Malaria Parasite DNA	RT HYB	CE	32, 48, 50, 64, 96, 150
BA0124	Malaria Typing PCR Kit	Detection of 3 of the 4 Plasmodia that infect humans (<i>P. malariae</i> , <i>P. ovale</i> or <i>P. vivax</i>) in DNA extracted from whole blood samples.	HYB	CE	48
BA0646	Malaria Detection and Strain Differentiation PCR Kit	Screening and differentiation of five species of <i>Plasmodium</i> (<i>P. falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> and <i>P. knowlesi</i>)	RT	CE	32, 64, 96

1.14 Bacteriology / Sepsis / Pyogenic infections

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0450	Neonatal Sepsis PCR Kit (7 Pathogens)	Multiplex detection and quantification of <i>cytomegalovirus</i> , <i>Group B Streptococcus (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	RT	CE	32, 64
BA0647	Meningitis/Sepsis PCR Kit	Multiplex detection of all <i>Neisseria meningitidis</i> serogroups (A, B, C, X, Y, W135, H, Z, 29 E, NT), all the 90 <i>Streptococcus pneumoniae</i> serotypes, serotypes b, c of <i>Haemophilus influenzae</i> and all <i>Adenovirus</i> serotypes (a-f).	RT	CE	8
BA0648	Prostate Infection PCR Kit	Multiplex diagnosis of chronic bacterial prostatitis (<i>Enterobacter spp.</i> , <i>Klebsiella spp.</i> , <i>Enterococcus faecalis</i> , <i>faecium</i> , <i>Escherichia coli</i> , <i>Proteus spp.</i> , <i>Pseudomonas aeruginosa</i> , <i>Serratia spp.</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus spp.</i>)	RT	RUO	96
BA0126	Streptococcus B PCR Kit	Quantitative detection of <i>Streptococcus B</i> DNA	RT	CE	100
BA0127	Streptococcus group A and pyogenic group C and G PCR Kit	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	RT	CE	96
BA0128	Streptococcus pyogenes PCR Kit	Quantitative detection of <i>Streptococcus pyogenes</i> DNA	RT	CE	50, 100
BA0449	Bartonella henselae PCR Kit	Detection of the <i>Bartonella henselae</i> genome by amplification of the <i>ribC</i> gene	RT	CE	50
BA0451	Rickettsia spp. PCR Kit	Detection of <i>Rickettsia spp.</i> genome by amplification of <i>gltA</i> gene	RT	CE	50
BA0649	Rickettsia conorii PCR Kit	Detection of <i>Rickettsia conorii</i> DNA	RT	CE	50
BA0650	Corynebacterium diphtheriae / tox-genes PCR Kit	Detection of <i>Corynebacterium diphtheriae</i> and their toxin genes	RT	CE	50

1.15 Bacterial and viral drug resistance

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0129	Carbapenems resistance PCR Kit	Detection of <i>Enterobacteriaceae</i> and <i>Pseudomonas</i> resistance against carbapenems, genes VIM, NDM, OXA-48, KPC	RT	RUO	60
BA0130	Cephalosporins resistance PCR Kit	Detection of <i>Enterobacteriaceae</i> resistance against cephalosporins, genes CTX-M, or <i>S. aureus</i> resistance against cephalosporins, genes MecA	RT	RUO	60
BA0131	Glycopeptides resistance PCR Kit	Detection of <i>Enterococcus faecalis</i> and <i>E. faecium</i> resistance to Vancomycin and Teicoplanin, genes VanA and VanB	RT	RUO	60
BA0132	Macrolides resistance PCR Kit I	Detection of <i>Streptococcus spp.</i> and <i>Staphylococcus spp.</i> resistance to macrolides, lincosamides, streptogramins; genes ErmB and Mef	RT	RUO	60
BA0651	Macrolides resistance PCR Kit II	Detection of for <i>Streptococcus spp.</i> resistance to macrolides; genes Mef	RT	RUO	60
BA0133	MDR KPC/OXA PCR Kit	Detection of the genes KPC, OXA-48 and OXA-162 in <i>Enterobacteriaceae</i> and <i>NFGNB</i>	RT	CE	100
BA0134	MDR MBL (VIM, IMP, NDM) PCR Kit	Detection of the genes VIM, IMP and NDM in <i>Enterobacteriaceae</i> and <i>NFGNB</i>	RT	CE	100
BA0652	Carbapenemases CRE PCR Kit	Multiplex detection of carbapenemases producing bacteria, including all described variants of metallo- β -lactamases of the VIM-, NDM, KPC-type, the OXA-48 family including OXA-181/-232; ESBL of the CTX-M-1 group and the CTX-M-9 group; for use with Genie II Mk2 instruments	RT	CE	24
BA0653	Carbapenemases Basic PCR Kit	Multiplex detection of carbapenemases producing bacteria, including metallo- β -lactamases of only the VIM-, NDM, KPC, OXA-48 and OXA-181 genes; for use with Genie II Mk2 instruments	RT	CE	24
BA0654	Mcr-1 Gene PCR Kit	Multiplex detection of the <i>mcr-1</i> gene which confers a resistance in gram negative bacteria to Colistin (Polymyxin B); for use with Genie II Mk2 instruments	RT	CE	24
BA0135	MRSA PCR Kit I	Detection or quantification of Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) DNA	RT HYB	CE	25, 32, 50, 96, 100
BA0655	MRSA PCR Kit II	Multiplex detection of <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , and the resistance genes <i>mecA</i> and <i>mecC</i> genes; for use with Genie II Mk2 instruments	RT	CE	12, 24, 60
BA0453	Q-MRSA Detection PCR Kit	Multiplex detection of the 3 MRSA markers <i>nuc</i> , <i>mecA</i> and <i>orfX-SCCmec</i>	RT	RUO	10, 20
BA0136	Penicillins resistance PCR Kit	Detection of <i>Enterobacteriaceae</i> and <i>Pseudomonas</i> resistance to penicillins and first-generation cephalosporins, genes TEM	RT	RUO	60
BA0137	PVL PCR Kit	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	RT	CE	100
BA0656	VRE PCR Kit	Isothermal detection of Vancomycin-resistant enterococci (VRE), particularly <i>E. faecium</i> , <i>E. faecalis</i> , <i>E. gallinarum</i> , <i>E. casseliflavus</i> and <i>E. durans</i> ; for use with Genie II Mk2 instruments	RT	CE	24
BA0657	Oseltamivir (Tamiflu) Resistance PCR Kit	Detection of Oseltamivir Resistance (H274Y) in Swine flu <i>H1N1</i>	RT	RUO	25, 150

1.16 Periodontitis

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0139	Periodontitis Screening PCR Kit	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	RT	RUO	96

1.17 Biothreat agents

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0140	Anthrax PCR Kit	Detection of <i>Bacillus anthracis</i> DNA	RT	CE	50, 96
BA0141	Botulinus PCR Kit	Detection of <i>Botulinus</i> (Types A/B/E/F) DNA	RT	CE	25
BA0142	Brucella spp. PCR Kit	Detection of <i>Brucella</i> DNA i.e. by amplification of the <i>bcs31</i> gene	RT	CE	50, 100

1.17 Biothreat agents

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0143	Set of PCR Kits for detection and quantification of Biothreat high risk pathogen DNA	Detection of <i>Bacillus anthracis</i> , <i>Burkholderia</i> spp. (<i>B. mallei</i> , <i>B. pseudomallei</i>), <i>Brucella</i> spp. (<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> .	RT	RUO	50
BA0144	Vibrio cholerae PCR Kit	Detection of <i>Vibrio cholerae</i> strains iCtxA, tcpA and/or O139 DNA	RT	CE	25, 50, 96
BA0145	Yersinia pestis PCR Kit	Detection of <i>Yersinia pestis</i> DNA	RT	RUO	50

2. ONCOLOGY

2.1 Oncogene expression quantification/Minimal residual disease (MRD)

Order number	Product name	Intended use	Method	Legal status	Tests/Size
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Cancers of the Haematopoietic System

BA0454	BCR-ABL P210/P190 PCR Kit	Multiplex one-step <i>in vitro</i> quantification of both the <i>BCR-ABL</i> fusion transcripts P210/P190 in one tube	RT	CE	24
BA0146	M-BCR/t(9;22) PCR Kit	Quantification of <i>BCR-ABL</i> fusion transcripts comprising the (Ph+) translocation t(9;22) major breakpoint cluster regions (<i>M-BCR</i>) b2a2 and b3a2 in CML	RT ELPHO	CE	25, 48, 50, 96, 120
BA0147	mi-BCR/t(9;22) PCR Kit	Quantification of <i>BCR-ABL</i> fusion transcripts comprising the (Ph+) translocation t(9;22) minor breakpoint cluster region (<i>M-BCR</i>) e1a2 in CML	RT ELPHO	CE	48, 96, 120
BA0658	Onco CLL PCR Kit	Analysis of mutational status of the Immunoglobulin variable heavy chain region gene (IGHV) to assess prognosis in CLL	RT	CE	10
BA0456	AML Fusion Screening PCR Kit I (16 translocations)	Multiplex detection and quantification of 16 fusion genes with 72 breakpoints in leukemia patients with AML	RT	CE	10, 20
BA0659	AML Fusion Screening PCR Kit II (11 translocations)	For high resolution detection of 11 fusion gene transcripts (AML1-ETO, BCR-ABL, CALM-AF10, CBFB-MYH11, DEK-CAN, MLL-AF6, MLL-AF9, MLL-ELL, MLL-PTD, NPM1-MLF1 and PML-RARA) with 34 transcript variants in total	FA	CE	10, 25, 100
BA0455	ALL Fusion Screening PCR Kit	Multiplex detection and quantification of 16 fusion genes with 71 breakpoints in leukemia patients with ALL	RT	CE	10, 20
BA0148	AML1-ETO/t(8;21) PCR Kit	Identification and quantitation of the t(8;21)(q22;q22) translocation with <i>AML1-ETO</i> fusion transcripts	RT	CE	25, 48, 96
BA0149	CBFB-MYH11 A/inv(16) PCR Kit	Identification and quantitation of inv(16)(p13;q22) inversion with <i>CBFB-MYH11</i> A fusion transcripts	RT	CE	25, 48, 96
BA0607	MLL-AFF1 t(4;11) PCR Kit	Screening test for chromosome translocation t(4;11)(q21;q23) (MLL-AFF1) associated with leukemia	RT	CE	25
BA0150	PML-RARa/t(15;17) PCR Kit	Quantification of <i>PML-RARa</i> /t(15;17) fusion transcripts covering all three known regions of the <i>PML</i> locus in AML M3	RT	CE	24, 25, 48, 96, 120
BA0151	TEL-AML1/t(12;21) PCR Kit	Quantification of <i>TEL-AML1</i> fusion transcripts t(12;21) in AML1	RT	RUO	25, 120
BA0601	TCF3-PBX1/t(1;19) PCR Kit	Test for chromosome translocation t(1;19) (q23;p13)(TCF3-PBX1) screening associated with leukemia	RT	CE	25
BA0733	ETV6-PDGFRB t(5;12) PCR Kit	Test for chromosome translocation <i>ETV6-PDGFRB</i> ; t(5;12)(q33;p13) screening associated with leukemia	ELPHO	CE	25,50
BA0154	Screening Kit for leukemia associated translocations (7 translocations)	Multiplex detection and/or quantification of 7 translocations found in AML, ALL and CML including: <ul style="list-style-type: none"> · <i>TCF3-PBX1</i>; t(1;19)(q23;p13) · <i>MLL-AFF1</i>; t(4;11)(q21;q23) · <i>RUNX1-RUNX1T1</i>; t(8;21)(q22;q22) · <i>BCR-ABL1</i> (<i>M-BCR</i>; P190, P210, P230); t(9;22)(q34;q11) · <i>ETV6-RUNX1</i>; t(12;21)(p13;q22) · <i>PML-RARA</i> (<i>bcr1</i>, <i>bcr2</i>, <i>bcr3</i>); t(15;17)(q24;q21) · <i>CBFB-MYH11</i>; inv(16)(p13;q22) 	RT	CE	12

2.1 Oncogene expression quantification/Minimal residual disease (MRD)

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0458	Screening Kit for leukemia associated translocations (28 translocations)	<p>Multiplex detection and quantification of 28 translocations found in AML, ALL and CML including:</p> <ul style="list-style-type: none"> - <i>CBFB-MYH11; inv(16)(p13;q22)</i> - <i>RUNX1-RUNX1T1; t(8;21)(q22;q22)</i> - <i>PML-RARA (bcr1, bcr2, bcr3); t(15;17)(q24;q21)</i> - <i>MLL-MLLT3; t(9;11)(p22;q23)</i> - <i>MLL; t(11;19)(q23;p13.3); ELL, MLLT1</i> - <i>FUS-ERG; t(16;21)(p11;q22)</i> - <i>ETV6-MN1; t(12;22)(p13;q11-12)</i> - <i>DEK-NUP214; t(6;9)(p23;q34)</i> - <i>MLL-EPS15; t(1;11)(p32;q23)</i> - <i>MLL-MLLT4; t(6;11)(q27;q23)</i> - <i>TCF3-PBX1; t(1;19)(q23;p13)</i> - <i>ETV6-RUNX1; t(12;21)(p13;q22)</i> - <i>MLL-AFF1; t(4;11)(q21;q23)</i> - <i>TCF3-HL; t(17;19)(q22;p13)</i> - <i>STIL-TAL1; del(1)(p32)</i> - <i>BCR-ABL1 (M-BCR; P190, P210, P230); t(9;22)(q34;q11)</i> - <i>SET-NUP214; t(9;9)(q34;q34)</i> - <i>ZBTB16-RARA, MLL-MLLT6; t(11;17)(q23;q21)</i> - <i>ETV6-ABL1; t(9;12)(q34;p13)</i> - <i>ETV6-PDGFRB; t(5;12)(q33;p13)</i> - <i>MLL-MLLT10; t(10;11)(p12;q23)</i> - <i>MLL-MLLT11; t(1;11)(q21;q23)</i> - <i>MLL-FOXO4; t(X;11)(q13;q23)</i> - <i>RUNX1-MECOM; t(3;21)(q26;q22)</i> - <i>NPM1-RARA; t(5;17)(q35;q21)</i> - <i>NPM1-MLF1; t(3;5)(q25.1;q35)</i> - Reference genes <i>c-ABL, GUS, B2M</i> 	RT	CE	12
BA0459	Leukemia Fusion Genes Screening PCR Kit (30 translocations)	<p>Multiplex detection of 30 fusion genes in leukemia patients including:</p> <ul style="list-style-type: none"> - <i>MLL-AF9; t(9;11)(p22;q23)</i> - <i>PML-RARα; t(15;17)(q24;q21)</i> - <i>AML1-ETO; t(8;21)(q22;q22)</i> - <i>MLL-AF4; t(4;11)(q21;q23)</i> - <i>TEL-AML1; t(12;21)(p13;q22)</i> - <i>E2A-PBX1; t(1;19)(q23;p13)</i> - <i>MLL-ENL; t(11;19)(q23;p13.3)</i> - <i>BCR-ABL1; t(9;22)(q34;q11)</i> - <i>SIL-TAL1; del(1)(p32)</i> - <i>MLL-AF10; t(10;11)(p12;q23)</i> - <i>CBFB-MYH11; inv(16)(p13;q22)</i> - <i>AML1-MDS1/EV11; t(3;21)(q26;q22)</i> - <i>FIP1L1-PDGFRα; del(4)(q12)</i> - <i>SET-CAN; del(9)(q34)</i> - <i>E2A-HLF; t(17;19)(q22;p13)</i> - <i>DEK-CAN; t(6;9)(p23;q34)</i> - <i>MLL-SEPT6; t(X;11)(q24;q23)</i> - <i>TLS-ERG; t(16;21)(p11;q22)</i> - <i>TEL-PDGFRB; t(5;12)(q33;p13)</i> - <i>MLL-ELL; t(11;19)(q23;p13.1)</i> - <i>MLL-AF17; t(11;17)(q23;q21)</i> - <i>NPM-RARα; t(5;17)(q35;q21)</i> - <i>NPM-MLF1; t(3;5)(q25;q34)</i> - <i>PLZF-RARα; t(11;17)(q23;q21)</i> - <i>MLL-AF1q; t(1;11)(q21;q23)</i> - <i>MLL-AF1P; t(1;11)(p32;q23)</i> - <i>TEL-ABL1; t(9;12)(q34;p13)</i> - <i>AML1-MTG16; t(16;21)(q24;q22)</i> - <i>AML1-EAP; t(3;21)(q26;q22)</i> - <i>MLL-AF6; t(6;11)(q27;q23)</i> 	RT	CE	10, 20

Haematopoietic Chimerism Detection/Quantification in Leukemia

BA0460	STR-VNTR PCR Kit	Multiplex detection of chimerism after allogeneic bone marrow transplantation by analysis of Short Tandem Repeats (STR) and Variable Number of Tandem Repeats (VNTR). Target regions: <i>HumARA, HumTH01, SE33, vWF2, D1S80, YNZ22, vWF1 and 3'-HVR</i>	HYB	CE	25, 50
BA0660	Chimerism monitoring PCR Kit	Multiplex chimerism monitoring after blood stem cell and bone marrow transplantation targeting the autosomal loci <i>D2S1360, D3S1744, D4S2366, D5S2500, D6S474, D7S1517, D8S1132, D10S2325, D12S391, D18S51, D21S2055, SE33 (ACTBP2)</i> , and the gender-specific locus <i>Amelogenin</i>	FA	CE	25, 100, 400

Other cancers

BA0156	WT1 PCR Kit	Identification and quantitation of the Wilm's tumor gene transcripts	RT	CE	48, 96
BA0158	HER2/NEU PCR Kit	Quantification of <i>HER2/NEU</i> transcripts	RT	RUO	120
BA0461	HPV E6/E7 mRNA RT-PCR Kit	Differentiation between persistent and transient high-risk <i>HPV</i> infection for all women over the age of 30, for cervical and oral testing of Cervical and Head-Neck Cancer	RT	CE	48, 92, 96

2.1 Oncogene expression quantification/Minimal residual disease (MRD)

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0159	AFP PCR Kit	Quantification of Fetoprotein (<i>AFP</i>) mRNA in peripheral blood and bone marrow in Hepatocellular cancer	RT	CE	25
BA0160	Tyrosinase PCR Kit	Quantification of <i>tyrosinase</i> transcripts in peripheral blood and bone marrow (marker of recurrence and survival in malignant melanoma)	RT	RUO	120
BA0161	Survivin PCR Kit	Quantification of total <i>survivin</i> transcripts, including all known splice variants (unfavourable prognostic factor of de novo AML, soft tissue sarcoma and bladder cancer)	RT	RUO	120

Radiation Toxicity Measurement

BA0734	c-ABL PCR Kit	Biodosimetry assay to measure radiation dosage by semi-quantitative detection of circulating cell-free Alu DNA in plasma obtained from whole blood	b-DNA	RUO	92
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Reference gene transcripts/ "housekeeping genes"

BA0162	c-ABL PCR Kit	Quantification of <i>c-ABL</i> transcripts	RT	RUO	120
BA0464	p53 PCR Kit	Quantification of <i>p53</i> cDNA	RT	RUO	120
BA0163	GAPDH PCR Kit	Quantification of <i>GAPDH</i> transcripts	RT	RUO	120
BA0164	18S rRNA PCR Kit	Quantification of <i>18S rRNA</i> transcripts	RT	RUO	120

2.2 Somatic Mutations with therapeutic implications in various cancers

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0157	BRCA Panel PCR Kit	Multiplex detection of <i>BRCA 1 + 2</i> in breast and ovarian cancer	RT	RUO	100
BA0661	BRCA1 & BRCA2 Amplicon Panel	Multiplex detection of germline mutations, for determination of 20.4 kb sequence comprising 48 coding <i>BRCA1</i> and <i>BRCA2</i> exons and limited flanking intron regions; Ion Torrent™ - or ILLUMINA®-compatible	NGS	RUO	8, 48, 96
BA0662	TP53 Mutation kit	Detection of germline mutations in the <i>TP53</i> gene, for targeting and sequencing of 12 exons of the <i>TP53</i> locus, Ion Torrent™ - or ILLUMINA®-compatible	NGS	RUO	8, 48, 96
BA0165	ABL Mutation Detection PCR Kit	Detection of the T315I (944C>T) somatic mutation in the <i>ABL</i> oncogene in CML patients with secondary resistance to Imanitib (Gleevec)	RT	RUO	24, 50
BA0663	FLT3 Mutation PCR Kit	Detection of FLT3 activating mutations in patients with acute myelogenous leukemia (AML)	ELPHO	CE	33, 333
BA0664	NPM1 mut A, B, & D PCR Kit	Quantification of Nucleophosmin-1 Gene (NPM1 mutA, B, & D) transcripts in Acute Myeloid Leukemia	RT	RUO	24
BA0665	IDH 1/2 PCR kit	Detection of mutations in isocitrate dehydrogenase (IDH) 1 and 2 genes in low and secondary high grade gliomas	RT	CE	20
BA0166A	BRAF Mutation PCR Kit I	Identification of the V600E mutation in the <i>BRAF</i> gene	RT	CE	12, 24, 36, 48, 60, 96
BA0166B	BRAF Mutation PCR Kit II	Identification of the <i>BRAF</i> Codon Specific Mutations in Codon 600	RT	CE	10, 30, 60
BA0168A	EGFR Mutation PCR Kit I	Identification of the <i>EGFR</i> gene L858R & del 746-750 mutations	RT	CE	12, 24, 36
BA0168B	EGFR Mutation PCR Kit II	Identification of the <i>EGFR</i> Codon Specific Mutation in Codons 719, Ex19Del, 790, 858 & 861	RT	CE	10, 30, 60
BA0169A	KRAS Mutation PCR Kit I	Identification of the seven most frequent mutations in the <i>KRAS</i> gene (G12D, G12V, G12A, G12C, G12S, G12R, G13D) by sequence specific primer (SSP) PCR	RT	CE	12, 24, 36, 48, 60, 96
BA0169B	KRAS Mutation PCR Kit II	Identification of the <i>KRAS</i> Codon Specific Mutations in Codons 12, 13, 59, 61, 117 & 146	RT	CE	10, 30, 60
BA0170A	NRAS Mutation PCR Kit I	Identification of the <i>NRAS</i> gene 35G>T (G12V) mutation in codon 12	RT	CE	12, 24, 60

2.2 Somatic Mutations with therapeutic implications in various cancers

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0170B	NRAS Mutation PCR Kit II	Identification of the <i>NRAS</i> Codon Specific Mutations in Codons 12, 13, 59, 61, 117 & 146	RT	CE	10, 30, 60
BA0468	HRAS Mutation PCR Kit	Detection of mutations in codon 61 of the human <i>HRAS</i> gene	RT	RUO	10, 30, 60
BA0470	PIK3CA Mutation PCR Kit	Detection of somatic mutations in and near <i>PIK3CA</i> Codons 542 and 545 in Exon 9 and Codon 1047 in Exon 20 in the human <i>PIK3CA</i> gene	RT	CE	10, 25, 30, 60, 100
BA0466	c-KIT Mutation PCR Kit	Detection of somatic mutations in Codon 861 of Exon 17 in the c-KIT proto-oncogene in genomic DNA from human cells or tissues	RT	RUO	10, 30, 60
BA0171	CALR Mutation PCR Kit	Detection of type 1 and type 2 mutations in exon 9 of the calreticulin (<i>CALR</i>) gene	ELPHO	CE	50
BA0172	JAK 2 Mutation PCR Kit	Identification and/or absolute quantification of codon 617 specific mutations in the Janus Kinase 2 (<i>JAK-2</i>) gene	RT	CE	10, 30, 60
BA0462	EML4-ALK Fusion Gene Detection Kit PCR Kit	Multiplex detection of 17 fusion variants for the detection of <i>EML4-ALK</i> associated fusion gene transcripts (<i>EML4-ALK V1, V2, V3a/b/c, V4, V5a/b, V6a/b, V7, V8a/b/c/d, V9, V10</i>) in total RNA from lung cancer tissues	RT	CE	10, 20
BA0463	Lung Cancer ALK/ROS1/ RET Panel PCR Kit	Multiplex detection of 6 lung cancer fusion genes (<i>KIF5B-RET, KIF5B-alk, CD74-ROS1, TGF-alk, SLRC34A2-ROS1, EML4-alk; 35 variants</i>) in total RNA from lung cancer tissues	RT	CE	10, 20
BA0666	Cancer- associated Mutations PCR Kit	Qualitative detection of colorectal cancer associated mutations including <i>APC</i> (codons 1309, 1367, 1450), <i>KRAS</i> (codons 12 and 13), <i>BRAF</i> (codon 600) and <i>CTNNB1</i> (codons 41 and 45) in liquid biopsies, native or FFPE tissue samples	RT	CE	6, 24

3. HUMAN GENETIC DISEASES AND GENETIC PREDISPOSITIONS

3.1 Thrombophilia

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0174	Cardio Thrombophilia Panel PCR Kit	Detection of 8 mutations: F2 20210 G>A, F5 1691 G>A (Arg506Gln), F710976 G>A (Arg353Gln), F13 G>T (Val34Leu), FGB -455 G>A, ITGA2 807 C>T (Phe224Phe), ITGB3 1565 T>C(Leu33Pro), SERPINE1(PAI1) -675 5G>4G	RT	RUO	96
BA0667	Thrombosis PCR Kit I	Detection of genetic variants associated with the risk of suffering from deep venous thrombosis: G1691A mutation in <i>Factor V</i> , G20210A mutation in <i>prothrombin</i> gene, and C677T polymorphism in <i>MTHFR</i> gene	HYB	CE	16
BA0668	Thrombosis PCR Kit II	Detection of the most important mutations related to thrombosis: Factor V Leiden, G1691A (Arg505Gln); Factor II, G20210A; MTHFR C677T; MTHFR A1298C; 20 tests; CE	HYB	CE	20
BA0602	Factor II PCR Kit	Identification and genotyping of the G20210A mutation in the human gene coding for Coagulation Factor II	RT	CE	25, 48, 50, 60, 96, 100
BA0176	Factor V Leiden PCR Kit	Identification and genotyping of either the G1691A (Leiden) or Y1702C or H1299R mutation in the human gene coding for Coagulation Factor V	RT	CE	12, 12, 48, 50, 60, 96, 100
BA0177	Factor VII PCR Kit	Identification and genotyping of the G1238A (R353Q) mutation in the human gene coding for Coagulation Factor VII	RT	RUO	50, 60, 96
BA0178	Factor VIII PCR Kit	Factor VIII Pack (Hemophilia A), optimized primer pairs for amplification of the gene fragment of interest, particularly those spanning a mutation	FA	RUO	400
BA0179	Factor XII PCR Kit	Identification and genotyping of the C4T (rs1801020) polymorphism in Factor XII gene from blood samples	RT	RUO	60, 96
BA0180	Factor XIII PCR Kit	Identification and genotyping of the G103T (Val35Leu; rs5985) polymorphism in Factor XIII A1 gene from blood samples	RT	RUO	25, 60, 96, 100
BA0181	Folates Metabolism Panel PCR Kit	Detection of polymorphism: MTHFR 677 C>T (Ala222Val), MTHFR 1298A>C (Glu429Ala), MTR 2756 A>G (Asp3919Gly), MTRR 66 A>G (Ile22Met)	RT	RUO	12, 48, 60
BA0669	PAI1 (4G/5G) PCR Kit	Detection of the 4G/5G mutation in PAI1 gene promoter in human genomic DNA	RT	CE	25, 100
BA0182	ACE (I/D) PCR Kit	Identification and genotyping of the insertion/deletion (I/D) polymorphism located on intron 16 of the human gene coding for angiotensin converter enzyme (ACE)	RT	CE	48, 50, 96
BA0183	FGB PCR Kit	Detection of fibrinogen beta gene polymorphism G455A (rs1800790)	RT	RUO	60, 50, 96

3.1 Thrombophilia

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0184	GPIBA1b PCR Kit	Detection of platelet glycoprotein Iba gene polymorphisms C482T (Thr145Met; rs6065) or T5C (Kozak sequence polymorphism; rs2243093)	RT	RUO	60, 96
BA0185	ITGA2 PCR Kit	Detection of Integrin alpha2 gene polymorphism T176C (rs1126643)	RT	RUO	60, 96
BA0186	ITGB3 PCR Kit	Detection of Integrin alpha2 gene polymorphism T176C (Leu33Pro; rs5918)	RT	RUO	60, 96
BA0187	MTHFR PCR Kit	Identification and genotyping of either the C677T or A1298C polymorphism in the human gene coding for MTHFR	RT	CE	25, 48, 50, 96, 100
BA0188	MTR PCR Kit	Detection of methionine synthase gene mutation A2756G (Asp919Gly; rs1805087)	RT	RUO	60, 96
BA0189	MTRR PCR Kit	Detection of A66G methionine synthase gene polymorphism (Ile22Met; rs1801394)	RT	RUO	60, 96
BA0190	PAI-1/Serpin PCR Kit	Identification and genotyping of the 675 4G/5G insertion/deletion polymorphism in the human gene coding for SERPINE1 or plasminogen activator type 1 inhibitor gene (rs1799768)	RT	CE	25, 48, 50, 96
BA0191	SELPLG PCR Kit	Detection of selectin P ligand gene polymorphism G186A (Met62Ile; rs2228315)	RT	RUO	60, 96
BA0192	β-Fibrinogen (G455A) PCR Kit	Allelic discrimination of polymorphisms G455A in β-Fibrinogen gene from blood	RT	CE	50

3.2 Cardiovascular Disease

Order number	Product name	Intended use	Method	Legal status	Tests/Size
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Hypertension

BA0193	AGT 1 PCR Kit	Detection of Angiotensinogen 1 polymorphism C521T (Thr207Met, rs4762)	RT	RUO	60, 96
BA0194	AGT 2 PCR Kit	Detection of Angiotensinogen 2 polymorphism C4072T (Met235Thr, rs699)	RT	RUO	60, 96
BA0195	AGTR1 PCR Kit	Detection of angiotensin II receptor, type 1 polymorphism A1166C (rs5186)	RT	RUO	60, 96
BA0471	CVD Panel PCR Kit	Detection of mutation FV:Q506 in factor V gen, of polymorphism 20210A in factor II gen, the MTHFR risk alleles for coronary disease, and the risk markers of PAI-1 gen in cardiovascular disease (CVD)	HYB	RUO	12, 20, 60
BA0670	Cardio PCR Kit	Genetic analysis of 11 of the most important polymorphisms associated to the Coronary Artery Disease	HYB	CE	25
BA0472	Coagulation panel PCR Kit	Detection of coagulation factors FII G20 210A, FV G1691A and Y1702C and MTHFR C677T and A1298C mutations	RT	CE	50
BA0198	NOS3 PCR Kit	Detection of Nitric oxide synthase 3 polymorphism C786T (rs2070744)	RT	RUO	60, 96

Myocardial infarction & ischemic stroke

BA0199	AGT1 PCR Kit	Detection of Angiotensinogen 1 polymorphism C521T (Thr207Met, rs4762)	RT	RUO	60, 96
BA0200	ApoB PCR Kit	Allelic discrimination of polymorphisms R3500Q in Apo B gene from blood	RT	CE	50
BA0201	ApoE PCR Kit 1	Detection of apolipoprotein E polymorphism T3100C (Leu48Pro, rs769452)	RT	RUO	60, 96
BA0202	ApoE PCR Kit 2	Allelic discrimination of polymorphisms T334C (C112R) and C472T (R158C) in apolipoprotein E gene from blood	RT	CE	50
BA0203	GP IIb/IIIa PCR Kit	Allelic discrimination of polymorphism T1565C in GPIIIa gene (ITGB3, most abundant receptor on platelet surface) from blood	RT	CE	50
BA0204	GP1BA1b PCR Kit	Detection of the Platelet glycoprotein Iba polymorphism C482T (Thr161Met, rs6065) or T5C (rs2243093)	RT	RUO	60, 96
BA0205	ITGA2 PCR Kit	Detection of integrin alpha 2 polymorphism C807T (Phe253Phe, rs1126643)	RT	RUO	60, 96

3.2 Cardiovascular Disease

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0206	ApoB PCR Kit	Allelic discrimination of polymorphisms R3500Q in Apo B gene from blood	RT	CE	50
BA0207	ApoE PCR Kit 1	Detection of apolipoprotein E polymorphism T3100C (Leu48Pro, rs769452)	RT	RUO	60, 96
BA0208	ApoE PCR Kit 2	Allelic discrimination of polymorphisms T334C (C112R) and C472T (R158C) in apolipoprotein E gene from blood	RT	CE	50
BA0209	LIPC PCR Kit	Detection of paraoxonase 1 polymorphism G250A (rs2070895)	RT	RUO	60, 96
BA0210	LPL PCR Kit	Detection of lipoprotein lipase polymorphism C1421G (Ser447Thr, rs328)	RT	RUO	60, 96
BA0211	PON1 PCR Kit	Detection of paraoxonase 1 polymorphism A575G (Gln192Arg, rs662)	RT	RUO	60, 96

3.3 Diabetes and obesity

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0212	ADRB2 PCR Kit	Detection of adrenoceptor beta 2, surface gene polymorphism G46A (Arg-16Gly, rs1042713) or C5318G (Gln27Glu, rs1042714)	RT	RUO	60, 96
BA0213	ADRB3 PCR Kit	Detection of β-adrenergic receptor gene polymorphism T190C (Trp64Arg, rs4994)	RT	RUO	60, 96
BA0214	FABP2 PCR Kit	Detection of Fatty Acid Binding Protein 2 gene polymorphism A163G (Ala54Thr, rs1799883)	RT	RUO	60, 96
BA0215	FTO PCR Kit	Detection of FTO gene polymorphism A23525T (rs9939609)	RT	RUO	60, 96
BA0216	PPARG2 PCR Kit	Detection of Peroxisome Proliferator-Activated Receptor-Gamma-2 polymorphism C34G (Pro12Ala, rs1801282)	RT	RUO	60, 96
BA0671	Obesity PCR Panel	Detection of polymorphisms of the LEP, LEPR, POMC and MC4R exons and flanking intron-exon boundaries; ILLUMINA®-compatible	NGS	RUO	8, 48, 96

3.4 Pharmacogenetics / Adverse Drug Reaction

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0217	Anticoagulants Genetic Resistance PCR Kit	Detection of Anticoagulants Genetic Resistance	RT	CE	25
Warfarin resistance					
BA0672	CYP2C9*2 PCR Kit	Detection of CYP2C9 gene polymorphism C430T (Arg144Cys; rs1799853)	RT	CE	24, 48, 60, 96
BA0218	CYP2C9*3 PCR Kit	Detection of CYP2C9 gene polymorphism A1075C (Ile359Leu; rs1057910)	RT	CE	24, 48, 60, 96
BA0219	Pharmacogenetics Warfarin Panel PCR Kit	Detection of 3 mutations: CYP2C9 430 C>T (Arg144Cys), CYP4F2 C>T, (Val-433Met), VKORC1 -1639 G>A	RT	RUO	20, 48
BA0220	VKORC1 PCR Kit	Detection of Vitamin K epoxide reductase complex subunit 1 gene polymorphism C1173T (Warfarin sensitivity rs9934438) or G3730A (Warfarin sensitivity rs7294)	RT	CE, US-FDA, TFDA	24, 48, 60, 96

3.4 Pharmacogenetics / Adverse Drug Reaction

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0673	Coumarin Panel PCR Kit	Detection of the polymorphisms p. R144C, p. I359L in CYP2C9 gen, the polymorphism V433M in the CYP4F2 gen, and the polymorphism C1173T in the VKORC1 gen, involved in the metabolism of Coumarin derivatives, phase I	RT	RUO	12, 60
BA0674	Glutathion-S-Transferase Polymorphism PCR Kit	Detection of the polymorphisms of Glutathion-S-Transferase (GST) M1, T1 and P1, phase II	RT	RUO	12, 60
BA0675	N-Acetyltransferase 2 (NAT2) Mutation PCR Kit	Detection of mutations G191A, C282T, T341C, C481T, G590A, A803G und G857A in N-Acetyl-transferase 2 Gen, phase II	RT	RUO	12, 60

Clopidogrel (Plavix) resistance

BA0221	CYP2C19*2 PCR Kit	Detection of cytochrome P450 CYP2C19 gene polymorphism G681A (rs4244285) (Poor Metabolizer Allel)	RT	RUO	12, 60, 96
BA0222	CYP2C19*3 PCR Kit	Detection of CYP2C19 gene polymorphism G636A (rs4986893)	RT	RUO	60, 96

Statins resistance

BA0224	SLCO1B1 PCR Kit	Detection of SLCO1B1 gene polymorphism T37041C (Val174Ala; rs4149056), a gene coding for the organic anion transporting polypeptide 1B1 (OATP1B1), an influx transporter produced in the liver that mediates the hepatic uptake and metabolism of statins	RT	RUO	60, 96
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Abacavir (ABC) resistance against AIDS Anti-viral therapy

BA0676	HLA-B* 5701 PCR Kit	Detection of the HLA-B* 5701 allele for the management of HIV-infected patients	RT	CE, US-FDA, TFDA	24, 48, 96
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Allopurinol resistance

BA0677	HLA-B* 5801 PCR Kit	Detection of the HLA-B* 5801 allele that is strongly associated with Allopurinol-induced severe cutaneous adverse reactions (SCARs) which include Hypersensitivity syndrome (HSS), Steven-Johnson Syndrome (SJS) and Toxic Epidermal necrolysis (TEN)	RT	CE, US-FDA, TFDA	24, 48, 96
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Carbamazepine & Phenytoin resistance

BA0678	HLA-B* 1502 PCR Kit	Detection of the HLA-B* 1502 allele that is strongly associated with Carbamazepine (CBZ)-induced Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) in patients of Asian descent.	RT	CE, US-FDA, TFDA	24, 48, 96
BA0679	HLA-A* 3101 PCR Kit	Detection of the A*3101 allele that is associated with Carbamazepine (CBZ)-induced hypersensitivity reactions in patients of Northern European and Japan ancestry	RT	CE, US-FDA, TFDA	24, 48, 96

3.5 Genetic diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0225	Duchenne Muscular Dystrophy PCR Kit	Target and sequence 86 exons of the <i>DMD</i> locus, Ion Torrent™- or ILLUMINA®-compatible	NGS	RUO	8, 48, 96
BA0680	Myotonic Dystrophy Screening PCR Kit	For the determination of the number of repeats (up to 200) of CTG of 3' UTR region of the DMPK gene located on chromosome 19 (Steinert Disease)	FA	CE	16
BA0681	Myotonic Dystrophy Confirmatory PCR Kit	For confirmation of homozygous and detection of false homozygous for the occurrence of a higher range allele obtained with Myotonic Dystrophy Screening kit.	FA	CE	16

Muscular dystrophy

3.5 Genetic diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
Fragile X syndrome					
BA0476	Fragile X Screening PCR Kit	Analysis of the FMR1 CGG triplet repeat region (healthy and premutated alleles: 10 to 200 CGG triplet repeats) by capillary electrophoresis in genetic analyzer	FA	CE	16, 48
BA0477	Fragile X Confirmatory PCR Kit	Detection of mutated alleles of the FMR1 gene for confirmation of normal homozygous female samples and determination of the AGG interruptions	FA	CE	16
Chorea Huntington					
BA0478	Huntington disease PCR Kit	Determination of the number of CAG repetitions in IT15 gene, detection of normal, premutated and mutated alleles	FA	CE	16
Friedrich's Ataxia					
BA0682	Friedrich's Ataxia PCR Kit	Determination of the number of GAA repeats of the FXN gene	FA	CE	16
Cystic fibrosis					
BA0226A	Cystic fibrosis PCR Kit	Identification of variants in the gene CFTR (Cystic Fibrosis Transmembrane Conductance Regulator), through the amplification of target sequences, reverse-hybridization and color development, covers gene variants F508del, I507del, F508C, I502T, 1706del17, 1677del TA, G542X, 1717-1G>A, R553X, Q552X, G551D, S549R A>C, N1303K, 4016insT, R1162X, R1158X, W1282X, G1244E, 2789+5G>A, 2183AA>G, 11+5G>A, 711+1G>T, G85E, 3849+10kbC>T, 621+1G>T, R117H, D1152H, L1065P, R1066H, L1077P, 4382delA, 1259insA, 852del22, R347P, T338I, S912X, I148T, 3199del6, Allele 5T-7T-9T	HYB	CE	25
BA0226B	Cystic fibrosis PLUS PCR Kit	Identification of variants in the gene CFTR (Cystic Fibrosis Transmembrane Conductance Regulator), through the amplification of target sequences, reverse-hybridization and color development, covers mutations D110H, H139R, G178R, 991del5, R334W, R347H, R352Q, 1717-8 G>A, D579G, 1874insT, E585X, 1898+1 G>A, 1898+3 A>G, 1898+5 G>T, 2184insA, 2522insC, 3120+1 G>A, R1066C, 3272-26 A>G, 3659delC, G1349D e 4015delA	HYB	CE	25
Phenylketonuria					
BA0683	Phenylketonuria PCR Panel Kit	For amplification and sequencing covering 2.7 kilobases comprising 14 coding exons of the phenylalanine hydroxylase (PAH) loci ,ILLUMINA®-compatible	NGS	RUO	8, 48, 96
Prader-Willi/Angelman Syndrome					
BA0684	Prader-Willi/Angelman PCR Kit	Methylation-specific CpG Prader-Willi/Angelman amplification Kit	ELPHO	RUO	25
Haemochromatosis					
BA0479	Haemochromatosis Panel PCR Kit	Detection of up to 3 or the single mutations of HFE 187 C>G (H63D) and/or HFE 193 A>T (S65C) and/or HFE 845 G>A (C282Y) in the human HFE gene	RT HYB	CE	12, 24, 25, 48, 50, 60, 96
Osteoporosis					
BA0480	Osteoporosis Panel PCR Kit	Simultaneous detection of the most important osteoporosis risk alleles for vitamin D receptor B/b and collagen I alpha 1 S/s allele	HYB	CE	12, 60
Thalassemia					
BA0228	Alpha-Globin PCR Kit	Detection of 21 mutations covering >90% of β-globin defects found in Mediterranean, Middle Eastern and Southeast Asian countries	HYB	CE	10
BA0229A	Beta-Globin MED PCR Kit	Detection of 14-22 mutations covering >90% of β-globin defects found in Mediterranean countries	HYB	CE	20
BA0229B	Beta-Globin Plus PCR Test	Detection of 14 polymorphisms of beta-globin gene and alpha-globin anti 3.7 gene triplication variant	HYB	CE	20
BA0230	BETA-Globin IME PCR Kit	Detection of 22 mutations covering >90% of β-globin defects found in the Middle East and India	HYB	CE	20
BA0231	BETA-Globin SEA PCR Kit	Detection of 22 mutations covering >90% of β-globin defects found in Southeast Asia	HYB	CE	20

3.5 Genetic diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
Thalassemia					
BA0481	Familial Mediterranean fever (FMF) PCR Kit	Detection of 12 mutations in the MEFV gene: E148Q, P369S, F479L, M680I (G >C, G >A), I692 del, M694V, M694I, K695R, V726A, A744S, R761H	HYB	CE	20
BA0685	Mediterranean Fever PCR Panel	Determination of a 4 kb sequence comprising 10 canonical exons in MEFV loci and flanking intron-exon boundaries; Ion Torrent™- or ILLUMINA®-compatible	NGS	RUO	8, 48, 96

Disorders of sugar metabolism

BA0233	Lactose Intolerance PCR Kit	Lactose Intolerance detection of the C/T, C/C, T/T (-13910) polymorphism within the regulatory region of the lactase persistence gene (LCT)	RT	CE	16, 32, 50, 96
BA0686	G6PD African PCR Kit	Screening of the Glucose-6-phosphate dehydrogenase-deficiency (<i>G6PD</i> gene mutation on X chromosome, African type) responsible for anemia	ELPHO		20
BA0687	G6PD Asian PCR Kit	Screening of the Glucose-6-phosphate dehydrogenase-deficiency (<i>G6PD</i> , Asian type)	ELPHO		20

Avellino Corneal Disease

BA0481	ACD PCR Kit	Screening of single nucleotide polymorphism of codon124 (exon4) which is coding igh3 gene in Avellino Corneal disease	RT	CE	12, 25, 50, 96, 100
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Genetic polymorphisms involved in anti-viral treatment

BA0236	IL28B Polymorphism PCR Kit	Detection and genotyping of polymorphisms C->T (rs12979860) or T->G (rs8099917), also rs17 / rs60, in the human gene coding for Interleukin 28B which are predictive of response to antiviral treatment	RT	CE	48, 96
BA0482	IL28B-ITPA PCR Kit	Detection and genotyping of polymorphisms in the genes for IL28B and inosine triphosphate pyrophosphatase (ITPA) leading to reduction of hemoglobin during peg-interferon plus ribavirin combination therapy for patients with chronic hepatitis C virus infection	HYB	CE	20

Infertility

BA0238	AZF PCR Kit	Multiplex detection of microdeletions in the azoospermia factor (AZF) of the Y chromosome causing azoospermia and oligospermia causing male infertility, deletions at AZF locus, target regions: sY84, sY86, DFFRY, DBY, sY95, sY117, sY125, sY127, sY134, sY254, sY255, ZFX/ZFY, SR.Y. Internal control: ZFX/ZFY	RT	CE	8, 12, 16, 25, 60, 100
BA0688	Female Infertility PCR Panel	Sequencing of all coding exons of the <i>FSHB</i> , <i>FSHR</i> , <i>LHB</i> , and <i>LHCGR</i> loci; ILLUMINA®-compatible		RUO	8, 48, 96

4. HLA AND BLOOD GROUP TYPING

4.1 HLA/HPA typing

Order number	Product name	Intended use	Method	Legal status	Tests/Size
HLA typing					
BA0239	HLA-A PCR Kit	Detection of HLA-A low resolution	EPF ELPHO	-	10, 40
BA0240	HLA-B PCR Kit	Detection of HLA-B low resolution	EPF ELPHO	-	10, 40
BA0241	HLA-C PCR Kit	End-point Fluorescence PCR test for detection of HLA-C low resolution, 24 rxn/test	EPF ELPHO	-	10, 40
BA0242	HLA-ABC PCR Kit	Detection of HLA-ABC low resolution	EPF ELPHO	-	10, 40
BA0243	HLA-ABDR PCR Kit	Detection of HLA-ABDR low resolution	EPF ELPHO	-	10, 20
BA0244	HLA-DR PCR Kit	Detection of HLA-DRB low resolution	EPF	-	10

4.1 HLA/HPA typing

Order number	Product name	Intended use	Method	Legal status	Tests/Size
HLA typing					
BA0245	HLA-DRB1 PCR Kit	Detection of HLA-DR B1 low resolution	EPF ELPHO	-	10
BA0246	HLA-DRDQ PCR Kit	Detection of HLA-DRB/DQB low resolution	EPF	-	10, 30
BA0247	HLA-DRDQDP PCR Kit	Detection of HLA-DRB/DQB low resolution	EPF	-	10
BA0483	HLA-A*29 PCR Kit	Detection of HLA-A*29 group of alleles	RT	-	24
BA0484	HLA-B*57 PCR Kit	For HLA-B*57:01 allele screening	RT	-	16, 48, 100
Narcolepsia					
BA0485	HLA Narcolepsy PCR Kit	Detection of HLA-DQB1*06:02 group of alleles	RT	-	48
Morbus Behçet					
BA0486	HLA-B5/57 PCR Kit	Detection of HLA-B*51 (associated with Morbus Behçet), HLA-B*57 (associated with HSR to Abacavir)	EPF	-	12
BA0487	HLA-B*51 & B*52 PCR Kit	Detection of HLA-B*51 & B*52 groups of alleles	RT	-	24,48
Celiac disease (gluten intolerance)					
BA0478	HLA-DQ PCR Kit	Analysis of HLA-DQ2 and HLA-DQ8 genetic regions by real time detection of the alleles DQA1*05, DQB1*02 and DQB1*0302. Distribution of these alleles gives an indication of a genetic predisposition for celiac disease (gluten intolerance)	RT HYB	CE	12, 16, 20, 24, 48, 50, 60, 96
Rheumatoid Arthritis / Ankylosing spondylitis					
BA0235	HLA-B27 PCR Kit	Analysis of the HLA-B27 genetic region that is highly associated with inflammatory rheumatic diseases, especially ankylosing spondylitis (Bechterew's disease), Reiter's syndrome, anterior uveitis and inflammatory bowel disease.	RT EPF HYB	CE	12, 16, 24, 25, 48, 50, 96, 100
BA0489	HLA-B*27/ CYP2D6*4 PCR Kit	Detection of the HLA-B and the CYP2D6*4 alleles	HYB	CE	12, 60
BA0490	HLA-DRB1 "Shared Epitope" QKRAA/ QRRAA/ RRAA PCR Kit	Detection of the "Shared Epitope" QKRAA/QRRAA/RRRAA of rheumatoid arthritis in all known HLA-DRB1 alleles, and discrimination between homozygous and heterozygous carriers	RT	CE	12, 60
Diabetes Mellitus					
BA0689	Type 1 Diabetes Mellitus PCR Kit	Detection of the alleles predisposing to Type 1 Diabetes Mellitus (DQA1*05/DQB1*02-DR3; DQA1*03/DQB1*03:02-DR4 and a limited number of alleles such as DRB1*04, DRB1*03, DQB1*03:02, DQB1*02, the protective allele DQB1*06:02 and the homozygosis or heterozygosis status of DRB1*04	RT	CE	25
BA0690	Diabetes PCR Panel	Targeting and sequencing of 26 exons of the <i>PAX4</i> <i>INS</i> and <i>BLK</i> loci; Ion Torrent™- or ILLUMINA®-compatible	NGS	RUO	8, 48, 96
HPA typing					
BA0249	HPA PCR Kit	For typing HPA-1,2,3,4,5,6,9 and 15 alleles	EPF	-	10, 48
BA0250	HPA-1 a/b PCR Kit	For screening of HPA-1 a/b alleles	EPF	-	48, 96

4.2 Blood group typing

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0251	RBC-ABO basic PCR Kit	For ABO detection (01, 02, B, A, A2)	EPF	-	10, 40
BA0252	RBC-Typing PCR Kit	For typing of various human red cell blood group alleles	EPF	-	10, 30
BA0253	RBC-CDE PCR Kit	Detection of Rhesus and D Variant	EPF	-	10, 40
BA0254	RBC-weak/ variant PCR Kit	Detection of Rhesus D weak and Dell	EPF	-	10, 48
BA0255	RBC-Rare PCR Kit	Detection of rare blood group alleles	EPF	-	10, 30
BA0256	RBC-D screen PCR Kit	Detection of RHD-Exon 3, 5 and 10	EPF	-	48
BA0257	RBC-Vel Screen PCR Kit	Detection of Vel+ and Vel-	EPF	-	48
BA0258	RBC-KKD PCR Kit	Detection of Kell/Kidd/Duffy	EPF	-	10
BA0259	RBC-MNS PCR Kit	Detection of MNSs, Vw and Mg	EPF	-	10

5. FOOD ANALYSIS

5.1 Identification of meat species in food

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0260	Beef Meat PCR Kit	Detection of beef meat DNA in food	RT	-	100
BA0261	Black/white Halibut Meat PCR Kit	Detection of halibut meat DNA in food	RT	-	100
BA0262	Camel Meat PCR Kit	Detection of camel meat DNA in food	RT	-	100
BA0263	Cat & dog Meat PCR Kit	Detection of cat & dog meat DNA in food	RT	-	100
BA0264	Chicken Meat PCR Kit	Detection of chicken meat DNA in food	RT	-	100
BA0265	Horse/Donkey Meat PCR Kit	Detection of horse/donkey meat DNA in food	RT	-	100
BA0266	Pork Meat PCR Kit	Detection of pork meat DNA in food	RT	-	100
BA0267	Rabbit Meat PCR Kit	Detection of rabbit meat DNA in food	RT	-	100
BA0268	Turkey Meat PCR Kit	Detection of turkey meat DNA in food	RT	-	100
BA0269	Waterbuffalo Meat PCR Kit	Detection of waterbuffalo meat DNA in food	RT	-	100

5.2 Genetically Modified Organisms (GMO)

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0691	GMO Screen PCR Kit	Multiplex screening of pFMV, p35s, and tNOS with internal positive control; 96 tests	RT	-	96
BA0270	GMO Cabbage (Ogura) PCR Kit	Detection or quantification of GMO Ogura (CMS)	RT	-	100

5.2 Genetically Modified Organisms (GMO)

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0271	GMO Canola PCR Kit	Detection or quantification of GMO Canola (GT 73, T45, GT73, MS8)	RT	-	100
BA0272	GMO Corn PCR Kit	Detection or quantification of GMO Corn (Bt176, Bt11, T25, MON810, MON 863, GA 21, NK 603, 35S, 3272)	RT	-	100
BA0273	GMO Rice PCR Kit	Detection or quantification of GMO Rice (P35S, LibertyLink 601, Bt63)	RT	-	100
BA0274	GMO Soya PCR Kit	Detection or quantification of GMO Soya (RoundUp Ready, 35S, RR2Y, A2704-12)	RT	-	100

5.3 Food pathogens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0275	Acetic acid bacteria PCR Kit	Detection of Acetic acid bacteria DNA	RT	-	100
BA0276	Alicyclobacillus ssp. PCR Kit	Detection of <i>Alicyclobacillus</i> DNA	RT	-	100
BA0277	Bottom fermented yeast PCR Kit	Detection of bottom fermented yeast DNA	RT	-	100
BA0278	Dekkera anomala PCR Kit	Detection of <i>D. anomala</i> DNA	RT	-	100
BA0279	Dekkera bruxellensis PCR Kit	Detection of <i>D. bruxellensis</i> DNA	RT	-	100
BA0280	Lactobacillus brevis/ L. brevisimilis PCR Kit	Detection of <i>L. brevis</i> / <i>L. brevisimilis</i> DNA	RT	-	100
BA0281	Lactobacillus buchneri/ parabuchneri PCR Kit	Detection of <i>L. buchneri</i> / <i>parabuchneri</i> DNA	RT	-	100
BA0282	Lactobacillus casei/ L. paracasei/ L. rhamnosus/L. zeae PCR Kit	Detection of <i>L. casei</i> / <i>L. paracasei</i> / <i>L. rhamnosus</i> / <i>L. zeae</i> DNA	RT	-	100
BA0283	Lactobacillus collinoides/ paracollinoides PCR Kit	Detection of <i>L. collinoides</i> / <i>paracollinoides</i> DNA	RT	-	100
BA0284	Lactobacillus coryniformis PCR Kit	Detection of <i>L. coryniformis</i> DNA	RT	-	100
BA0285	Lactobacillus lindneri PCR Kit	Detection of <i>L. lindneri</i> DNA	RT	-	100
BA0286	Lactobacillus perolens PCR Kit	Detection of <i>L. perolens</i> DNA	RT	-	100
BA0287	Lactobacillus plantarum/ paraplantarum/ L. pentosus PCR Kit	Detection of <i>L. plantarum</i> / <i>paraplantarum</i> / <i>L. pentosus</i> DNA	RT	-	100
BA0288	Lactobacillus rossiae PCR Kit	Detection of <i>L. rossiae</i> DNA	RT	-	100
BA0289	Lactobacillus/Pediococcus PCR Kit	Detection of <i>Lactobacillus</i> / <i>Pediococcus</i> DNA	RT	-	100
BA0290	Legionella ssp. PCR Kit	Detection and quantification of <i>Legionella</i> spp.	RT	-	70
BA0291	Leuconostoc citreum PCR Kit	Detection of <i>L. citreum</i> DNA	RT	-	100
BA0292	Megasphaera cerevisiae PCR Kit	Detection of <i>M. cerevisiae</i> DNA	RT	-	100

5.3 Food pathogens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0293	Oenococcus oeni PCR Kit	Detection of <i>O. oeni</i> DNA	RT	-	100
BA0294	Pectinatus cerevisiiphilus PCR Kit	Detection of <i>P. cerevisiiphilus</i> DNA	RT	-	100
BA0295	Pectinatus frisingensis PCR Kit	Detection of <i>P. frisingensis</i> DNA	RT	-	100
BA0296	Pectinatus spp. PCR Kit	Detection of <i>Pectinatus spp.</i> DNA	RT	-	100
BA0297	Pedicoccus damnosus PCR Kit	Detection of <i>P. damnosus</i> DNA	RT	-	100
BA0298	Pichia anomala PCR Kit	Detection of <i>P. anomala</i> DNA	RT	-	100
BA0299	Pichia membranaefaciens PCR Kit	Detection of <i>P. membranaefaciens</i> DNA	RT	-	100
BA0300	Salmonella PCR Kit	Detection of pathogenic <i>Salmonella ssp.</i> DNA that causes typhoid fever, paratyphoid fever and foodborne illness	RT	-	50, 96, 100
BA0692	Salmonella PCR Kit	Detection of Salmonella ssp. in meat samples including enrichment medium, DNA extraction and qPCR, >100 different Salmonella serotypes detected	RT	Nord Val	96, 960
BA0301	Salmonella differentiation PCR Kit	Detection of <i>S. typhi</i> , <i>S. paratyphi</i> , <i>Salmonella H1 flagellar antigen</i> types (<i>S. stanley</i> , <i>S. isangi</i> , <i>S. muenchen</i> , <i>S. gaminara</i> , <i>S. utrecht</i>)	RT	-	50
BA0302	Saccharomyces diastaticus PCR Kit	Detection of <i>S. diastaticus</i> DNA	RT	-	100
BA0303	Top fermented yeast PCR Kit	Detection of top fermented yeast DNA	RT	-	100

5.4 Food Allergens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0516	Soya Allergen PCR Kit	Detection of Soya DNA	RT	-	100
BA0497	Hazelnut Allergen PCR Kit	Detection of Hazelnut DNA	RT	-	100
BA0504	Peanut Allergen PCR Kit	Detection of Peanut DNA	RT	-	100
BA0491	Almond Allergen PCR Kit	Detection of Almond DNA	RT	-	100
BA0493	Celery Allergen PCR Kit	Detection of Celery DNA	RT	-	100
BA0496	Gluten Allergen PCR Kit	Detection of DNA in gluten-containing cereals from wheat, barley, rye, oat, spelt and kamut	RT	-	100
BA0517	Walnut Allergen PCR Kit	Detection of DNA from walnut	RT	-	100
BA0515	Sesame Allergen PCR Kit	Real Time PCR test for qualitative detection of Sesame DNA	RT	-	100
BA0503	Mustard Allergen PCR Kit	Detection of Mustard DNA	RT	-	100
BA0495	Fish Allergen PCR Kit	Detection of Fish DNA	RT	-	100
BA0501	Lupin Allergen PCR Kit	Detection of Lupin DNA	RT	-	100
BA0494	Crustaceans Allergen PCR Kit	Detection of Crustaceans DNA	RT	-	100
BA0502	Molluscs Allergen PCR Kit	Detection of Molluscs DNA	RT	-	100

5.4 Food Allergens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0505	Pistachio Allergen PCR Kit	Detection of Pistachio DNA	RT	-	100
BA0492	Cashew Allergen PCR Kit	Detection of Cashew DNA	RT	-	100
BA0499	ID Macadamia Allergen PCR Kit	Detection of Macadamia DNA according to directive (EC) 1169/2011	RT	-	100
BA0498	ID Brazil Nut Allergen PCR Kit	Detection of Brazil nut DNA according to directive (EC) 1169/2011	RT	-	100
BA0600	ID Pecan Allergen PCR Kit	Detection of Pecan t DNA according to directive (EC) 1169/2011	RT	-	100
BA0513	Quant Soya Allergen PCR Kit	Quantitative detection of of Soya DNA according to directive (EC) 1169/2011 detection of Hazelnut DNA	RT	-	100
BA0508	QUANT Hazelnut Allergen PCR Kit	Quantitative detection of Hazelnut DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0510	QUANT Peanut Allergen PCR Kit	Quantitative detection of Peanut DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0506	QUANT Celery Allergen PCR Kit	Quantitative detection of Celery DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0507	QUANT Gluten Allergen PCR Kit	Quantitative detection of DNA of gluten-containing cereals (wheat, rhy, barley, oat, spelt and kamut) according to directive (EC) 1169/2011	RT	-	100
BA0514	QUANT Walnut Allergen PCR Kit	Quantitative detection of Walnut DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0512	QUANT Sesame Allergen PCR Kit	Quantitative detection of Sesame DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0509	QUANT Lupin Allergen PCR Kit	Quantitative detection of Lupin DNA in food samples according to EU regulation 2007/68 EC	RT	-	100
BA0511	QUANT Pistachio Allergen PCR Kit	Quantitative detection of Pistachio DNA in food samples according to EU regulation 2007/68 EC	RT	-	100

5.5 Kit for concentration of water samples

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0304	Water Microbial Concentration Kit	Kit for concentration of the microbes present in water samples, for later testing of the presence of bacteria by PCR techniques, incl. membranes and cartridges	-	-	35

5.6 Beer and wine differentiation

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0305	Beer Differentiation PCR Kit	Multiplex screening and differentiation of beer spoilage bacteria and yeast in beer and beer mixing drinks. The following bacteria and yeast are differentiated: <i>L. acetotolerans</i> , <i>L. backii</i> , <i>L. brevis</i> / <i>L. brevisimilis</i> / <i>L. parabravis</i> , <i>L. lindneri</i> , <i>L. casei</i> / <i>L. paracasei</i> , <i>L. buchneri</i> / <i>L. parabuchneri</i> , <i>L. collinoides</i> / <i>L. paracollinoides</i> , <i>L. perolens</i> / <i>L. harbinensis</i> , <i>L. plantarum</i> / <i>L. paraplantarum</i> , <i>L. coryniformis</i> , <i>L. rossiae</i> , <i>Pediococcus</i> spp. (<i>P. acidilactici</i> , <i>P. parvulus</i> , <i>P. inopinatus</i> , <i>P. pentosaceus</i> , <i>P. damnosus</i>), <i>P. claussenii</i> , <i>P. damnosus</i> , <i>Pektinatus</i> spp., <i>Megasphaera</i> spp., <i>Enterobacteriaceae</i> , <i>S. diastaticus</i> , <i>Pichia anomala</i> .	RT	-	96
BA0306	Wine Screening PCR Kit	Multiplex screening to detect <i>Lactobacillus</i> , <i>Pediococcus</i> , <i>Oenococcus oeni</i> , Bacteria forming acetic acid, and yeasts	RT	-	50

6. ANIMAL RELATED DISEASES / ZONOSSES

6.1 Cattle / Ruminants

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0308	Bovine Virusdiarrhoe Virus (BVDV) RT-PCR Kit	Detection of <i>BVDV</i> RNA	RT	FLI	50, 100
BA0519	BVDV/BDV RT-PCR Kit	Multiplex detection of <i>BVDV</i> and <i>BDV</i> RNA	RT	-	48, 96
BA0309	Foot-and-Mouth Disease Virus (FMDV) RT-PCR Kit	Detection of <i>Foot-and-Mouth Disease Virus (FMDV)</i> RNA	RT	-	25
BA0311	Schmallenberg Virus real time RT-PCR Kit	Detection of <i>Schmallenberg Virus</i> RNA	RT	FLI	100
BA0518	Bovine Coronavirus RT-PCR Kit	Detection of RNA of the N gene of the bovine coronavirus (BCoV)	RT	-	50, 100, 150
BA0518B	Bovine Torovirus RT-PCR Kit	Detection of RNA of the M gene of the bovine torovirus (BToV)	RT	-	50, 100, 150
BA0520	Mastitis PCR Kit (4, 8 or 12 pathogens)	Multiplex detection of 48 or 12 pathogens including <i>Staphylococcus aureus</i> , CNS, Beta-Lactamase gene (<i>Staphylococci</i>), <i>Streptococcus agalactiae</i> , <i>Streptococcus dysgalactiae</i> , <i>Streptococcus uberis</i> , <i>Mycoplasma bovis</i> , <i>Mycoplasma species</i> , <i>Prototheca</i> , <i>E.coli</i> , <i>Klesiella</i> , <i>Enterococcus</i> and <i>Lacotococcus lactis</i>	RT	-	386
BA0693	BTV PCR Kit	Detection of <i>Bluetongue Virus (BTV)</i> RNA	RT	-	50, 100
BA0694	Bovine Herpesvirus I PCR Kit	Detection of <i>Bovine Herpesvirus I</i> DNA	RT	-	50, 100
BA0695	Bovine Nebovirus PCR Kit	Detection of <i>Bovine Nebovirus</i> RNA	RT	-	50, 100
BA0696	Bovine Norovirus PCR Kit	Detection of <i>Bovine Norovirus</i> RNA	RT	-	50, 100
BA0697	Bovine Parainfluenza Virus 3	Detection of <i>Bovine Parainfluenza Virus 3</i> RNA	RT	-	50, 100
BA0698	BRSV PCR Kit	Detection of Bovine respiratory syncytial virus (<i>BRSV</i>) RNA	RT	-	50, 100

6.2 Swine

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0699	Swine Influenza Virus H1 RT-PCR Kit	Real Time PCR test for detection of Swine Influenza Virus A/H1 RNA	RT	-	50
BA0312	African Swine Fever (ASF) PCR Kit	Detection of <i>ASF</i> DNA	RT	-	50, 100
BA0313	Classical Swine Fever Virus (CSFV) RT-PCR Kit	Detection of <i>CSFV</i> RNA	RT	-	50, 100
BA0314	Porcine reproductive and respiratory syndrome virus (PRRSV) RT-PCR Kit	Detection of <i>PRRSV</i> RNA	RT	-	25, 50, 100
BA0521	PCMV PCR Kit	Detection of the DPOL gene of the porcine cytomegalovirus (PCMV)	RT	-	50, 100
BA0522	PCV2 PCR Kit	Detection of the ORF1 of the porcine circovirus type 2 (PCV2) including the three genotypes A, B and C	RT	-	50, 100
BA0524	PEDV PCR Kit	Detection of RNA of the N gene of the porcine epidemic diarrhea virus (PEDV)	RT	-	50, 100
BA0315	TGEV PCR Kit	Detection and differentiation of the S region of the <i>transmissible gastroenteritis virus (TGEV)</i>	RT	-	50, 100
BA0700	PEDV & TGEV PCR Kit	Detection and differentiation of RNA of the N gene of the <i>porcine epidemic diarrhea virus (PEDV)</i> and of the S region of the <i>transmissible gastroenteritis virus (TGEV)</i>	RT	-	50, 100
BA0525	PHEV RT-PCR Kit	Detection of RNA of the N gene of the porcine <i>hemagglutinating encephalomyelitis virus (PHEV)</i>	RT	-	50, 100

6.2 Swine

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0526	Porcine Parvovirus PCR Kit	Detection of the NS1 gene of the <i>porcine parvovirus (PPV)</i>	RT	-	50, 100
BA0527	SDCV RT-PCR Kit	Detection of RNA of the 3'UTR of the <i>swine delta coronavirus (SDCV)</i>	RT	-	50, 100
BA0528	SIV RT-PCR Kit	Detection of RNA of the matrix protein gene of the <i>Swine Influenza A (SIV)</i>	RT	-	50, 100
BA0701	SHV-1 PCR Kit	Detection of RNA of the <i>Pseudorabiesvirus (SHV-1)</i>	RT	-	50, 100

6.3 Poultry

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0316	AI H5N1 RT-PCR Kit	Semi-quantitative detection of Avian Influenza virus <i>H5N1</i> RNA	RT	-	60, 120
BA0317	AI H5N2 RT-PCR Kit	Detection of Avian Influenza virus <i>H5N2</i> RNA	RT	-	25
BA0318	AI H5N7 RT-PCR Kit	Detection of Avian Influenza virus <i>H5N7</i> RNA	RT	-	25
BA0319	Infectious Bronchitis virus (IBV) RT-PCR Kit	Detection of <i>IBV</i> RNA	RT	-	100
BA0320	Infectious Bursal Disease Virus (IBDV) RT-PCR Kit	Detection of <i>IBDV</i> RNA	RT	-	100, 150
BA0321	Infectious Laryngotracheitis Virus (ILT) PCR Kit	Detection of <i>ILT</i> DNA	RT	-	100
BA0322	Newcastle Disease Virus (NDV) RT-PCR Kit	Detection of <i>Newcastle Disease Virus (NDV)</i> RNA	RT	-	150
BA0323	Mycobacterium tuberculosis avium PCR Kit	Detection of <i>M. tuberculosis avium</i> DNA	RT	-	32, 96
BA0324	Mycoplasma iowae PCR Kit	Detection of <i>Mycoplasma iowae</i> DNA	RT	-	100
BA0529	Gallid Herpesvirus 2 (GaHV-2) PCR Kit	Detection of <i>Gallid herpesvirus 2</i> (Marek's Disease Virus, MDV) DNA	RT	-	150

6.4 Feline & canine

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0325	Canine Babesia PCR Kit	Detection of <i>Babesia species</i> (<i>Babesia canis</i> & <i>Babesia gibsoni</i>)	RT	-	32, 96
BA0327	Canine Ehrlichia PCR Kit	Differentiation of <i>Ehrlichia spec. and Anaplasma spec.</i>	RT	-	32
BA0530	Echinococcus multilocularis PCR Kit	Real Time PCR test for detection of the cyclophyllid tapeworm <i>Echinococcus multilocularis</i> DNA	RT	-	100

6.5 Equine

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0332	Equine Babesia PCR Kit	Detection of <i>Babesia species</i> (<i>Babesia caballi</i> & <i>Babesia equi</i>) DNA	RT	-	32, 96
BA0333	Equine Anaplasma PCR Kit	Detection of <i>Anaplasma phagocytophilum</i> (auch <i>Ehrlichia phagocytophilum</i> , <i>Ehrlichia equi</i>)	RT	-	32, 96

6.6 Sheep

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0531	Capripoxvirus PCR Kit	Detection of <i>Capripoxvirus</i> via the LSDV116 RNA polymerase subunit (LSDV116)	RT	–	150

6.7 Primates

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0334	Monkeypox Virus PCR Kit	Detection of <i>Monkeypox Virus</i> DNA	RT	–	25

6.8 Honey bee

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0532	American foulbrood PCR Kit	Detection of the 16S rRNA gene of <i>Paenibacillus larvae</i> in honey bees	RT	–	50, 100
BA0533	European foulbrood PCR Kit	Detection of the 16S rRNA gene of <i>Melissococcus plutonius</i> in honey bees	RT	–	50, 100
BA0534	Foulbrood European & American PCR Kit	Detection of the 16S rRNA gene of <i>Melissococcus plutonius</i> and <i>Paenibacillus larvae</i>	RT	–	50, 100

6.9 Animal-related mycoses

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0535	Nosema apis & ceranae PCR Kit	Detection of <i>Nosema apis</i> & <i>ceranae</i> microscopic fungi that typically parasitize insects such as Eastern honey bee	RT	–	50, 100

6.10 Animal-related parasites

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0536	Histomonas meleagridis PCR Kit	Detection of the 18S rRNA gene of <i>H. meleagridis</i>	RT	–	50, 100
BA0537	Neospora caninum PCR Kit	Detection of the mitochondrial NC5 gene of <i>N. caninum</i>	RT	–	50, 100
BA0538	Trichinella spiralis & britovi PCR Kit	Detection and differentiation of the internal transcribed spacer of <i>Trichinella spiralis</i> and <i>T. britovi</i>	RT	–	50, 100

6.11 Further animal-related bacterial and viral pathogens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0539	Actinobacillus pleuropneumoniae PCR Kit	Detection of the apxIVA gene of <i>A. pleuropneumoniae</i>	RT	–	50, 100
BA0540	Aerococcus viridans PCR Kit	Detection of the 16S rRNA gene of <i>A. viridans</i>	RT	–	50, 100
BA0541	Bartonella spp. PCR Kit	Detection of the gltA gene of <i>B. clarridgeiae</i> , <i>B. elizabethae</i> , <i>B. grahamii</i> , <i>B. henselae</i> , <i>B. koehlerae</i> , <i>B. quintana</i> , <i>B. volans</i> and <i>B. washoensis</i>	RT	–	50, 100
BA0542	Bordetella bronchiseptica PCR Kit	Detection of the bfrA gene of <i>B. bronchiseptica</i>	RT	–	50, 100
BA0543	Borrelia burgdorferi sensu lato PCR Kit	Detection of the ospA gene of <i>Borrelia</i> species belonging to the <i>Borrelia burgdorferi</i> sensu lato complex (<i>B. spielmanii</i> is not well detected)	RT	–	50, 100

6.11 Further animal-related bacterial and viral pathogens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0544	Brachyspira PCR Kit	Single or combined detection of the nox gene of <i>B. hyopneumoniae</i> and/or <i>B. pilosicoli</i>	RT	-	50, 100
BA0702	Brachyspira hyodysenteriae PCR Kit	Detection of the <i>Brachyspira hyodysenteriae</i> DNA	RT	-	50, 100
BA0703	Brachyspira pilosicoli PCR Kit	Detection of the <i>Brachyspira pilosicoli</i> DNA	RT	-	50, 100
BA0545	Chlamydiaceae PCR Kit	Detection of the 23S rRNA gene of <i>C. muridarum</i> , <i>C. suis</i> , <i>C. trachomatis</i> , <i>C. abortus</i> , <i>C. caviae</i> , <i>C. felis</i> , <i>C. pecorum</i> , <i>C. pneumoniae</i> and <i>C. psittaci</i>	RT	-	50, 100
BA0546	Chlamydophila psittaci/abortus PCR Kit	Detection of the omp1 gene of <i>C. abortus</i> and <i>C. psittaci</i>	RT	-	50, 100
BA0547	Clostridium perfringens PCR Kit	Detection of the 16S rRNA gene of <i>Clostridium perfringens</i>	RT	-	50, 100
BA0548	Corynebacterium pseudotuberculosis PCR Kit	Detection of the pld gene of <i>Corynebacterium pseudotuberculosis</i>	RT	-	50, 100
BA0549	Enterococcus ssp. PCR Kit	Detection of the 23S rRNA gene of <i>Enterococcus</i> species	RT	-	50, 100
BA0550	Haemophilus parasuis PCR Kit	Detection of the 16S rRNA gene of <i>H. parasuis</i>	RT	-	50, 100
BA0551	Lawsonia intracellularis PCR Kit	Detection of the 16S rRNA gene of <i>L. intracellularis</i>	RT	-	50, 100
BA0552	Leptospira spp. Differentiation PCR Kit	Detection and differentiation of LipL32 gene of pathogenic and 16S rRNA gene of pathogenic and intermediately pathogenic <i>Leptospira</i> species	RT	-	50, 100
BA0553	Mannheimia haemolytica PCR Kit	Detection of the 16S rRNA gene of <i>M. haemolytica</i>	RT	-	50, 100
BA0554	Mycobacterium avium ssp. Paratuberculosis PCR Kit	Detection the IS900 region of <i>M. avium</i> subspecies <i>paratuberculosis</i>	RT	-	50, 100
BA0556	Mycoplasma bovis PCR Kit	Detection of the rpoB gene of <i>M. bovis</i>	RT	-	50, 100
BA0557	Mycoplasma gallisepticum PCR Kit	Detection of <i>M. gallisepticum</i> via the mgc2 gene (cytadhesin-like protein encoding gene)	RT	-	50, 100
BA0557B	Mycoplasma gallisepticum & synoviae PCR Kit	Detection and differentiation of DNA of <i>Mycoplasma gallisepticum</i> and <i>Mycoplasma synoviae</i> via the mgc2 gene (cytadhesin-like protein encoding gene)	RT	-	50, 100
BA0558	Mycoplasma hyopneumoniae PCR Kit	Detection of the rpoB gene of <i>M. hyopneumoniae</i>	RT	-	50, 100
BA0559	Mycoplasma hyorhinis PCR Kit	Detection of the rpoB gene of <i>M. hyorhinis</i>	RT	-	50, 100
BA0560	Mycoplasma suis PCR Kit	Detection of the 16S rRNA gene of <i>M. suis</i>	RT	-	50, 100
BA0561	Mycoplasma synoviae PCR Kit	Detection of the vlhA gene of <i>M. synoviae</i>	RT	-	50, 100
BA0562	Nocardia spp. PCR Kit	Detection of the 16S rRNA gene of <i>Nocardia</i> species	RT	-	50, 100
BA0563	Ornithobacterium rhinotracheale PCR Kit	Detection the 16S rRNA gene of <i>Ornithobacterium rhinotracheale</i>	RT	-	50, 100
BA0564	Pasteurella multocida PCR Kit	Detection of the 16S rRNA gene of <i>Pasteurella multocida</i> (subspecies <i>P. multocida</i> , <i>P. gallicida</i> , <i>P. septica</i> , <i>P. tigris</i>)	RT	-	50, 100
BA0565	Pasteurella multocida toxA PCR Kit	Detection of the toxA gene of toxigenic <i>Pasteurella multocida</i> strains	RT	-	50, 100
BA0704	Riemerella anatipestifer PCR Kit	Detection of <i>Riemerella anatipestifer</i> DNA	RT	-	50, 100
BA0566	Salmonella enterica PCR Kit	Detection of the invA gene of <i>Salmonella enterica</i>	RT	-	50, 100
BA0568	Staphylococcus ssp. PCR Kit	Detection of the 23S rRNA gene of <i>Staphylococcus</i> species	RT	-	16

6.11 Further animal-related bacterial and viral pathogens

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0705	Staphylococcus serotyping PCR Kit	Identification of 42 different serotypes of <i>S. pneumoniae</i> (1, 2, 3, 4, 5, 6A, 6B, 6C, 6D, 7F/7A, 8, 9N/9L, 9A/9V, 10A, 10B, 10F/C, 11A/D, 11B, 11C, 11F, 12F, 14, 15B/15C, 17F, 18A, 18B/18C, 18F, 19A, 19F, 20, 22F/22A, 23F, 33F/33A) in DNA samples extracted from bacterial culture	HYB	CE	50, 100
BA0567	Staphylococcus aureus PCR Kit	Detection of the nuc gene of <i>S. aureus</i>	RT	-	50, 100
BA0571	Streptococcus spp. PCR Kit	Detection of the 23S rRNA gene of <i>Streptococcus</i> species DNA	RT	-	50, 100
BA0569	Streptococcus agalactiae PCR Kit	Detection of the cfb gene of <i>S. agalactiae</i> DNA	RT	-	50, 100
BA0570	Streptococcus dysgalactiae PCR Kit	Detection and differentiation of 23S rRNA gene of <i>S. dysgalactiae</i> and <i>S. canis</i> and of 16S rRNA gene of <i>Streptococcus</i> species except <i>S. canis</i> DNA	RT	-	50, 100
BA0736	Streptococcus suis PCR Kit	Detection of the cfb gene of <i>S. suis</i> DNA	RT	-	50, 100
BA0572	Streptococcus uberis PCR Kit	Detection of the ITS2 region of <i>S. uberis</i> DNA	RT	-	50, 100
BA0573	Trueperella pyogenes PCR Kit	Detection of the 16S rRNA gene of <i>T. pyogenes</i>	RT	-	50, 100
BA0574	EMCV (Encephalomyocarditis-Virus) RT-PCR Kit	Detection of RNA of the 3'UTR of the encephalomyocarditis virus (EMCV), synonyms: Mengovirus, Columbia SK virus, mouse Elberfield virus	RT	-	50, 100
BA0575	Rabies Virus RT-PCR Kit	Detection of Rabies RNA	RT	-	50, 100

6.12 Further animal-related fungal diseases

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0706	Batrachochytrium dendrobatidis PCR Kit	Detection of the ITS2 region of <i>Batrachochytrium dendrobatidis</i> DNA	RT	RT	50, 100
BA0707	Batrachochytrium & dendrobatidis salamandrivorans PCR Kit	Detection and differentiation of the of <i>Batrachochytrium dendrobatidis</i> and <i>dendrobatidis salamandrivorans</i> DNA	RT	RT	50, 100
BA0708	Nosema apis & ceranae PCT Kit	Detection and differentiation of the 18S rRNA gene of <i>Nosema apis</i> & <i>ceranae</i> DNA	RT	RT	50, 100

7. NUCLEIC ACIDS PURIFICATION

7.1 DNA preparation

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0336	Blood DNA Mini Purification Kit	System for the isolation and purification of DNA from fresh, or frozen human or animal blood, buffy coat, and bone marrow	SC MB	CE	50, 96, 100, 250
BA0337	Clean Water DNA Extraction Kit (incl. Filtration membranes)	System for the extraction and purification of DNA from water samples in which it is assumed that the microbe population is low, Filtration membranes (100 units)	SC	RUO	70
BA0338	Dirty Water DNA Extraction Kit (incl. Filtration membranes)	System for the extraction and purification of DNA from "dirty" water samples (for example, water from refrigeration towers).	SC	RUO	70
BA0339	Kit for extraction of DNA from microorganisms	System for isolation of microbial DNA from bacteria, yeasts and fungi	SC MB	RUO	50
BA0340	Kit for extraction of DNA fragments	System for ultra-fast purification and concentration of DNA fragments after PCR reactions, restriction digestion, ligation, cDNA synthesis	SC	RUO	50, 250
BA0341	Kit for extraction of DNA fragments from gels and PCR-clean-up	System for Gel and PCR Clean-up including Clean-up Columns, Collection Tubes, buffers	SC	RUO	250
BA0342	Plasmid DNA Mini, Midi or Maxi extraction Kit	System for purification of ultrapure supercoiled plasmid DNA with high yield, transfection-grade DNA	SC	CE	25, 100

7.1 DNA preparation

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0343	Tissue DNA Purification Kit	System for purification of high quality DNA from human whole blood, bone marrow, buffy coat, buccal cells, body fluids, cultured cells, tissue, mouse tail, yeast, bacteria	SC MB	CE	50
BA0344	Virus DNA Purification Kit	System for the isolation and purification of viral DNA	SC MB	CE	50, 250
BA0577	Basic food and feed DNA extraction Kit (Plants)	For efficient DNA preparation from food and feed (Plants)	SC	-	50, 100
BA0576	Advanced food and feed DNA extraction Kit (highly processed food & feed)	For efficient DNA preparation from highly processed food and feed	SC	-	50
BA0709	Stool DNA Extraction Kit	System for purification of high quality DNA from stool samples	SC MB	-	50, 480
BA0710	Forensic DNA Mini Extraction Kit	System for purification of high quality DNA from stool samples	SC MB	-	50, 480

7.2 RNA preparation

Order number	Product name	Intended use	Method	Legal status	Tests/Size
BA0345	Blood RNA Mini Purification Kit	System for the isolation and purification of total RNA from blood from up to 400 µl of sample	SC MB	CE	50, 100
BA0346	Universal RNA Mini Kit	System for isolation of total RNA from human and animal cells, tissue samples, paraffin embedded tissue, whole blood samples	SC MB	CE	50, 100
BA0347	Virus RNA Purification Kit	System for the isolation and purification of viral RNA based on micro column technology	SC MB	CE	50, 100, 250
BA0348	Total RNA Purification Kit (from cells, tissues)	System for the isolation and purification of total RNA from cells, tissues etc. based on micro column technology	SC MB	CE	50, 100, 250

8. PCR REAGENTS & ADDITIVES

8.1 PCR/RT-PCR enzymes/Mastermixes

Order number	Product name	Intended use	Tests/Size
BA0351	Taq DNA Polymerase (hot start)	Recombinant thermostable DNA polymerase, heat activated, 5 U/µL	100, 500, 2500, 10,000 U
BA0711	Pfu DNA Polymerase	Recommended for use in PCR and primer extension reactions that require high fidelity, 5 U/µL	500, 2500 U
BA0352	Taq Master Mix	Set contains Polymerase & dNTPs, 25 µL PCR reactions	200, 5x200 rxn
BA0712	Master Mix TaqMan Probe	For DNA amplification by real time PCR containing all components except primers, with or without passive reference dye or intercalating dyes e.g. ROX, CYBR green	96, 150, 200, 400, 1000 rxn
BA0713	Master Mix One-step TaqMan Probe	For one-step RNA amplification by real time PCR containing all components except primers, with or without passive reference dye or intercalating dyes e.g. ROX, CYBR green	96, 100, 150, 200, 400, 500, 1000 rxn

8.2 Reverse transcription

Order number	Product name	Intended use	Tests/Size
BA0714	Reverse transcription/cDNA Synthesis Kit	Rapid and sensitive kit for first-strand cDNA synthesis for use in real-time PCR studies	25, 50, 100, 250 rxn
BA0353	Reverse Transcriptase	Enzyme for first-strand cDNA synthesis, cDNA library construction, and the production of templates for RT-PCR analysis of gene expression	4 x 10,000 U

8.2 Reverse transcription

Order number	Product name	Intended use	Tests/Size
BA0579	Recombinant Ribonuclease Inhibitor	Recombinant 50 kDa proteins that inhibit RNase A family and human placental RNases by non-covalently binding to RNases	2,500 U
BA0578	M-MLV Reverse Transcriptase	Moloney Murine Leukemia Virus Reverse Transcriptase (M-MLV RT), RNA-dependent DNA polymerase that can be used in cDNA synthesis with long messenger RNA templates (>5kb); 200 U/μL	10,000u

8.3 PCR additives

Order number	Product name	Intended use	Tests/Size
BA0354A BA0354B	Deoxynucleoside 5'-triphosphates	Set of 4 dNTPs 10 mM, 4 x 10 mM Set of 3 + 1 dNTPs, with dUTP, 4 x 100 mM	200 μL, 1 mL 200 μL, 1 mL
BA0355	Uracil-DNA Glycosylase (UDG)	For control of carry-over contamination in PCR, fully inactivated without retaining residual activity	200, 1000 U
BA0580	50x ROX solution	ROX passive reference dye, for use with low ROX (7500 Fast, StepOne) and high ROX (ABI PRISM® 7000/7300/7700) requiring ABI real time PCR platforms; 50x conc.M;	1x 0.20 mL

8.4 DNA electrophoresis

Order number	Product name	Intended use	Tests/Size
BA0715	Agarose	Agarose Standard, for DNA/RNA electrophoresis by routine gels, education and simple analyses in the lab (1 kb-20 kb fragments)	
BA0581	1 kb DNA Ladder	Molecular DNA (1 kb) marker for electrophoresis, ready-to-use	50 μg
BA0582	100 bp DNA Ladder	Molecular DNA (100 bp) marker for electrophoresis, ready-to-use	50 or 250 μg
BA0583	50 bp DNA	Molecular DNA (50 bp) marker for electrophoresis, ready-to-use	50 or 250 μg
BA0584	TAE buffer 10-fold concentration	Buffer for agarose gel electrophoresis	1 L
BA0585	TBE 5-fold concentration	Buffer for PAA gel electrophoresis	1 L
BA0586	Gel loading buffer, ready-to-use	For electrophoresis, 1x conc. Gel loading buffer (with Glycerin), ready-to-use, DNAse-free	5x1 mL
BA0587	Ethidium bromide	For electrophoresis, for fluorescence staining of nucleic acids in agarose and PAA gels; , 1% or 0.07% (ready for use),	10 mL
BA0588	SYBR® Green I	For electrophoresis, for fluorescence staining of nucleic acids in agarose and PAA gels, 10,000X concentrate in DMSO	500 μL
BA0589	Eva Green® Fluorescence dye	For electrophoresis, for fluorescence staining of nucleic acids in agarose and PAA gels, sufficient to stain about 500 lanes,	500 μL

9. PCR LAB EQUIPMENT

9.1 Thermal Cycler

Order number	Product name	Intended use	Legal status	Tests/Size
BA0356	Advanced thermal cycler	96-well block, Peltier-based, 6.5 inch, 262, 144 color LCD display and touch screen, heating/cooling ramp rate 4°C/sec, 30°C gradient function, 220 V	CE	1
BA0590	Interchangeable blocks	For 96 x 0.2 mL, 30 x 0.5 mL, 48 x 0.2 mL, and for standard in situ plates	CE	1
BA0357	Standard thermal cycler	30, 48, 60, 96, 384-well block, Peltier-based, 320*240 LCD, 5.7 inch display, 220 V	CE	1

9.2 Isothermal Amplification

Order number	Product name	Intended use	Legal status	Tests/Size
BA0716	IVD Genie	Instrument complete with 150W mains power adaptor, power cable, USB cable, software and internal rechargeable battery runtime 1 working day	CE	1
BA0717	IVD Genie equipment	Cooling Blocks A + B for reaction preparation, FastGene Mini incl.heating block 2.0/1.5 ml tubes, eazyReport™ – IVD – Software, DYMO Labelwriter 450 Printer incl. 1 role labels, USB-Barcode-Scanner	CE	1

9.3 Endpoint Fluorescence Detection

Order number	Product name	Intended use	Legal status	Tests/Size
BA0358	FluoVista System	FluoVista Analyzer incl. PC System, Monitor, Barcode Reader, IQOQ Kit and software package	CE	1
BA0359		FluoVista Calibration System	CE	1

9.4 PCR Onset and PCR Product Detection

Order number	Product name	Intended use	Legal status	Tests/Size
BA0718	Vortex Mixer	750-3000 RPM, for up to 50 mL tubes	CE	1
BA0719	Thermomixer, heating function	Mixing Block with temperature setting range 0 ~ 105, temp. control range RT-14 ~ 100, 300 rpm – 1500 rpm (rotation), Standard Blocks 40x1.5 mL, 54x 0.5mL, 96x 0.2mL, 100-240 V / 50-60 Hz	CE	1
BA0720	Thermomixer, cooling and heating functiin	Mixing Block with temperature setting range 0 ~ 105, temp. control range RT-14 ~ 100, 300 rpm – 1500 rpm (rotation), cooling ≤ 8min (100°C ~ 4°C), Standard Blocks 40x1.5 mL, 54x 0.5mL, 96x 0.2mL, 100-240 V / 50-60 Hz	CE	1
BA0721	Power Supply	Power Supply for Electrophoresis Units 300 V, 400 mA	CE	1
BA0722	Horizontal electrophoresis systems (for mini, midi, maxi agarose gels)	Horizontal chambers for DNA and RNA separation, including: UV-transparent gel casting tray, combs, colored loading strips	CE	1
BA0723	Gel Documentation System	Gel Documentation System including 18 MP Camera, transilluminator with sliding table,UV shield, analysis software	CE	1
BA0724	UV transilluminator	UV transilluminator with 2 wavelengths 4 tubes of 8 watt, 254 nm	CE	1
BA0725	PCR Workstation	For clean operations with DNA samples and protection against contamination	CE	1

9.5 Real time PCR Instruments & equipment

Order number	Product name	Intended use	Legal status	Tests/Size
BA0726	All-in-One Automation System (AIO 24)	Fully integrated system providing a non-stop automation of nucleic acid extraction, PCR setup, qPCR to report, model AIO 24, throughput 1-24 samples	CE	1
BA0727	All-in-One Automation System (AIO 48)	Fully integrated system providing a non-stop automation of nucleic acid extraction, PCR setup, qPCR to report, model AIO 24, throughput 1-48 samples	CE	1
BA0728	All-in-One Automation System (AIO 96)	Fully integrated system providing a non-stop automation of nucleic acid extraction, PCR setup, qPCR to report, model AIO 24, throughput 1-96 samples	CE	1
BA0594	Real-Time PCR System 2 channels	Real Time PCR Detection System, 96 x 0.2 mL, 2 channels, bluetooth, F1: FAM, SYBR Green I; F2: VIC, HEX, TET, JOE	CE	1
BA0595	Real-Time PCR System 4 channels	Real Time PCR Detection System, 48 and 96 x 0.2 mL, 4 channels, bluetooth, F1: FAM, SYBR Green I; F2: VIC, HEX, TET, JOE; F3: ROX, TEXAS-RED; F4: Cy5	CE	1
BA0360	Real-Time PCR System 5 channels, Fixed	Real Time PCR Detection System with 5 channels (SYBR/FAM, HEX, ROX, CY3, CY5), 2-year base warranty sold with the instrument	CE	1

9.5 Real time PCR Instruments & equipment

Order number	Product name	Intended use	Legal status	Tests/Size
BA0596	Real-Time PCR System 6 channels	Real Time PCR Detection System, 96 x 0.2 mL, 6 channels, bluetooth, F1: FAM, SYBR Green I; F2: VIC, HEX, TET, JOE; F3: Cy3, NED, TAMRA; F4: ROX, TEXAS-RED; F5: Cy5; F6: Cy5.5	CE	1
BA0597	Real-Time PCR System 8 channels	Real Time PCR Detection System, 96 x 0.2 mL, 8 channels, bluetooth, F1: FAM, SYBR Green I; F2: VIC, HEX, TET, JOE; F3: Cy3, NED, TAMRA; F4: ROX, TEXAS-RED; F5: Cy5; F6: Cy5.5, F7, F8 for customized applications	CE	1
BA0361	Desktop DNA Analyzer (12)	2 channels (SYBR/FAM, ROX) Real Time PCR Instrument, 12x 0.1 mL, including user manual, 1 accessory kit, CD with Graphing Software, Tube Rack & Centrifuge Adaptors; 1-year base warranty sold with the instrument	CE	1

9.6 High-throughput Nucleic Acids Extraction

Order number	Product name	Intended use	Legal status	Tests/Size
BA0729	Magnetic rack	Magnetic separator for manual extraction of DNA or RNA, 12 tubes (1.5 ml or 2.0 mL), starting volume 450 µL	CE	1
BA0363	Automated Magnetic Particle Processor	Automated low to intermediate throughput sample preparation system for processing volumes up to 1 mL, 12, 15, 24, 32, 48, 96 processed samples per run, Integrated barcode reader for sample ID	CE	1

9.7 Automated Liquid Handling

Order number	Product name	Intended use	Legal status	Tests/Size
BA0364	Pipetting Unit	For automated PCR setup	CE	1

9.8 DNA Blot Processing

Order number	Product name	Intended use	Legal status	Tests/Size
BA0598	DNA Blot Processor	Compact and stand-alone instrument for automatic processing of hybridization tests, Maximal number of strips: 30 or 48	CE	1
BA0599	Robotic Blot Processor	Complete automation of strip assays - from sample preparation to result, up to 48 samples per run, Integrated barcode reader for sample ID, integrated PC for connection to LIMS and Interpretation Software, volume range 10 µL to 2.5 mL, pressure sensing for sample level detection in sample tubes, 100-240V / 50-60Hz	CE	1

10. CONSUMABLES FOR REAL-TIME PCR AND CONVENTIONAL PCR

10.1 PCR Tubes

Order number	Product name	Intended use	Legal status	Tests/Size
BA0385	Optical 96-well Reaction plate	For use with all real time PCR instruments and conventional thermal cyclers supporting the 96-well format	-	20
BA0386	Optical Fast Plate	For use with all real time PCR instruments and conventional thermal cyclers supporting the 96-well format	-	20
BA0387	LightCycler capillaries	For use with LightCycler® 1.x and 2.x System	-	480
BA0388	PCR reaction vessels 0.2 mL	For use with block and carousel cyclers supporting the 0.2 mL format	-	1000
BA0389	PCR reaction vessels 0.1 mL, 4-well/strips with attached cap	For use with Rotor-Gene™ 3000/6000, Rotor-Gene Q	-	1000

10.1 PCR Tubes

Order number	Product name	Intended use	Legal status	Tests/Size
BA0390	SmartCycler Tubes, 25 µL	Reaction vessels (25 µl) for SmartCycler® I/II, 20 bags, 50 tubes each	-	1000
BA0391	Spartan Tubes & Caps	Plastic tubes (clear) and caps for use with Spartan DX-12 Desktop DNA Analyzer	-	1000
BA0392	Low Profile Strips (white), 8-well/strips, 0.2 mL	For use with real time PCR instruments and conventional thermal cyclers supporting the 8-well/strip format	-	100
BA0393	Optical Cap Strips (clear)	Cap strips for use with for use with Low Profile Strips	-	100
BA0394	Optical Tape	Transparent, self-adhesive covers to seal 96-well reaction plates	-	100

10.2 Reaction vessels / reagent tubes

Order number	Product name	Intended use	Legal status	Tests/Size
BA0395A	Reaction vessels, with or without caps	Safe seal tubes, 1.5 mL, clear	-	1000
BA0395B	Reaction vessels, with or without caps	Reaction vessel, 5 mL	-	250
BA0395C	Reaction vessels, with or without caps	Safe-lock tubes, 2 mL	-	1000
BA0395D	Reaction vessels, with or without caps	Reaction vessels, 1.5 mL, clear and amber	-	500
BA0395E	Reaction vessels, with or without caps	Reaction vessels, 2,0 mL, clear, for screw cap	-	500
BA0395F	Reaction vessels, with or without caps	Reaction vessels, 0,5 mL, clear, for screw cap	-	500
BA0396	Screw caps	Screw caps, different colours	-	500
BA0397A	Reagent tubes	Reagent tubes, 15 mL, sterile	-	500
BA0397B	Reagent tubes	Reagent tubes, 50 mL, sterile	-	500

1) Caution: Some of the products listed in this catalogue may be not available in selected countries.:

Contraction	Explanation
ELPHO	Conventional PCR/methylation-specific PCR and subsequent agarosegel electrophoresis
EPF	End point fluorescence detection
FA	Fragment analysis by capillary electrophoresis and fluorescence signal recording on conventional genetic analyzers, e.g. ABI 3130, 3730 or 3500
FLI	Registered with Friedrich-Loeffler-Institut, Germany
HYB	PCR product detection by hybridization, usually reverse dot blot or line blot on strips
MB	Magnetic beads based extraction of nucleic acids
NGS	Next generation sequencing e.g. on Ion Torrent™ or ILLUMINA®
NORDVAL	Registered with NordVal International / NMKL
RT	Real time PCR
SC	Spin column based extraction of nucleic acids
TFDA	Registered with Federal Drug Administration Taiwan
USFDA	Registered with Federal Drug Administration USA
b-DNA	Branched DNA (b-DNA) technology

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Who we are

bioactiva diagnostica GmbH, founded in 2001 by the biologist Adnan Dawoud, is an experienced and innovative company located in Bad Homburg near Frankfurt, Germany. We are a manufacturer and distributor of in-vitro diagnostics and lab ware. All of the products we manufacture are CE-certified and our customers can be confident that they will get pre-selected and optimized quality products. Our working process strictly follows the guidelines of DIN EN ISO 13485-2016. Beside our own produced kits we have exclusive agreements with leading European, American and Asian manufacturers.

We can offer moderately priced and high quality products to our customers. Many years of experience and detailed knowledge of the markets put us in the position to help our customers fulfill their very special needs. Direct sales to clinics, specialized labs and hospitals are performed through our subsidiaries as well as through our local partners in the relevant markets. Due to the excellent position of our headquarters in Bad Homburg (near Frankfurt international airport) in the heart of Europe we are able to ship our products worldwide just in time. To maintain a close relationship with our customers and suppliers we regularly exhibit at major trade fairs like Arab Health, Arab Lab and Medica

The way to us

From the North (Kassel/Hannover):

Take Autobahn A5 (Kassel-Frankfurt) direction Frankfurt and change to Autobahn A661 direction Bad Homburg. After 1km take exit Bad Homburg. Pass Fresenius on the left, direction city center.

From the South or the West (Airport/Basel/Cologne):

Take Autobahn A5 (Frankfurt-Basel) direction Hassel and change to Autobahn A661 direction Bad Homburg. After 1km take exit Bad Homburg. Pass Fresenius on the left, direction city center.





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