

1.15 Bacterial Drug Resistance

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

1.16 Periodontitis

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

1.17 Biothreat Agents

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

2. ONCOLOGY

2.1 Oncogene Expression Quantification / Minimal Residual Disease (MRD)

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

2.1 Oncogene Expression Quantification / Minimal Residual Disease (MRD)

Order number	Product name	Intended use	Legal Status	Tests/Size
Acute Myelogenous / Acute Lymphatic Leukaemia				
BA455	ALL Fusion Screening PCR Kit	Multiplex Reverse Transcription Real-time PCR test for simultaneous detection and quantification of 16 fusion genes with 71 breakpoints in leukemia patients with ALL	CE	10, 20
BA456	AML Fusion Screening PCR Kit	Multiplex Reverse Transcription Real-time PCR test for simultaneous detection and quantification of 16 fusion genes with 72 breakpoints in leukemia patients with AML	CE	10, 20
BA148	AML1-ETO/t(8;21) PCR Kit	Real-time PCR test for identification and quantitation of the t(8;21) (q22;q22) translocation with <i>AML1-ETO</i> fusion transcripts	CE	25, 48, 96
BA149	CBFB-MYH11 A/inv(16) PCR Kit	Real-time PCR test for the identification and quantitation of inv(16) (p13;q22) inversion with <i>CBFB-MYH11 A</i> fusion transcripts	CE	25, 48, 96
BA150	PML-RARa/t(15;17) PCR Kit	Real-time PCR test for in vitro quantification of <i>PML-RARa/t(15;17)</i> fusion transcripts covering all three known regions of the PML locus in AML M3	CE	48, 96, 120
BA151	TEL-AML1/t(12;21) PCR Kit	Real-time PCR test for in vitro quantification of <i>TEL-AML1</i> fusion transcripts t(12;21) in AML1	RUO	120
BA601	TCF3-PBX1/ t(1;19) PCR Kit	Multiplex Real-time PCR test for chromosome translocation t(1;19) (q23;p13) (<i>TCF3-PBX1</i>) screening associated with leukemia	CE	25
BA607	MLL-AFF1 t(4;11) PCR Kit	Multiplex RT-PCR screening test for chromosome translocation t(4;11)(q21;q23) (<i>MLL-AFF1</i>) associated with leukemia	CE	25
Lymphoma				
BA152	BCL-2/t(14;18) PCR Kit	Kit for the detection of the <i>BCL-2 gene</i> t(14;18) (q32;q21) translocation. Target regions (nested PCR): Major Break-point Region (<i>MBR</i>), minor cluster region (<i>mcr</i>)	CE	25, 50
BA153	Cyclin D1/BCL-1/t(11;14) PCR Kit	Real-time PCR test for the detection of the <i>bcl-1 gene</i> t(11,14) (q13;q32) translocation. Target regions: Major Translocation Cluster (<i>MTC</i>) region	CE	25, 50
CML / AML / ALL Translocation Screening				
BA154	Screening Kit for leukemia associated translocations (7 translocations)	Multiplex Real-time PCR test for the 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 (M-BCR; P190, P210, P230)</i>; t(9;22)(q34;q11) · <i>ETV6-RUNX1</i>; t(12;21)(p13;q22) · <i>PML-RARA (bcr1, bcr2, bcr3)</i>; t(15;17)(q24;q21) · <i>CBFB-MYH11; inv(16)(p13;q22)</i> 	CE	12
BA457	Screening Kit for leukemia associated translocations (9 translocations)	Multiplex Real-time PCR test for the detection and/or quantification of 7 translocations found in AML, ALL and CML including: <ul style="list-style-type: none"> · <i>MLL-AF9</i>; t(9;11)(p22;q23) · <i>PML-RARa</i>; t(15;17)(q24;q21) · <i>AML1-ETO</i>; t(8;21)(q22;q22) · <i>MLL-AF4</i>; t(4;11)(q21;q23) · <i>TEL-AML1</i>; t(12;21)(p13;q22) · <i>E2A-PBX1</i>; t(1;19)(q23;p13) · <i>MLL-ENL</i>; t(11;19)(q23;p13.3) · <i>BCR-ABL1</i>; t(9;22)(q34;q11) · <i>SIL-TAL1</i>; del(1)(p32) 	CE	10, 20
BA458	Screening Kit for leukemia associated translocations (28 translocations)	Multiplex Real-time PCR test for the detection and/or quantification of 28 translocations found in AML, ALL and CML including: <ul style="list-style-type: none"> · <i>CBFB-MYH11; inv(16)(p13;q22)</i> · <i>RUNX1-RUNX1T1</i>; t(8;21)(q22;q22) · <i>PML-RARA (bcr1, bcr2, bcr3)</i>; t(15;17)(q24;q21) · <i>MLL-MLLT3</i>; t(9;11)(p22;q23) · <i>MLL</i>; t(11;19)(q23;p13.3); <i>ELL, MLLT1</i> · <i>FUS-ERG</i>; t(16;21)(p11;q22) · <i>ETV6-MN1</i>; t(12;22)(p13;q11-12) · <i>DEK-NUP214</i>; t(6;9)(p23;q34) · <i>MLL-EPS15</i>; t(1;11)(p32;q23) · <i>MLL-MLLT4</i>; t(6;11)(q27;q23) · <i>TCF3-PBX1</i>; t(1;19)(q23;p13) · <i>ETV6-RUNX1</i>; t(12;21)(p13;q22) · <i>MLL-AFF1</i>; t(4;11)(q21;q23) · <i>TCF3-HL</i>; t(17;19)(q22;p13) · <i>STIL-TAL1</i>; del(1)(p32) · <i>BCR-ABL1 (M-BCR; P190, P210, P230)</i>; t(9;22)(q34;q11) · <i>ET-NUP214</i>; t(9;9)(q34;q34) · <i>ZBTB16-RARA, MLL-MLLT6</i>; t(11;17)(q23;q21) · <i>ETV6-ABL1</i>; t(9;12)(q34;p13) · <i>ETV6-PDGFRB</i>; t(5;12)(q33;p13) · <i>MLL-MLLT10</i>; t(10;11)(p12;q23) · <i>MLL-MLLT11</i>; t(1;11)(q21;q23) · <i>MLL-FOXO4</i>; t(X;11)(q13;q23) · <i>RUNX1-MECOM</i>; t(3;21)(q26;q22) · <i>NPM1-RARA</i>; t(5;17)(q35;q21) · <i>NPM1-MLF1</i>; t(3;5)(q25.1;q35) · Reference genes <i>c-ABL, GUS, B2M</i> 	CE	12

2.1 Oncogene Expression Quantification / Minimal Residual Disease (MRD)

Order number	Product name	Intended use	Legal Status	Tests/Size
CML / AML / ALL Translocation Screening				
BA459	Leukemia Fusion Genes Screening PCR Kit (30 translocations)	Multiplex Reverse Transcription Real-time PCR test for simultaneous detection of 30 fusion genes in leukemia patients including: <ul style="list-style-type: none"> · MLL-AF9; t(9;11)(p22;q23) · PML-RARα; t(15;17)(q24;q21) · AML1-ETO; t(8;21)(q22; q22) · MLL-AF4; t(4;11)(q21;q23) · TEL-AML1; t(12;21)(p13;q22) · E2A-PBX1; t(1;19)(q23;p13) · MLL-ENL; t(11;19)(q23;p13.3) · BCR-ABL1; t(9;22)(q34;q11) · SIL-TAL1; del(1)(p32) · MLL-AF10; t(10;11)(p12;q23) · CBFβ-MYH11; inv(16)(p13;q22) · AML1-MDS1/EV11; t(3;21)(q26; q22) · FIP1L1-PDGFRα; del(4)(q12) · SET-CAN; del(9)(q34) · E2A-HLF; t(17;19)(q22;p13) · DEK-CAN; t(6;9)(p23;q34) · MLL-SEPT6; t(X;11)(q24;q23) · TLS-ERG; t(16;21)(p11;q22) · TEL-PDGFRB; t(5;12)(q33;p13) · MLL-ELL; t(11;19)(q23;p13.1) · MLL-AF17; t(11;17)(q23; q21) · NPM-RARα; t(5;17)(q35;q21) · NPM-MLF1; t(3;5)(q25;q34) · PLZF-RARα; t(11;17)(q23;q21) · MLL-AF1q; t(1;11)(q21;q23) · MLL-AF1P; t(1;11)(p32;q23) · TEL-ABL1; t(9;12) (q34;p13) · AML1-MTG16; t(16;21)(q24;q22) · AML1-EAP; t(3;21)(q26; q22) · MLL-AF6; t(6;11)(q27;q23) 	CE	10, 20
Chimerism Detection in Leukemia				
BA460	STR-VNTR PCR Kit	Kit for detection of chimerism after allogenic bone marrow transplantation by analysis of Short Tandem Repeats (STR) and Variable Number of Tandem Repeats (VNTR). Target regions: HumARA, HumTH01, SE33, vWF2, D1S80, YNZ22, vWF1 and 3'-HVR	CE	25, 50
Nephroblastoma				
BA156	WT1 PCR Kit	Real-time PCR test for identification and quantitation of the <i>Wilm's tumor</i> gene transcripts	CE	48, 96
Breast and Ovarian Cancer				
BA157	BRCA Panel PCR Kit	Real-time PCR Kit for <i>in vitro</i> detection of <i>BRCA 1 + 2</i>	RUO	100
BA158	HER2/NEU PCR Kit	Real-time PCR test for <i>in vitro</i> quantification of <i>HER2/NEU</i> transcripts	RUO	120
Cervical and Head-Neck Cancer				
BA461	HPV E6/E7 mRNA RT-PCR Kit	Real-time RT-PCR Kit for differentiation between persistent and transient high-risk <i>HPV</i> infection for all women over the age of 30, for cervical and oral testing	CE	92
Hepatocellular Cancer				
BA159	AFP PCR Kit	Real-time PCR test for <i>in vitro</i> quantification of α Fetoprotein (<i>AFP</i>) mRNA in peripheral blood and bone marrow	CE	25
Lung Cancer				
BA462	EML4-ALK Fusion Gene Detection Kit PCR Kit	Multiplex Reverse Transcription Real-time PCR test for simultaneous detection of 17 fusion variants for the detection of EML4-ALK associated fusion gene transcripts (EML4-ALK V1, V2, V3a/b/c, V4, V5a/b, V6a/b, V7, V8a/b/c/d, V9, V10) in total RNA from lung cancer tissues	CE	10, 20
BA463	Lung Cancer ALK / ROS1 / RET Panel PCR Kit	Multiplex Reverse Transcription Real-time PCR test for simultaneous detection of 6 lung cancer fusion genes (KIF5B-RET, KIF5B-alk, CD74-ROS1, TGF-alk, SLRC34A2-ROS1, EML4-alk; 35 variants) in total RNA from lung cancer tissues	CE	10, 20
Malignant Melanoma				
BA160	Tyrosinase PCR Kit	Real-time PCR test for <i>in vitro</i> quantification of <i>tyrosinase</i> transcripts in peripheral blood and bone marrow (marker of recurrence and survival)	RUO	120
Soft Tissue Sarcoma and Bladder Cancer				
BA161	Survivin PCR Kit	Real-time PCR test for <i>in vitro</i> 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)	RUO	120

2.1 Oncogene Expression Quantification / Minimal Residual Disease (MRD)

Order number	Product name	Intended use	Legal Status	Tests/Size
Reference Gene Transcripts/ "Housekeeping Genes"				
BA164	18S rRNA PCR Kit	Real-time PCR Kit for <i>in vitro</i> quantification of 18S rRNA transcripts	RUO	120
BA162	c-ABL PCR Kit	Real-time PCR Kit for <i>in vitro</i> quantification of c-ABL transcripts	RUO	120
BA163	GAPDH PCR Kit	Real-time PCR Kit for <i>in vitro</i> quantification of GAPDH transcripts	RUO	120
BA464	p53 PCR Kit	Real-time PCR test for <i>in vitro</i> quantification of p53 cDNA	RUO	120

2.2 Somatic Mutations with Therapeutic Implications in Various Cancers

Order number	Product name	Intended use	Legal Status	Tests/Size
BA165	ABL Mutation Detection PCR Kit	Real-time PCR test for <i>in vitro</i> detection of the T315I (944C>T) somatic mutation in the ABL oncogene in CML patients with secondary resistance to Imatinib (Gleevec)	RUO	24, 50
BA166	BRAF Mutation PCR Kit I	Real time PCR test for the identification of the V600E mutation in the BRAF gene by sequence specific primer (SSP) PCR	CE	12, 24, 36, 48, 60, 96
BA465	BRAF Mutation PCR Kit II	Real time PCR test for the identification of the BRAF Codon Specific Mutations in Codon 600	CE	10, 30, 60
BA171	CALR Mutation PCR Kit	PCR test for detection of type 1 and type 2 mutations in exon 9 of the calreticulin (CALR) gene (agarose gel detection!!)	CE	50
BA167	CC-MSI PCR Kit	Test for the analysis of microsatellite instability in colon-rectal cancer by multiplex amplification with fluorescent primers and subsequent fragment analysis by automatic DNA sequencing	CE	24, 48
BA466	c-KIT Mutation PCR Kit	Real-time qualitative PCR assay for the detection of somatic mutations in Codon 861 of Exon 17 in the c-KIT proto-oncogene in genomic DNA from human cells or tissues	RUO	10, 30, 60
BA168	EGFR Mutation PCR Kit I	Real time PCR test for the identification of the EGFR gene L858R & del 746-750 mutations	CE	12, 24, 36
BA467	EGFR Mutation PCR Kit II	Real time PCR test for the identification of the EGFR Codon Specific Mutation in Codons 719, Ex19Del, 790, 858 & 861	CE	10, 30, 60
BA468	HRAS Mutation PCR Kit	Real-time qualitative PCR test for the detection of mutations in codon 61 of the human HRAS gene	RUO	10, 30, 60
BA172	JAK-2 Mutation PCR Kit	Real time PCR test for the identification and/or absolute quantification of codon 617 specific mutations in the Janus Kinase 2 (JAK-2) gene	CE	10, 30, 48, 60, 96
BA169	KRAS Mutation PCR Kit I	Real time PCR test for the identification of the seven most frequent mutations in the KRAS gene (G12D, G12V, G12A, G12C, G12S, G12R, G13D) by sequence specific primer (SSP) PCR	CE	12, 24, 36, 48, 60, 96
BA469	KRAS Mutation PCR Kit II	Real time PCR test for the identification of the KRAS Codon Specific Mutations in Codons 12, 13, 59, 61, 117 & 146	CE	10, 30, 60
BA170	NRAS Mutation PCR Kit	Real time PCR test for the identification of the NRAS gene 35G>T (G12V) mutation in codon 12	CE	12, 24, 60
BA470	PIK3CA Mutation PCR Kit	Real-time qualitative PCR test for the detection of somatic mutations in and near PIK3CA Codons 542 and 545 in Exon 9 and Codon 1047 in Exon 20 in the human PIK3CA gene	CE	10, 30, 60

3. HUMAN GENETIC DISEASES AND GENETIC PREDISPOSITIONS

3.1 Thrombophilia

Order number	Product name	Intended use	Legal Status	Tests/Size
BA182	ACE (I/D) PCR Kit	Real Time PCR test for the identification and genotyping of the insertion/deletion (I/D) polymorphism located on intron 16 of the human gene coding for angiotensin converter enzyme (ACE)	CE	48, 50, 96
BA174	Cardio Thrombophilia Panel PCR Kit	Real Time PCR test for 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	RUO	48
BA602	Factor II PCR Kit	Real-time PCR test for the identification and genotyping of the G20210A mutation in the human gene coding for Coagulation Factor II	CE	48, 50, 60, 96
BA176	Factor V Leiden PCR Kit	Real-time PCR test for identification and genotyping of either the G1691A (Leiden) or Y1702C mutation in the human gene coding for Coagulation Factor V	CE	12, 48, 50, 60, 96, 100