



product catalogue
2026

in vitro diagnostics

generi biotech

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generi biotech

Manufacture of products and provision of services at GENERI BIOTECH is certified according to:

regulation (EU) 2017/746 of the European Parliament and of the Council - *in vitro* diagnostics

EN ISO 13485:2016 - *in vitro* diagnostics

EN ISO 9001:2016 - oligonucleotides and life sciences products, life sciences services

current versions of implemented standards can be found on <https://www.generi-biotech.com/about-us/standards/>

www.generi-biotech.com

in vitro diagnostics

HEMO 7
IVD kits for thrombophilic mutations



GENETIC 9
IVD kits for human genetics



PHARM 11
IVD kits for pharmacogenetics

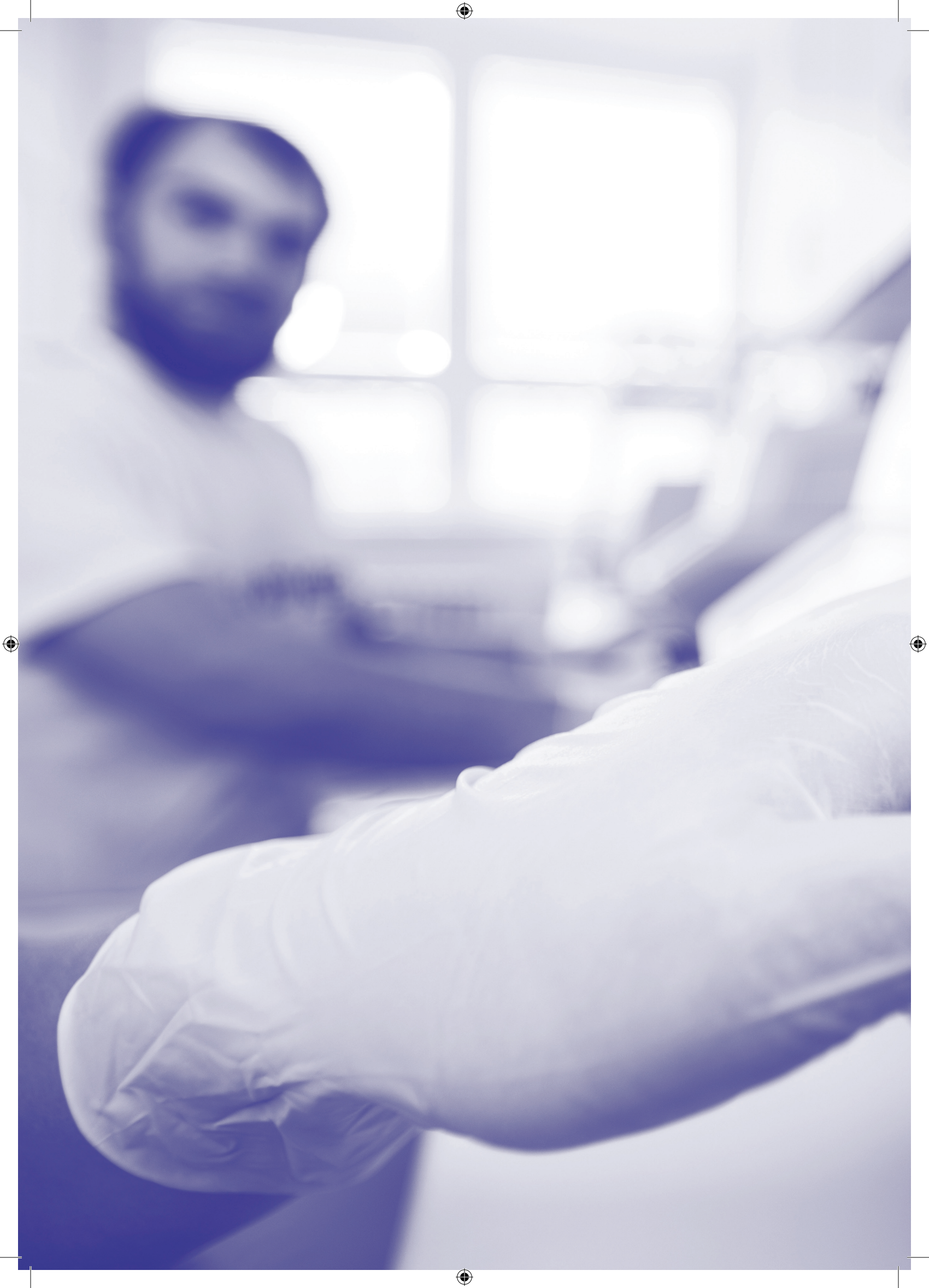


ONCO 13
IVD kits for oncology



MICRO 17
IVD kits for microbiology







in vitro diagnostics

hematology | genetics | pharmacogenetics
oncology | microbiology

generi biotech

Kits for *in vitro* diagnostics



You can find the current list of cyclers on which our IVD kits are validated on our web. The list of cyclers is being regularly extended.

www.generi-biotech.com/ivd

gb HEMO – IVD kits for thrombophilic mutations



Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code
gb HEMO FII (G20210A) <ul style="list-style-type: none"> • <i>prothrombin</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	G20210A	25 rxn	3201-025	
					100 rxn	3201	
<ul style="list-style-type: none"> • <i>increased risk of developing blood clots</i> • positive controls for each genotype and a negative control • fluorescence channels FAM and HEX 							
	gb HEMO FV (G1691A) <ul style="list-style-type: none"> • <i>Leiden mutation</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	G1691A	25 rxn	3200-025
100 rxn						3200	
<ul style="list-style-type: none"> • <i>increased risk of developing blood clots</i> • positive controls for each genotype and a negative control • fluorescence channels FAM and HEX 							
	gb HEMO FXIII (V34L) <ul style="list-style-type: none"> • <i>recurrent pregnancy losses</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	V34L	25 rxn	3209-025
100 rxn						3209	
<ul style="list-style-type: none"> • <i>reduced risk of venous thrombosis and myocardial infarction</i> • positive controls for each genotype and a negative control • fluorescence channels FAM and HEX 							
	gb HEMO MTHFR (C677T) <ul style="list-style-type: none"> • <i>increased risk of developing blood clots</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	C677T	25 rxn	3202-025
100 rxn						3202	
<ul style="list-style-type: none"> • <i>increased risk of developing blood clots</i> • positive controls for each genotype and a negative control • fluorescence channels FAM and HEX 							
	gb HEMO MTHFR (A1298C) <ul style="list-style-type: none"> • <i>increased risk of developing blood clots</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	A1298C	25 rxn	3203-025
100 rxn						3203	

* Where marked ✓ - identical temperature profile of HEMO, GENETIC and PHARM products (except ☆)

Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert

Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code
gb HEMO PAI (4G/5G)	✓	✓	✓	4G/5G	25 rxn	3204-025	
					100 rxn	3204	
<ul style="list-style-type: none"> recurrent pregnancy losses increased risk of developing blood clots <ul style="list-style-type: none"> real-time PCR allelic discrimination ready-to-use positive controls for each genotype and a negative control fluorescence channels FAM and HEX 							
gb HEMO GPIa (C807T)	✓	✓	✓	C807T	25 rxn	3211-025	
					100 rxn	3211	
<ul style="list-style-type: none"> risk factor of myocardial infarction and stroke in younger persons <ul style="list-style-type: none"> real-time PCR allelic discrimination ready-to-use positive controls for each genotype and a negative control fluorescence channels FAM and HEX 							
gb HEMO GPIIa (L33P)	✓	✓	✓	L33P	25 rxn	3212-025	
					100 rxn	3212	
<ul style="list-style-type: none"> mild risk factor for coronary disease and myocardial infarction in younger persons risk of preeclampsia for pregnant women <ul style="list-style-type: none"> real-time PCR allelic discrimination ready-to-use positive controls for each genotype and a negative control fluorescence channels FAM and HEX 							

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Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert






gb GENETIC – IVD kits for human genetics



Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code
gb GENETIC APOB (R3500Q) <ul style="list-style-type: none"> • <i>familial hypercholesterolemia</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	R3500Q	25 rxn	3205-025	
<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							
gb GENETIC APOE <ul style="list-style-type: none"> • <i>risk factor for atherosclerosis</i> • <i>Alzheimer's disease</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓		C112R, R158C	25 rxn 50 rxn	3206-025 3206-050	
<ul style="list-style-type: none"> • <i>hyperlipoproteinemia type III (increased plasma triglycerides)</i> • <i>increased risk of myocardial infarction</i> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							
gb GENETIC HFE <ul style="list-style-type: none"> • <i>hereditary hemochromatosis (HHC)</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	C282Y, H63D, S65C	25 rxn 50 rxn	3208-025 3208-050	
<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							
gb GENETIC LACTO <ul style="list-style-type: none"> • <i>lactose intolerance</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	C13910T, G22018A	25 rxn 50 rxn	3219-025 3219-050	
<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							
gb GENETIC FRUCTO <ul style="list-style-type: none"> • <i>hereditary fructose intolerance (HFI)</i> • real-time PCR • allelic discrimination • ready-to-use 	✓	✓	✓	A149P, A174D, N334K, del4E4	25 rxn 50 rxn	3252-025 3252-050	
<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							

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Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert

Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code
gb GENETIC A1AT	✓	✓	✓	PI*S, PI*Z	25 rxn	3251-025	
					50 rxn	3251-050	
<ul style="list-style-type: none"> • <i>alpha-1-antitrypsin deficiency</i> • <i>chronic obstructive pulmonary disease (COPD)</i> • real-time PCR • allelic discrimination • ready-to-use • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 							
gb GENETIC Gilbert	✓		☆	7TA	25 rxn	3216-025	
					50 rxn	3216-050	
<ul style="list-style-type: none"> • <i>Gilbert's syndrome</i> • <i>hyperbilirubinemia</i> • ready-to-use • melting curve analysis • positive control for each of the genotypes and a negative control • fluorescence channel FAM 							
gb GENETIC HLA-B*27	✓	✓	✓	HLA-B*27	25 rxn	3257-025	
					100 rxn	3257-100	
<ul style="list-style-type: none"> • <i>Bechterew's disease</i> • <i>ankylosing spondylitis</i> • ready-to-use • real-time PCR • positive and a negative control included • fluorescence channels FAM and HEX 							
gb GENETIC Human DNA				POLR2A	100 rxn	3142	
<ul style="list-style-type: none"> • <i>detection and quantification of human genomic DNA</i> • ready-to-use • quantitative real-time PCR • fluorescence channel FAM • positive and a negative control included • internal control included in the assay (fluorescence channel HEX) 							
gb GENETIC SRY				SRY	100 rxn	3143	
<ul style="list-style-type: none"> • <i>detection and quantification of human male genomic DNA</i> • ready-to-use • quantitative real-time PCR • fluorescence channel FAM • positive and a negative control included • internal control included in the assay (fluorescence channel HEX) 							

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Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert

gb PHARM– IVD kits for pharmacogenetics







CE 0123
IVD

Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code	
gb PHARM TPMT	✓	✓	✓	TPMT*2	25 rxn	3217-025		
				TPMT*3A TPMT*3B TPMT*3C	50 rxn	3217-050		
<ul style="list-style-type: none"> • thioguanine and mercaptopurine (antitumor drugs - hematooncology) • before initiating treatment with azathioprine (immunosuppressant) 								
<ul style="list-style-type: none"> • real-time PCR • allelic discrimination • ready-to-use 		<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX • merged standards 						
COMING SOON								
gb PHARM NUDT15 (R139C)	✓	✓	✓	R139C	25 rxn	3258-025		
				(c.415C>T)	50 rxn	3258-050		
<ul style="list-style-type: none"> • clinical suspicion or history of adverse events caused by reduced metabolism of thiopurine drugs 								
<ul style="list-style-type: none"> • real-time PCR • allelic discrimination • ready-to-use 		<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 						
gb PHARM DPYD	✓	✓	✓	*2A (c.1905+1G>A),	25 rxn	3255-025		
				*13 (c.1679T>G), HapB3 (c.1236G>A), c.2846A>T	50 rxn	3255-050		
<ul style="list-style-type: none"> • before initiating treatment with fluoropyrimidine chemotherapeutics (5-fluorouracil) 								
<ul style="list-style-type: none"> • real-time PCR • allelic discrimination • ready-to-use 		<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX • merged standards 						
COMING SOON								
gb PHARM DPYD Plus	✓	✓	✓	c.1129-5923C>G, c.868A>G, c.557A>G, c.2279C>T	25 rxn	3259-025		
					50 rxn	3259-050		
<ul style="list-style-type: none"> • clinical suspicion or history of severe fluoropyrimidine-related toxicities 								
<ul style="list-style-type: none"> • real-time PCR • allelic discrimination • ready-to-use 		<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX • merged standards 						
gb PHARM Warfarin	✓	✓	✓	CYP2C9*2	25 rxn	3250-025		
				CYP2C9*3 G1639A VKORC1	50 rxn	3250-050		
<ul style="list-style-type: none"> • before initiating treatment with coumarin-type anticoagulants 								
<ul style="list-style-type: none"> • real-time PCR • allelic discrimination • ready-to-use 		<ul style="list-style-type: none"> • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX 						

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Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert

Product	CE IVD	IVDR certified	Identical temp. profile *	Detection	Package size	Cat. No.	QR code
gb PHARM CYP2C19	✓	✓	✓	CYP2C19*2	25 rxn	3254-025	
				CYP2C19*3 CYP2C19*17	50 rxn	3254-050	
<ul style="list-style-type: none"> • before initiating treatment with anticoagulants (clopidogrel) • treatment with antidepressants and antimycotics • real-time PCR • allelic discrimination • ready-to-use • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX • merged standards 							
gb PHARM UGT1A1	✓	✓	☆	5TA/6TA/ 7TA/8TA	25 rxn	3253-025	
					50 rxn	3253-050	
<ul style="list-style-type: none"> • before initiating treatment with irinotecan and atazanavir • Gilbert's syndrome • hyperbilirubinemia • melting curve analysis • fluorescence channel FAM • positive and a negative control 							
COMING SOON							
gb PHARM UGT1A1*6	✓	✓	☆	UGT1A1*6 (c.211G>A)	25 rxn	3260-025	
					50 rxn	3260-050	
<ul style="list-style-type: none"> • clinical suspicion or history of severe UGT1A1-metabolizing drug toxicities, Gilbert's syndrome • melting curve analysis • fluorescence channel FAM • positive control for each of the genotypes and a negative control 							
gb PHARM BCHE	✓		✓	A (D70G) K (A539T) F1 (T243M) F2 (G390V) S1 (FS117)	25 rxn	3256-025	
<ul style="list-style-type: none"> • before initiating treatment with myorelaxants (e.g. suxamethonium, mivacurium) • Butyrylcholinesterase - pseudocholinesterase deficiency • real-time PCR • allelic discrimination • ready-to-use • positive controls for each of the genotypes and a negative control • fluorescence channels FAM and HEX • merged standards 							





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Where marked ☆ - identical temperature profile of gb PHARM UGT1A1, gb PHARM UGT1A1*6 and gb GENETIC Gilbert

gb ONCO – IVD kits for oncology



Product	CE IVD	IVDR certified	Detection	Package size	Cat. No	QR code
gb ONCO CLL <ul style="list-style-type: none"> • <i>assessment of prognosis in patients with chronic lymphocytic leukemia (CLL)</i> • 6 ready-to-use assays • two-step RT-qPCR • fluorescence channel FAM • determination of expression of genes B2M, HPRT1, LPL, ZAP70, COBLL1, CD3D • reagents for reverse transcription procedure included • negative and positive controls included 	✓		B2M HPRT1 LPL ZAP70 COBLL1 CD3D	10 tests	3240-010	
gb ONCO BCR-ABL MAJOR/ABL <ul style="list-style-type: none"> • <i>monitoring of chronic myeloid leukemia (CML)</i> • quantification of BCR-ABL1 and ABL1 in 1 tube • one-step real-time PCR • set of standards and negative control included • <i>monitoring of acute lymphocytic leukemia (ALL)</i> • fluorescence channel FAM, ABL1 in channel HEX • calculator table 	✓		b2a2 b3a2 ABL1	48 rxn 96 rxn	3243-048 3243-096	
gb ONCO BCR-ABL MAJOR/GUSB <ul style="list-style-type: none"> • <i>monitoring of chronic myeloid leukemia (CML)</i> • quantification of BCR-ABL1 and GUSB in 1 tube • one-step real-time PCR • set of standards and negative control included • <i>monitoring of acute lymphocytic leukemia (ALL)</i> • fluorescence channel FAM, GUSB in channel HEX • calculator table 	✓		b2a2 b3a2 GUSB	48 rxn 96 rxn	3249-048 3249-096	
STANDARD MMR BCR-ABL MAJOR <ul style="list-style-type: none"> • RNA standard • the defined ratio of BCR-ABL1 in MAJOR (b3a2) on the background of the ABL1/GUSB reference gene at the major molecular response level (MMR) • to convert the BCR-ABL1 MAJOR results to IS, it is necessary to include the STANDARD MMR into own analysis and adjust the obtained results by calculation 	✓		determined for cat. no. 3243 and 3249 (add 5 µl/rxn)	4 x 20 µl	3280-004	
gb ONCO BCR-ABL MINOR/ABL <ul style="list-style-type: none"> • <i>monitoring of chronic myeloid leukemia (CML)</i> • quantification of BCR-ABL1 and ABL1 in 1 tube • one-step real-time PCR • set of standards and negative control included • <i>monitoring of acute lymphocytic leukemia (ALL)</i> • fluorescence channel FAM, ABL1 in channel HEX • calculator table 	✓		e1a2 ABL1	48 rxn	3247-048	

Product	CE IVD	IVDR certified	Detection	Package size	Cat. No	QR code
gb ONCO BCR-ABL MICRO/ABL <ul style="list-style-type: none"> • <i>monitoring of chronic neutrophile leukemia (CML-N)</i> • quantification of BCR-ABL1 and ABL1 in 1 tube • one-step real-time PCR • set of standards and negative control included 	✓		e19a2 ABL1	48 rxn	3248-048	
<ul style="list-style-type: none"> • fluorescence channel FAM, ABL1 in channel HEX • calculator table 						
gb ONCO BCR-ABL DETECT <ul style="list-style-type: none"> • <i>confirmation of CML and ALL diagnosis</i> • one-step real-time PCR • fluorescence channels FAM, HEX, ROX, Cy5 • GUSB as a positive control 	✓		e14a2, e13a2, e14a3 + e13a3, e1a2 + e1a3, e19a2 + e19a3, e6a2	48 rxn	3246-048	
<ul style="list-style-type: none"> • multiplex detection of most common variants of fusion gene BCR-ABL1 • calculator table with the possibility of indicative quantification 						
COMING SOON gb ONCO JAK2 (V617F) <ul style="list-style-type: none"> • <i>myeloproliferative neoplasms, including polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF)</i> • semi-quantitative real-time PCR • positive and negative control 	✓	✓	V617F	24 rxn 48 rxn	3286-024 3286-048	
<ul style="list-style-type: none"> • fluorescence channel FAM • identical temperature profile of gb HEMO, gb GENETIC and gb PHARM products 						
gb ONCO BRAF (V600E) <ul style="list-style-type: none"> • <i>colorectal cancer</i> • <i>malignant melanoma, non-Hodgkin's lymphoma, thyroid papillary cancer, non-small cell lung cancer and adenocancer of the lung</i> • semi-quantitative real-time PCR • positive and negative control 	✓		V600E/E2/D/D2	24 rxn 48 rxn	3241-024 3241-048	
<ul style="list-style-type: none"> • fluorescence channel FAM • identical temperature profile of gb HEMO, gb GENETIC and gb PHARM products 						
gb ONCO BRAF (V600) <ul style="list-style-type: none"> • <i>colorectal cancer</i> • <i>malignant melanoma, non-Hodgkin's lymphoma, thyroid papillary cancer, non-small cell lung cancer, and adenocancer of the lung</i> • semi-quantitative real-time PCR • positive and negative control 	✓		V600E/ E2/D/D2/K/R/M	24 rxn 48 rxn	3281-024 3281-048	
<ul style="list-style-type: none"> • fluorescence channel FAM • identical temperature profile of gb HEMO, gb GENETIC and gb PHARM products 						

Product	CE IVD	IVDR certified	Detection	Package size	Cat. No	QR code
gb ONCO EGFR (T790M)	✓		T790M	24 rxn	3245-024	
				48 rxn	3245-048	
<ul style="list-style-type: none"> • <i>before treatment with osimertinib</i> • semi-quantitative real-time PCR • positive and negative control • <i>lungtumors (non-small cell lung cancer)</i> • fluorescence channel FAM • identical temperature profile of gb HEMO, gb GENETIC and gb PHARM products 						
gb ONCO EGFR	✓		G719X, T790M, L861Q/R, L858R, E20ins, E19del, S768I, plus *	24 rxn	32482-024	
<ul style="list-style-type: none"> • <i>in case of treatment with tyrosine kinase inhibitors (TKIs)</i> • quantitative real-time PCR • 3 specific assays for the detection of 7 mutation groups and 40 individual mutations • positive and negative control • <i>lung tumors (non-small cell lung cancer)</i> • fluorescence channels FAM, HEX, ROX and Cy5 • identical temperature profile of gb HEMO, gb GENETIC and gb PHARM products 						


* list of all detected mutations

No.	Mutation	Sequence change	Cosmic ID	Exon	
1	p.G719A	c.2156G>C	6239	18	
2	p.G719C	c.2155G>T	6253		
3	p.G719D	c.2156G>A	18425		
4	p.G719S	c.2155G>A	6252		
5	p.E746_A750del	c.2235_2249del	6223	19	
6	p.E746_A750del	c.2236_2250del	6225		
7	p.E746_A750delinsQP	c.2236_2248delinsCAAC	13557		
8	p.E746_T751del	c.2236_2253del	12728		
9	p.E746_T751delinsA	c.2237_2251del	12678		
10	p.E746_T751delinsI	c.2235_2252delinsAAT	13551		
11	p.E746_T751delinsQ	c.2236_2253delinsCAA	22999		
12	p.E746_T751delinsT	c.2236_2253delinsACG	-		
13	p.E746_T751delinsV	c.2237_2252delinsT	12386		
14	p.E746_S752delinsA	c.2237_2254del	12367		
15	p.E746_S752delinsD	c.2238_2255del	6220		
16	p.E746_S752delinsEQ	c.2238_2256delinsGCAA	-		
17	p.E746_S752delinsV	c.2237_2255delinsT	12384		
18	p.E746_K754delinsEQHL	c.2238_2261delinsGCAACATCT	-		
19	p.L747_P753delinsS	c.2240_2257del	12370		
20	p.L747_A750delinsP	c.2238_2248delinsGC	12422		
21	p.L747_A750delinsP	c.2239_2248delinsC	12382		
22	p.L747_A750delinsP	c.2239_2250delinsCCC			
23	p.L747_T751del	c.2238_2252del	23571		
24	p.L747_T751del	c.2239_2253del	6254		
25	p.L747_T751del	c.2240_2254del	12369		
26	p.L747_T751delinsP	c.2239_2251delinsC	12383		
27	p.L747_T751delinsQ	c.2238_2252delinsGCA	12419		
28	p.L747_T751delinsS	c.2240_2251del	6210		
29	p.L747_S752del	c.2239_2256del	6255		
30	p.L747_S752delinsQ	c.2239_2256delinsCAA	12403		
31	p.L747_P753delinsQ	c.2239_2258delinsCA	12387		
32	p.L747_K754delinsQL	c.2239_2261delinsCAATT	-		
33	p.D770_N771insG	c.2310_2311insGGT	12378		20
34	p.D770_N771insSVD	c.2311_2312insGCGTGGACA	13428		
35	p.H773_V774insNPH	c.2319_2320insAACCCAC	12381		
36	p.S768I	c.2303G>T	6241		
37	p.T790M	c.2369C>T	6240		
38	p.L858R	c.2573T>G	6224	21	
39	p.L861Q	c.2582T>A	6213		
40	p.L861R	c.2582T>G	12374		

gb MICRO – IVD kit for microbiology



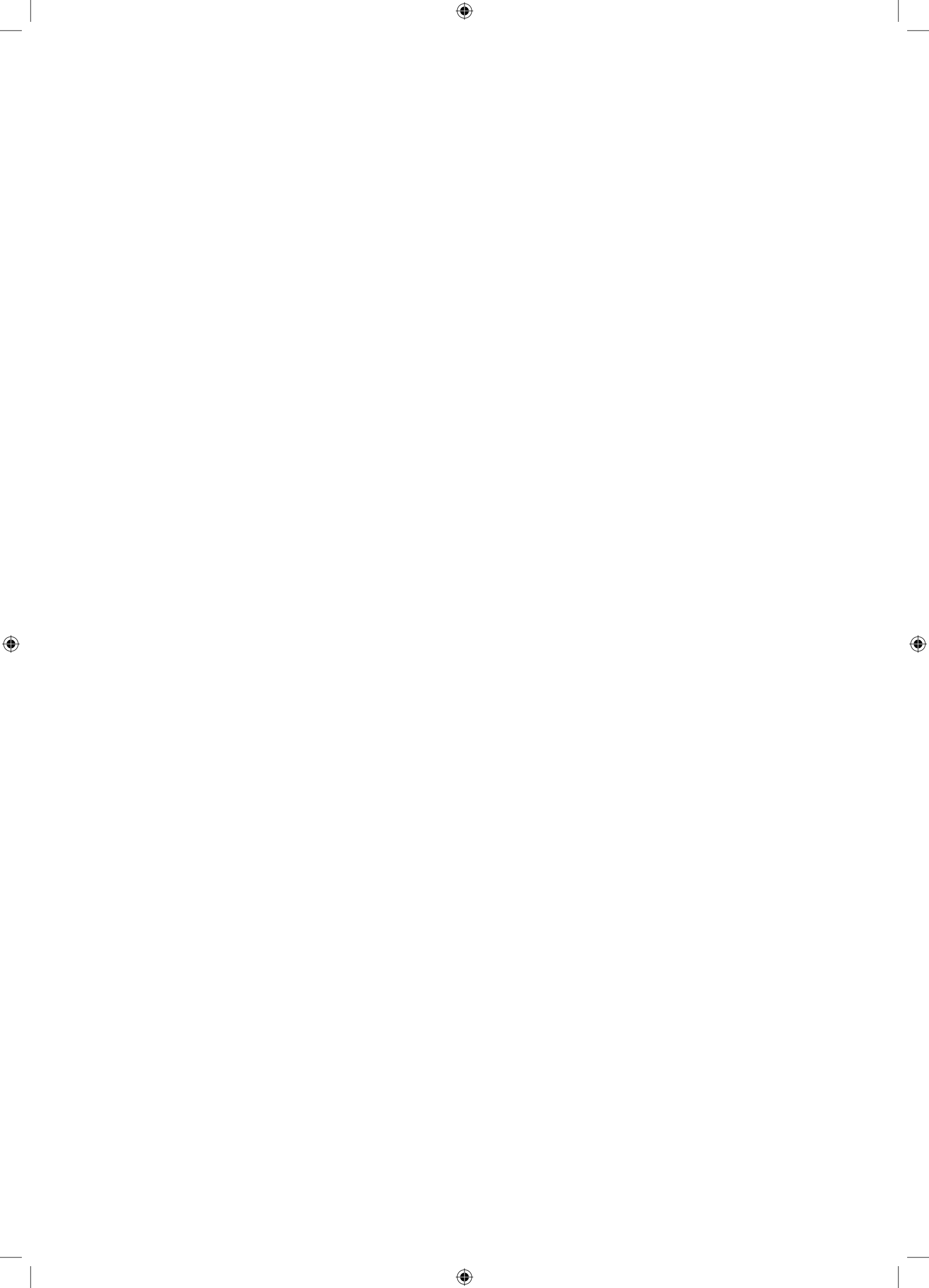
Kit for Aspergillus spp. detection

Product	CE IVD	IVDR certified	Detection limit [copies/μl]	Package size	Cat. No	QR code
gb MICRO Aspergillus (<i>A. fumigatus</i> , <i>A. flavus</i> , <i>A. niger</i> , <i>A. terreus</i>)	✓		0.19 - 9.10	25 tests	3222-025	

• *invasive aspergillosis in immunocompromised patients (transplantation, hematooncology)*

- ready-to-use
- quantitative real-time PCR
- fluorescence channel FAM
- internal positive control included
- standards and negative control included
- suitable input material: DNA from BAL, lung tissue, blood serum, sputum, cerebrospinal fluid

Note



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