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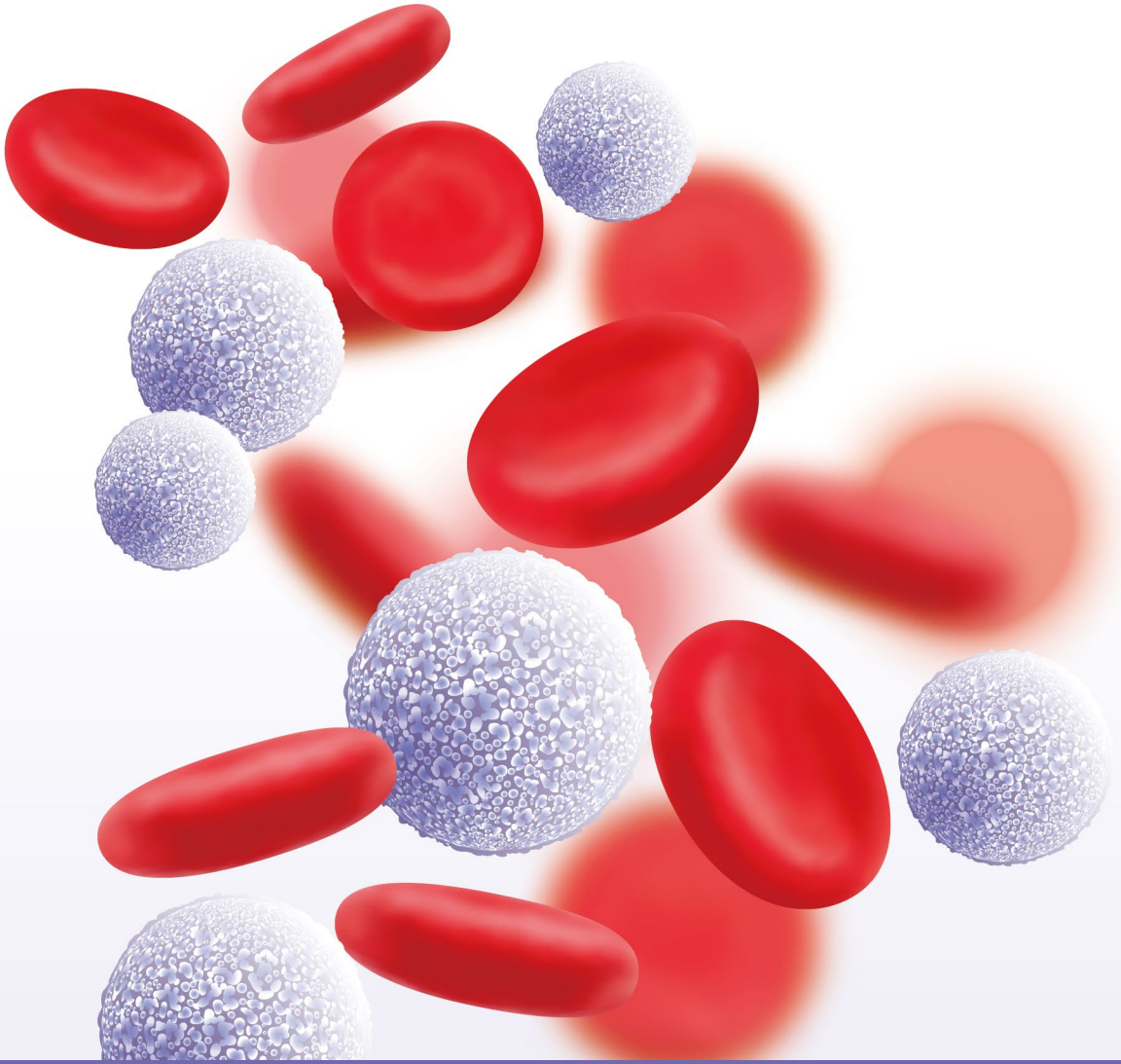
致善生物



Leukemia Fusion Genes Screening & Quantification

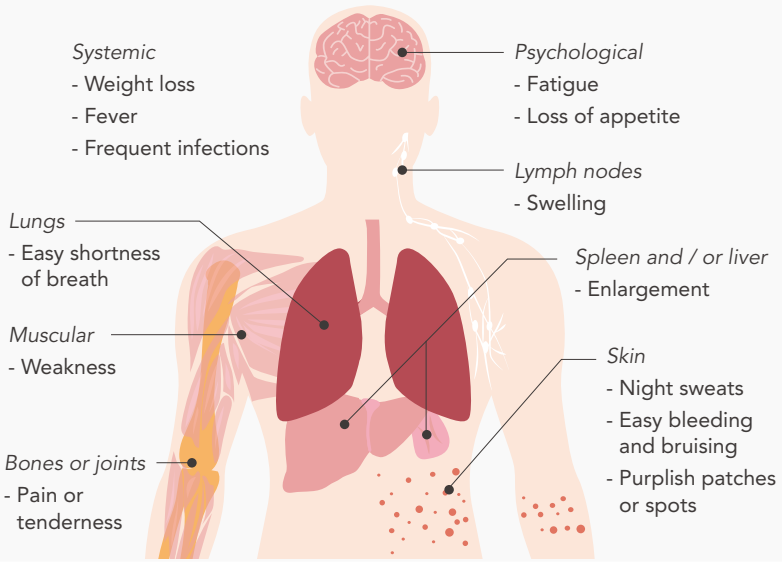
Extensive real-time PCR assays for the detection of leukemia fusion genes to facilitate accurate diagnosis and therapeutic management

CE IVD

Leukemia, also known as blood cancer, usually begins in the bone marrow and results in high numbers of abnormal blood cells.

The exact cause of leukemia is unclear. A combination of genetic factors and environmental factors are believed to play a role.

Common Symptoms of Leukemia



Leukemia patients are often accompanied by chromosomal abnormalities. Abnormal genes formed by chromosomal recombination are called fusion genes, which code for fusion proteins with altered functionality.

A better understanding of leukemia fusion genes may benefit patient with leukemia by providing accurate diagnosis and classification, as well as the assessment of prognosis and treatment planning.

Real-time PCR based genetic testing is one of the most effective methods.[1]

Screening

Targeted Therapy

BCR-ABL1: The BCR-ABL1-positive patient may benefit from tyrosine kinase inhibitor (TKI) therapy.[2]

PML-RAR α : All-trans retinoic acid (ATRA) and arsenic trioxide are treatment options for the patient with PML-RAR α positive.[3,4]

Prognosis

CBF β -MYH11, PML-RARα, AML1-ETO may indicate a relatively favorable prognosis.[5]

Quantification

Treatment Monitoring

See how patients respond to treatment by measuring the level of specific genes periodically.

Minimal Residual Disease (MRD) Testing

Measuring MRD is an important way to understand whether the patient is getting the most effective treatment to ensure a lasting remission from leukemia.[6]

1. Understanding Lab and Imaging Tests. Leukemia & Lymphoma Society. 2020
2. Tyrosine kinase inhibitor (TKI) therapy. Leukemia & Lymphoma Society. Available from: https://www.lls.org/
3. Raffoux E, et al. Journal of clinical oncology, 2003, 21(12): 2326-2334.
4. Estey E, et al. Blood, 2006, 107(9): 3469-3473.
5. Schnittger S, et al. Blood, 2003, 102(8): 2746-2755.
6. Minimal Residual Disease (MRD) | Leukemia & Lymphoma Society. 2019

Key Features

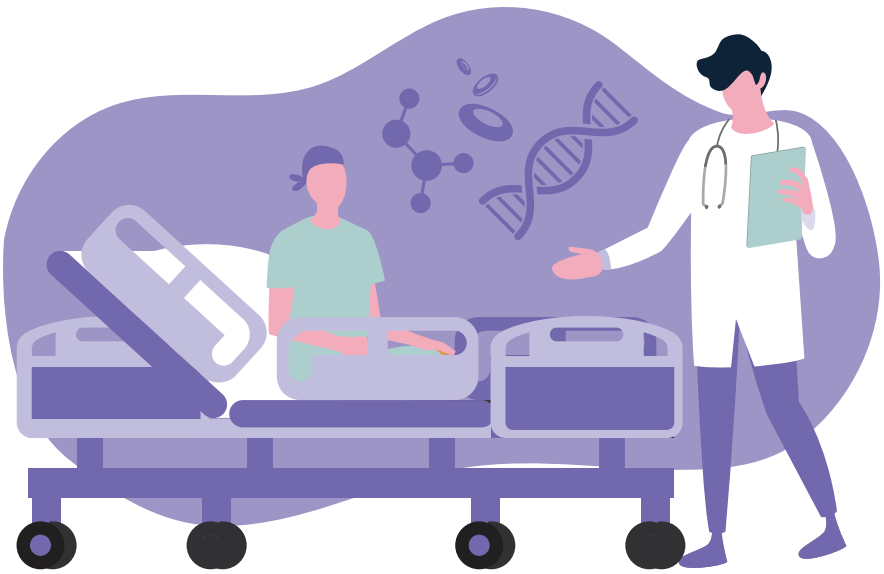
- Sample Type: Blood or bone marrow
- Compatible with common real-time PCR thermal cyclers
- Screening of up to 55 fusion genes in one kit
- Short TAT: within 3 hours

Leukemia Fusion Genes Screening Kits

No.	Fusion Gene		Product		
	HGNC Nomenclature	Former Nomenclature	Q30	Q51	Q55
1	BCR::ABL1	BCR-ABL1	◆		●
2	BCR::ABL1 p190	BCR-ABL1 p190		★	●
3	BCR::ABL1 p210	BCR-ABL1 p210		★	●
4	BCR::ABL1 p230	BCR-ABL1 p230			●
5	CBFβ::MYH11	CBFβ-MYH11	◆	★	●
6	DEK::NUP214	DEK-CAN	◆	★	●
7	dup MLL	dup MLL		★	●
8	ETV6::ABL1	TEL-ABL1	◆	★	●
9	ETV6::JAK2	TEL-JAK2		★	●
10	ETV6::PDGFRA	ETV6-PDGFRA		★	●
11	ETV6::PDGFRB	TEL-PDGFRB	◆	★	●
12	ETV6::RUNX1	TEL-AML1	◆	★	●
13	FIP1L1::PDGFRA	FIP1L1-PDGFRA	◆	★	●
14	FIPIL1::RARα	FIPIL1-RARα		★	●
15	FUS::ERG	TLS-ERG	◆	★	●
16	KMT2A::AF1p	MLL-AF1p	◆	★	●
17	KMT2A::AFDN	MLL-AF6	◆	★	●
18	KMT2A::AFF1	MLL-AF4	◆	★	●
19	KMT2A::ELL	MLL-ELL	◆	★	●
20	KMT2A::FOXO4	MLL-AFX1		★	●
21	KMT2A::MLLT1	MLL-ENL	◆	★	●
22	KMT2A::MLLT10	MLL-AF10	◆	★	●
23	KMT2A::MLLT11	MLL-AF1q	◆	★	●
24	KMT2A::MLLT3	MLL-AF9	◆	★	●
25	KMT2A::MLLT6	MLL-AF17	◆	★	●
26	KMT2A::SEPT6	MLL-SEPT6	◆	★	●
27	MECOM	EVI1		★	●
28	NPM1::ALK1	NPM1-ALK1		★	●

No.	Fusion Gene		Product		
	HGNC Nomenclature	Former Nomenclature	Q30	Q51	Q55
29	NPM1::MLF1	NPM1-MLF1	◆	★	●
30	NPM1::RARα	NPM1-RARα	◆	★	●
31	NUMA::RARα	NUMA-RARα		★	●
32	NUP98::HOTAIR	NUP98-HOXC11		★	●
33	NUP98::HOTTIP	NUP98-HOXA13		★	●
34	NUP98::HOXA11	NUP98-HOXA11		★	●
35	NUP98::HOXA9	NUP98-HOXA9		★	●
36	NUP98::HOXD13	NUP98-HOXD13		★	●
37	NUP98::PMX1	NUP98-PMX1		★	●
38	PICALM::MLLT10	CALM-AF10		★	●
39	PML::RARα	PML-RARα	◆		●
40	PML::RARα L	PML-RARα L		★	●
41	PML::RARα S	PML-RARα S		★	●
42	PML::RARα V	PML-RARα V		★	●
43	PRKAR1A::RARα	PRKAR1A-RARα		★	●
44	RUNX1::CBFA2T3	AML1-MTG16	◆	★	●
45	RUNX1::MECOM	AML1-MDS1/EVI1	◆	★	●
46	RUNX1::RPL22	AML1-EAP	◆	★	●
47	RUNX1::RUNX1T1	AML1-ETO	◆	★	●
48	SET::NUP214	SET-CAN	◆	★	●
49	STAT5::RARα	STAT5-RARα		★	●
50	STIL::TAL1	SIL-TAL1	◆	★	●
51	TCF3::PBX1	E2A-PBX1	◆	★	●
52	TFPT::HLF	E2A-HLF	◆	★	●
53	TLX1	HOX11		★	●
54	TLX3	HOX11L2		★	●
55	ZBTB16::RARα	PLZF-RARα	◆	★	●

◆ Targets included in Q30 kit ★ Targets included in Q51 kit ● Targets included in Q55 kit



Applicable for the real-time PCR thermal cycler with FAM, HEX, ROX and Cy5 detection channels.

Validated real-time PCR models: CFX96, ABI7500, Light Cycler 96, Mx3005P / 3000P, SLAN 96s

Quantification of Specific Leukemia Fusion Genes

BCR-ABL1 Genetic Testing

The presence of the gene sequence known as BCR-ABL1 confirms the diagnosis of CML and a form of acute lymphoblastic lymphoma (ALL), called Philadelphia chromosome (Ph)-positive ALL.

Once CML or Ph-positive ALL has been diagnosed, BCR-ABL1 quantitative genetic testing is ordered periodically (typically every 3 months) to monitor the response to treatment and monitor for recurrence.

- BCR-ABL1 Genotyping Kit: Differentiation of BCR-ABL1 p210, BCR-ABL1 p190, BCR-ABL1 p230 splice variants
- BCR-ABL1 p190 Kit: Quantification of BCR-ABL1 p190 transcripts
- BCR-ABL1 p210 Kit: Quantification of BCR-ABL1 p210 transcripts, with integrated results that comply with WHO standards and are convertible for reporting on the International Scale (IS)

PML-RAR α Genetic Testing

Up to 98% of cases of acute promyelocytic leukemia (APL), a subtype of AML, have a characteristic t(15;17) PML-RAR α reciprocal chromosomal translocation.

Definitive diagnosis of APL requires testing for the PML-RARα fusion gene.

- PML-RARα Genotyping Kit: Differentiation of the subtype of PML-RARα L, S and V transcripts
- PML-RARα L Detection Kit: Quantification of PML-RARα L transcripts
- PML-RARα S Detection Kit: Quantification of PML-RARα S transcripts
- PML-RARα V Detection Kit: Quantification of PML-RARα V transcripts

Quantification Kits for Other Fusion Genes

The detection kits of 55 fusion genes are available individually. Please contact your sales representative or local distributor for more details.

Ordering Information

Cat. No	Product	Size
803041	Leukemia Fusion Genes (Q30) Screening Kit	20 Tests/Kit
803100	Leukemia Fusion Genes (Q51) Screening Kit	20 Tests/Kit
803540	Leukemia Fusion Genes (Q55) Screening Kit	20 Tests/Kit
803317	BCR-ABL1 p190 Kit	20 Tests/Kit
803318	BCR-ABL1 p210 Kit	20 Tests/Kit
803215	BCR-ABL1 Genotyping Kit	20 Tests/Kit
803212	PML-RARα L Detection Kit	20 Tests/Kit
803213	PML-RARα S Detection Kit	20 Tests/Kit
803214	PML-RARα V Detection Kit	20 Tests/Kit
803216	PML-RARα Genotyping Kit	20 Tests/Kit
803209	AML1-ETO Detection Kit	20 Tests/Kit
803319	WT1 Detection Kit	20 Tests/Kit
803409	CBFβ-MYH11 Detection Kit	20 Tests/Kit
	Quantitative Detection Kits for Other Fusion Genes	20 Tests/Kit

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