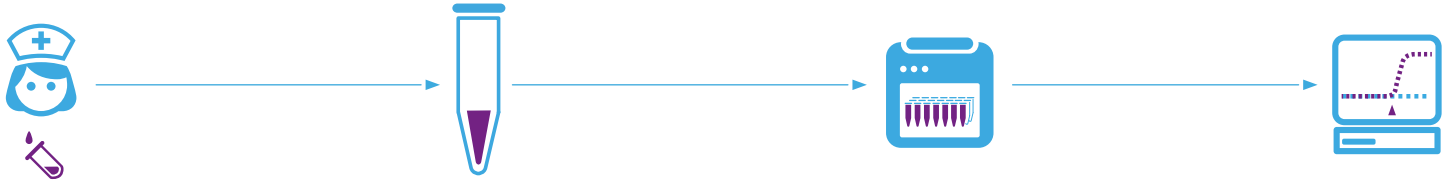
DNA-DIAGNOSTIC

Time is short
The list is not

del1(p32)(STIL-TAL1)
t(1;11)(p32;q23)(MLL-EPS15)
t(1;11)(q21;q23)(MLL-MLLT11)
t(1;19)(q23;p13)(TCF3-PBX1)
t(3;5)(q25;q34)(NPM1-MLF1)
t(3;21)(q26;q22)(RUNX1-MECOM)
t(4;11)(q21;q23)(MLL-AFF1)
t(5;12)(q33;p13)(ETV6-PDGFRB)
t(5;17)(q35;q21)(NPM1-RARA)
t(6;9)(p23;q34)(DEK-NUP214)
t(6;11)(q27;q23)(MLL-MLLT4)
t(8;21)(q22;q22)(RUNX1-RUNX1T1)
t(9;9)(q34;q34)(SET-NUP214)
t(9;11)(p22;q23)(MLL-MLLT3)
t(9;12)(q34;p13)(ETV6-ABL1)
t(9,22)(q34;q11)(BCR-ABL1)
t(10;11)(p12;q23)(MLL-MLLT10)
t(11;17)(q23;q21)(MLL-MLLT6)
t(11;17)(q23;q21)(ZBTB16-RARA)
t(11;19)(q23;p13.1)(MLL-ELL)
t(11;19)(q23;p13.3)(MLL-MLLT1)
t(12;21)(p13;q22)(ETV6-RUNX1)
t(12;22)(p13;q11)(ETV6-MN1)
t(15;17)(q24;q21)(PML-RARA)
inv(16)(p13;q22)(CBFB-MYH11)
t(16;21)(p11;q22)(FUS-ERG)
t(17;19)(q22;p13)(TCF3-HLF)
t(X;11)(q13;q23)(MLL-FOXO4)

Run a
HemaVision® 28Q
28 Translocations
145+ Breakpoints
In just 4 hours
CE IVD

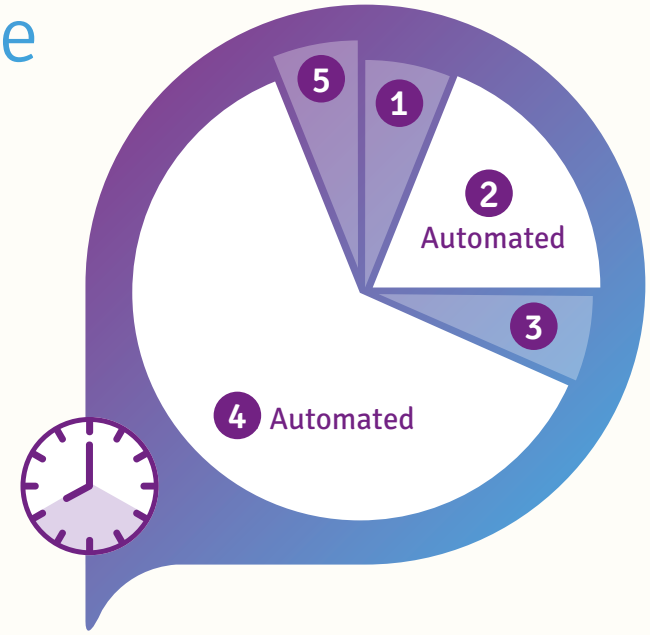


Visitation / RNA extraction — HemaVision® 28Q screen — For all major qPCR platforms — Treatment planning

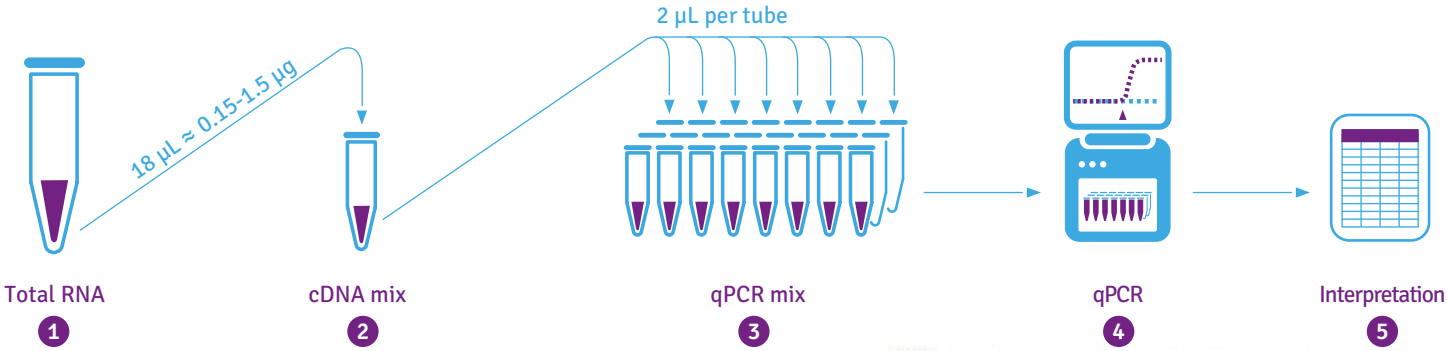
The most comprehensive **screening test**

HemaVision® 28Q

- Screening test for AML, ALL and CML
- Detection of 28 translocations
- Detection of +145 breakpoints and splice variants
- In just 4 hours



Level of automation in 4 hour screening process



Working steps – which are as follows:

1. RNA is extracted from peripheral blood or bone marrow using a RNA extraction kit.

2. 0.15-1.5 µg RNA is added to a ready-to-use HemaVision® 28Q cDNA reaction tube and incubated for 45 minutes.

3. 2 µL cDNA reactions is transferred to each of the 23 pre-mixed HemaVision® 28Q qPCR reaction tubes.

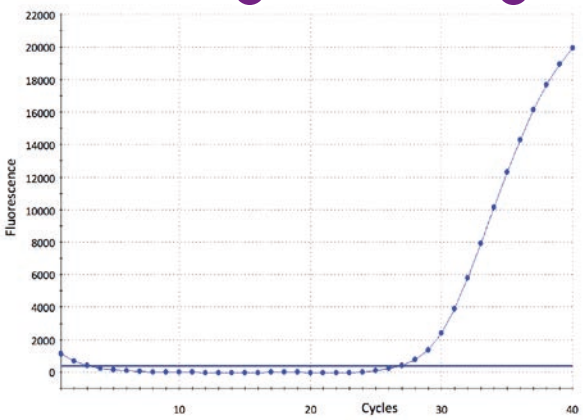
4. Run a qPCR in a real-time PCR instrument for 2.5 hours.

5. Results from the qPCR are used for identification of the translocation using a simple interpretation table. See interpretation overview on the next page.

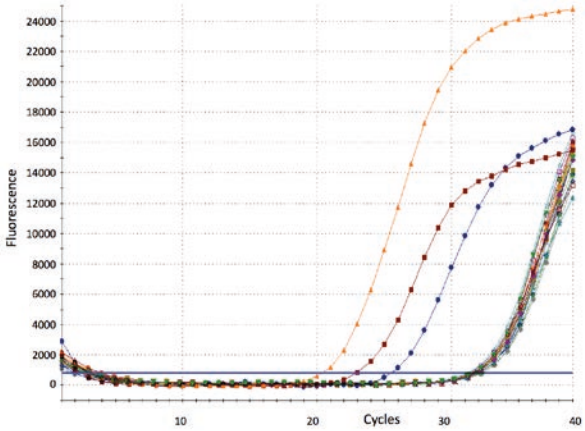
Instrument compatibility

HemaVision® 28Q is designed to be used in real-time PCR instruments having optical filters for FAM, ROX and Cy5 fluorescent light and is compatible with ABI 7500, ABI 7500 Fast, ABI ViiA7, Agilent/Stratagene Mx3005, BioRad CFX96, Corbett Rotor-Gene 6000, Qiagen Rotor-Gene Q and Roche LightCycler 480 I/II.

The cDNA reaction tubes contain specific primers for fusion genes and reference genes plus an Internal Amplification Control (IAC) DNA template. It also contains nucleotides, buffers and RT-enzyme. The IAC is a control for equal amounts of cDNA reaction have been transferred into each of the qPCR reaction tubes. In addition the IAC functions as an internal marker for the performance of the qPCR. See amplification plot 2.



HV28Q amplification plot 1:
FAM signal from positive t(15;17) PML-RARA (S)(tube no. 4)



HV28Q amplification plot 2:
FAM signal from GUS (blue), B2M (yellow) and ABL1 (red) reference genes (tube no. 7, 8, 16), and Cy5 signal from the IAC (tube no. 1-23)

The qPCR reaction tubes contain primers and probes plus nucleotides, buffer and enzyme enabling specific detection of fusion gene and reference gene transcripts plus the IAC. Primers are designed to detect both common and rare breakpoints in 28 translocations associated with leukemia. Specific amplification of fusion gene transcripts are detected using FAM and ROX labeled hydrolysis probes. The IAC is detected by a Cy5 labeled hydrolysis probe. HemaVision® 28Q detects the transcript level of three reference genes, Abelson (ABL-1), beta-glucuronidase (GUS) and beta-2-microglobin (B2M). These reference genes have stable transcription in different types of samples and are recommended by Europe Against Cancer. The reference genes serve as controls for the integrity of the RNA and cDNA synthesis.

Interpretation overview

Tube	Translocation	Fusion Gene	Fw primer - Rev primer	Flourochrome	
1	t(15;17)(q24;q21)	PML-RARA (bcr2, V)	PML ex5-RARA ex5	FAM	CY5
	inv(16)(p13;q22)	CBFB-MYH11	CBFB ex3-MYH11 ex30	ROX	CY5
2	inv(16)(p13;q22)	CBFB-MYH11	CBFB ex4-MYH11 ex34	FAM	CY5
	t(8;21)(q22;q22)	RUNX1-RUNX1T1	RUNX1 ex6-RUNX1T1 ex9	ROX	CY5
3	t(15;17)(q24;q21)	PML-RARA (bcr1, L)	PML ex6a-RARA ex5	FAM	CY5
	t(9;11)(p22;q23)	MLL-MLLT3	MLL ex7-MLLT3 ex7	ROX	CY5
4	t(15;17)(q24;q21)	PML-RARA (bcr3, S)	PML ex3-RARA ex5	FAM	CY5
	t(9;11)(p22;q23)	MLL-MLLT3	MLL ex8-MLLT3 ex11	ROX	CY5
5	t(11;19)(q23;p13.3)	MLL-ELL	MLL ex7-ELL ex3	FAM	CY5
	t(16;21)(p11;q22)	FUS-ERG	FUS ex6-ERG ex14	ROX	CY5
6	t(12;22)(p13;q11-12)	ETV6-MN1	ETV6 ex2-MN1 ex2	FAM	CY5
	t(6;9)(p23;q34)	DEK-NUP214	DEK ex9-NUP214 ex19	ROX	CY5
7	Reference gene	GUS	GUS ex11-GUS ex12	FAM	CY5
8	Reference gene	B2M	B2M ex2-B2M ex4	FAM	CY5
9	t(1;11)(p32;q23)	MLL-EPS15	MLL ex8+9-EPS15 ex3	FAM	CY5
	t(6;11)(q27;q23)	MLL-MLLT4	MLL ex8+9-MLLT4 ex2	ROX	CY5
10	t(1;19)(q23;p13)	TCF3-PBX1	TCF3 ex16-PBX1 ex3	FAM	CY5
	t(12;21)(p13;q22)	ETV6-RUNX1	ETV6 ex5-RUNX1 ex4b	ROX	CY5
11	t(11;19)(q23;p13.3)	MLL-MLLT1	MLL ex8+9-MLLT1 ex2	FAM	CY5
	t(4;11)(q21;q23)	MLL-AFF1	MLL ex8+9-AFF1 ex10	ROX	CY5
12	t(17;19)(q22;p13)	TCF3-HLF	TCF3 ex14-HLF ex4	FAM	CY5
	del(1)(p32)	STIL-TAL1	STIL ex1-TAL1 ex1	ROX	CY5
13	t(9;22)(q34;q11)	BCR-ABL1 (m-bcr, P190)	BCR ex1-ABL1 ex4	FAM	CY5
	t(9;9)(q34;q34)	SET-NUP214	SET ex9-NUP214 ex19	ROX	CY5
14	t(11;19)(q23;p13.3)	MLL-MLLT1	MLL ex7-MLLT1 ex9	FAM	CY5
	t(9;22)(q34;q11)	BCR-ABL1 (M-bcr, P210)	BCR ex12-ABL1 ex4	ROX	CY5
15	t(9;22)(q34;q11)	BCR-ABL1 (µ-bcr, P230)	BCR ex19-ABL1 ex4	FAM	CY5
	t(11;17)(q23;q21)	ZBTB16-RARA	ZBTB16 ex4-RARA ex5	ROX	CY5
16	Reference gene	ABL1	ABL1 ex3-ABL1 ex4	FAM	CY5
17	t(9;12)(q34;p13)	ETV6-ABL1	ETV6 ex2+5-ABL1 ex4	FAM	CY5
	t(5;12)(q33;p13)	ETV6-PDGFRB	ETV6 ex2+5-PDGFRB ex12	ROX	CY5
18	t(10;11)(p12;q23)	MLL-MLLT10	MLL ex8+9-MLLT10 ex20	FAM	CY5
	t(1;11)(q21;q23)	MLL-MLLT11	MLL ex8+9-MLLT11 ex2	ROX	CY5
19	t(X;11)(q13;q23)	MLL-FOXO4	MLL ex7-FOXO4 ex2	FAM	CY5
	t(11;17)(q23;q21)	MLL-MLLT6	MLL ex7-MLLT6 ex12	ROX	CY5
20	t(3;21)(q26;q22)	RUNX1-MECOM	RUNX1 ex6-MECOM ex2	FAM	CY5
	t(10;11)(p12;q23)	MLL-MLLT10	MLL ex7-MLLT10 ex9	ROX	CY5
21	t(5;17)(q35;q21)	NPM1-RARA	NPM1 ex4-RARA ex5	FAM	CY5
	t(3;5)(q25.1;q35)	NPM1-MLF1	NPM1 ex4-MLF1 ex4	ROX	CY5
22	t(10;11)(p12;q23)	MLL-MLLT10	MLL ex7-MLLT10 ex13	FAM	CY5
	t(3;21)(q26;q22)	RUNX1-MECOM	RUNX1 ex6-MECOM ex9	ROX	CY5
23	t(10;11)(p12;q23)	MLL-MLLT10	MLL ex8-MLLT10 ex12	ROX	CY5
24	-	-	-	-	-

Compatible with **all major qPCR platforms**

28 Translocations. 145+ Breakpoints. In one test.
The HemaVision® 28Q provides information about 28 translocations including PML-RARA and alternative splice variants in 4 hours. The fast, accurate and cost-effective test allows professionals to react with rapid precision in the treatment of patients suspected for Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL) or Chronic Myeloid Leukemia (CML).

The Real-Time Quantitative PCR detects 28 fusion gene transcripts. The test includes more than 145 clinically relevant breakpoints permitting identification of rare translocations and fusion products, which cannot be detected with other commercial screening kits.

Fast visual results. Fast optimum treatment.
Time is vital when dealing with the treatment of leukemia patients. Run a HemaVision® 28Q and get a comprehensive visual result from the amplification plot in just 4 hours. This unique and cost-effective process ensures early and optimum treatment planning, which benefits the patient, the professional and the entire medical organisation.

HemaVision® 28Q tube formats.
A HemaVision® 28Q kit contains 12 sets of ready-to-use cDNA and qPCR reaction tubes for 12 tests.

HemaVision® 28Q qPCR reaction tubes are available in three formats, white low profile, white regular profile and frosted regular profile. The qPCR reaction tubes are delivered in 12 blocks each containing 3x8 tubes.

Want to know more?
Our team and distributors are always on hand to provide assistance, if you have questions about HemaVision® 28Q. To learn more and to find your nearest distributor, please contact us: info@dna-diagnostic.com.

Contact us on
info@dna-diagnostic.com
for more information

CE-marked for in vitro diagnostic (CE IVD)

About us

DNA Diagnostic A/S (previously named DNA Technology A/S) was established in 1992. DNA Diagnostic A/S is an ISO 9001:2008 certified developer, manufacturer, and worldwide supplier of PCR based CE IVD marked in vitro diagnostic kits.

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