Instruction For Use

HemaVision®-9;22N

Screening test for chromosome translocation t(9;22)(q34;q11)(BCR-ABL1) associated with leukemia

Instruction For Use
Cat No. HV02-922N

DNA Diagnostic A/S
www.dna-diagnostic.com
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IVD CE

HemaVision®-9;22N

Multiplex RT-PCR test

Instruction For Use for HemaVision®-9;22N
Cat. No. HV02-922N
25 tests per kit

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HemaVision®-9;22N

Nested RT-PCR System

for

detection of translocation t(9;22)(q34;q11)(BCR-ABL1)

Instruction Manual

Catalog Number: HV02-922N

25 Reactions per kit

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1. PURPOSE OF THE TEST (INTENDED USE)

HemaVision®-9;22N is a CE-marked *in vitro* diagnostic test for qualitative testing of chromosome translocations using total RNA extracted from human blood or bone marrow. Tests should be performed and results should be analysed by professionals only. The test is intended for use as an adjunct to evaluation of Leukemia in conjunction with other clinicopathological factors for stand-alone diagnosis of Leukemia (aid to diagnosis).

HemaVision®-9;22N detects human translocation t(9;22)(q34:q11)(BCR-ABL1) associated with leukemia. This translocation fuses the BCR gene on chromosome 22q11 with the ABL1 gene on chromosome 9q34 (Ref 1-3). HemaVision®-9;22N identifies chromosomes, genes and exons at the breakpoint in fusion genes. Furthermore, the test identifies mRNA splice variants from fusion genes. The test uses reverse transcription of RNA to cDNA followed by multiplex nested polymerase chain reactions, agarose gel electrophoresis, and interpretation. The kit contains primers for 25 cDNA reactions and 25 nested PCR tests.

HemaVision®-9;22N contains the same primers as the split-out reaction M6B and M8F in the HemaVision®-28N kit.

HemaVision®-9;22N is a fast one day test with very high sensitivity (>99%) and specificity (>99%) (Ref 4, 5). Limit of detection is 10^{-9} μg of fusion RNA in a sample of 1 μg total RNA when the RNA quality is good.

This test provides a more detailed description of the exon organization of fusion genes originating from chromosome translocations.

The test is for professional use only.

2. PRINCIPLES OF THE PROCEDURE

RNA is used as template for synthesis of cDNA in a reaction with the enzyme Reverse Transcriptase (RT). The resultant cDNA provides a template for diplex nested PCR amplification of the region containing the breakpoint of the fusion mRNA. This process, called RT-PCR, is useful for the examination of the chromosomal translocation of interest.

A flowchart illustrating the steps involved in the detection of translocations by the HemaVision® kit is shown below (Figure1).

RNA Preparation

RNA prepared from human whole blood, cell lines, or bone marrow cells provides the template for the synthesis of cDNA. For RNA extraction, use QIAamp® RNA Blood Mini Kit from Qiagen Cat. No. 52304.

cDNA Synthesis

cDNA is synthesized from the isolated RNA using the cDNA primer Mix from HemaVision®-9;22N and Reverse Transcriptase, nucleotides and buffer from HemaVision® Reagent Modules Cat No. HV04-RM or HV06-RMP. Use two HV06-RMP kits together with each HemaVision®-9;22N kit.

First PCR Amplification followed by Nested PCR

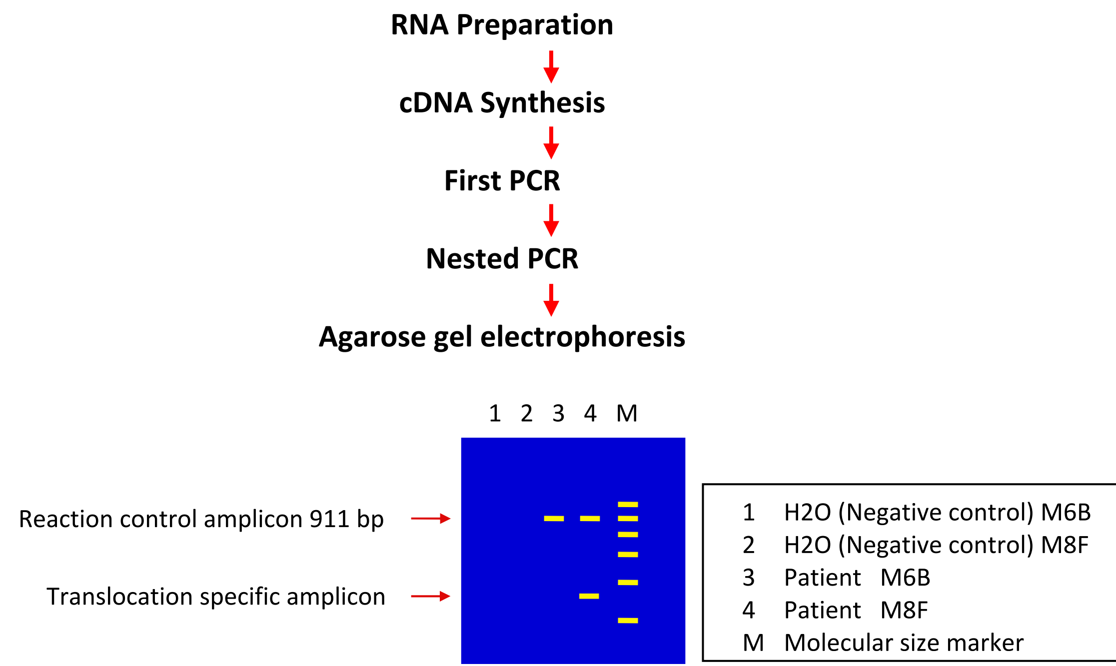
The resultant cDNA is used as a template for a PCR-I amplification reaction that is subsequently followed by nested PCR-II amplification. PCR primers are from HemaVision®-9;22N. Nucleotides are from HemaVision® Reagent Modules Cat No. HV04-RM or HV06-RMP. HotStarTaq DNA polymerase (5U/uL) and buffer are from HemaVision® kit HV06-RMP or Qiagen.

PCR Product Detection

The amplification products from the nested PCR amplifications are analyzed by agarose gel electrophoresis. The presence of a specific band (in addition to the control band) indicates the presence of a translocation. The Interpretation Table links the size of the specific band with the breakpoint of the fused genes.

The reaction control fragment results from amplification of RNA from the house keeping gene biotinidase. This reaction control checks for the integrity of the RNA sample and for the functionality of the RT-PCR.

Figure 1: HemaVision® -9;22N Flow Chart



3. KIT COMPONENTS AND STORAGE

The HemaVision®-9;22N kit must be stored at -20°C. While performing the test, always keep test components on ice. Each kit contains sufficient material for 25 tests.

The HemaVision®-9;22N kit consists of a User Manual and a box with 5 tubes containing oligonucleotide primer solutions:

cDNA primer mix (120 µL), M6B PCR-I primer mix (150µL), M6B PCR-II primer mix (150µL), M8F PCR-I primer mix (150µL), M8F PCR-II primer mix (150µL).

NOTE:

It is absolutely essential to obtain and use the reagents provided by DNA Diagnostic A/S in HemaVision® kit ***Cat No.: HV04-RM****: (MMLV-RT; 5x MMLV-RT buffer; DTT; dNTP) or* ***HV06-RMP****: (MMLV-RT; 5x MMLV-RT buffer; DTT; dNTP; 10xPCR buffer; PCR enzyme) . Otherwise, DNA Diagnostic A/S cannot guarantee the result.*

4. ADDITIONAL EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

RNA extraction Room

For RNA extraction, use QIAamp® RNA Blood Mini Kit from Qiagen Cat. No. 52304.

Spectrophotometer.

Pre-Amplification Room (no template area):

Micropipettes, 0.5-10 µL, 2-20 µL,20-200 µL, 100-1,000 µL
Aerosol barrier micropipette tips, 0.5-10 µL, 2-20 µL, 20-200 µL, 100-1,000 µL
0.2 mL thin-walled PCR tubes including caps
1.5 mL Standard Micro Test Tube
HemaVision® Cat. No. HV06-RMP or alternatively HV04-RM plus HotStarTaq DNA Polymerase from Qiagen
Vortex
Disposable gloves
RNase free

cDNA Synthesis Area:

Micropipettes, 0.5-10 µL, 20-200 µL
Aerosol barrier micropipette tips, 0.5-10 µL, and 20-200 µL
Micro centrifuge and Heating Block/Water Bath
RNAse free water
Disposable gloves, RNAse free tubes.

PCR set-up Areas:

Micropipettes, 0.5-10 µL or 8 channel pipette 0.5-10 µL
Aerosol barrier micropipette tips, 0.5-10 µL
Micro centrifuge
Disposable gloves, RNAse free tubes.

Amplification Detection Area:

Micropipettes, 0.5-10 µL, 2-20 µL, 20-200 µL, 100-1,000 µL
Aerosol barrier micropipette tips, 0.5-10 µL, 2-20 µL, 20-200 µL, 100-1,000 µL
Equipment for Agarose gel electrophoresis
Agarose
1 x TBE buffer
Size standards
Ethidium Bromide
Loading buffer
8 channel pipette (1-50 µL)
Thermal Cycler (Perkin Elmer GeneAmp 9700)
Disposable gloves

5. PRECAUTIONS

General precautions

- The quality and concentration of the RNA sample greatly affects the results of this test. To minimize the risk of degradation by ribonucleases, we strongly recommend purification of total RNA immediately after blood or bone marrow extraction. Optionally, mononuclear cells can be purified prior to RNA extraction using Ficoll Hypaque. Do not freeze Ficoll purified cells without adding a denaturing solution [e.g. containing guanidinium isothiocyanate (GTC)] immediately after isolation and before freezing.
- Use blood from venipuncture collected into a tube containing EDTA. Alternatively, use bone marrow collected into a tube containing EDTA. Do not freeze the blood or bone marrow sample.
- Do NOT use Heparin for stabilization of blood samples.
- Always store cell samples and aqueous RNA solutions at -80°C. Even an overnight storage at -20°C may result in RNA degradation. Do not freeze the blood or bone marrow sample.
- When working with RNA always use gloves, as hands are a major source of ribonuclease contamination.
- The integrity and purity of RNA is important for the efficiency of the cDNA synthesis and thus detection of translocations. The quality of RNA can be checked by OD 260/280 nm measurements, agarose gel electrophoresis, or using RIN number from the Agilent Bioanalyzer.
- For more guidance on specimen collection, RNA isolation and storage please refer to "ISO 20186:2019 Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 1: isolated cellular RNA" and CLSI guidance MM13-A "Collection, Transport, Preparation and Storage of Specimens for Molecular Methods; Approved guideline.
- RT-PCR is a very sensitive technique. Therefore, precautions must be taken to avoid false positive results caused by contamination with RNA, cDNA or PCR products from other samples.
- Dedicate four separate rooms/areas to the following activities:
    - Master mix production – no templates in here
    - cDNA synthesis
    - PCR
    - Gel electrophoresis
- A set of micropipettes, aerosol barrier pipette tips, disposable gloves and clean lab coats should be kept in each of the four rooms. The work must be organized so that mixes and reaction products only moves in the direction from 1-4. NEVER move mixes or reaction products in the opposite direction.
- Laboratory workbenches, pipettes, and lab coats must be cleaned on a regular basis.
- Use of aerosol barrier pipette tips is highly recommended during the entire procedure. It is essential to change gloves very often when handling tubes containing RNA or cDNA.
- For more general guidance on best practice in PCR testing please refer to the CLSI guidance document MM01: Molecular Methods for Clinical Genetics and Oncology Testing, 3rd Edition

Safety

- Read and understand the procedure before starting.
- Normal laboratory aseptic technique should be followed at all times.
- Treat each sample as if it is infectious.
- Wear eye protection and disposable gloves during all steps of the assay.
- The products can be discarded as normal laboratory waste
- Check the safety data sheet for the product on our website for further information or ask for a copy of it.

6. PROCEDURE

Procedural notes

- Store all test components as described in the Kit Components and Storage section.
- A negative control should be run with each set of patient samples.
- Do not mix reagents from different lots.
- Careful pipetting technique is essential for accurate results.
- This protocol is optimized for the Perkin Elmer GeneAmp 9700 thermal cycler. Use of another thermal cycler may require optimization by the user.
- A reaction control fragment of 911bp must be amplified in all samples.
- The concentration of the translocation-specific PCR primers is greater than the concentration of the primers for the synthesis of the control fragment. Therefore, in some circumstances when both fragments are co-amplified, the intensity of the control fragment may be weak.
- It is mandatory to use hot start *Taq* DNA Polymerase. This protocol is optimized for the use of the PCR enzyme in HemaVision Cat. No. HV06-RMP or HotStarTaq DNA Polymerase (5U/uL) from Qiagen. Successful results using hot start DNA Polymerases from other vendors are not guaranteed. The use of hot start DNA Polymerases from other vendors requires optimization by the user.
- DNA Diagnostic A/S will not be liable for failure of the HemaVision kit's performance if not used in conjunction with our Reagent Module HV06-RMP.

RNA preparation

- Due to the inherent instability of RNA use patient samples as fresh as possible. Within 24 hours of sample collection, extract total RNA.
- For RNA preparation from whole blood or mononuclear cells isolated with Ficoll Hypaque, we recommend the use of the QIAamp® RNA Blood Mini Kit (Qiagen Cat. No. 52304). The yield of RNA from 1 $x10^7$ mononuclear cells from blood is approximately 5-10 μg.
- Measure the RNA concentration by reading the optical density at 260 nm. An absorbance of 1 unit at 260 nm corresponds to 40 μg of RNA per ml (A260 = 1 = 40 μg/ml). Adjust the concentration of RNA to 0.1 μg/μL with RNase free water.
- Prepare at least two aliquots of each RNA sample in RNAse free tubes. Add 10 μL of 0.1 μg/μL RNA to each tube. Store RNA aliquots at –80°C if not used immediately for cDNA synthesis.

Step 1 cDNA Synthesis

***Note**: Keep reagents and mixes on ice.*

1.1 In the cDNA synthesis area: To each RNase free tube containing 1 μg of sample RNA (dissolved in 10 μL RNase free water as described above) add 4 μL of the supplied cDNA primer mix. Mix and spin down for 10 seconds.

1.2 In a separate RNase free tube, add 10 μL of RNase free water and 4 μL cDNA primer mix (Negative reaction control).

1.3 Incubate the tubes in a heating block or water bath at 65°C for 5 min. Chill on ice.

Note: To prevent contamination, the cDNA Synthesis Mix must be prepared and liquated in a separate area (pre-amplification room) using pipettes never allowed coming in contact with any RNA or DNA. Prepare cDNA Synthesis Mix in an RNase free tube.

1.4 Prepare cDNA Synthesis Mix according to **Table 1**. Do not add additional volume to compensate for liquid loss. This has already been factored into the table numbers.

Table 1: cDNA Synthesis Mix

Number of cDNA reactions	**1**	**2**	**3**
5x MMLV-RT Buffer (μL)	5.5	11	16.5
100 mM DTT (μL)	2.75	5.5	8.25
10 mM dNTP Mix (μL)	2.75	5.5	8.25
MMLV-RT, 200U (μL)	1.1	2.2	3.3
Total volume (μL):	12.1	24.2	36.3

1.5 Add 11 μL cDNA Synthesis Mix into each sample tube and the negative reaction control tube (from step 1.2). Mix gently and spin down for 10 seconds.

1.6 Incubate at 37°C for 45 minutes.

1.7 Add 25 μL RNase free H_2O to each cDNA reaction tube to dilute the cDNA reactions.

1.8 Incubate at 95°C for 5 min to inactivate the MMLV-RT.

1.9 Chill on ice. The cDNA reaction(s) is now ready for the First PCR amplification (PCR-I).

Step 2 PCR-I

***Note**: The following tasks must be performed in the Pre-amplification area devoted to PCR reaction set-up.*

2.1 Prepare the two ***PCR-I Mix (M6B PCR-I Mix and M8F PCR-I Mix)*** according to Table 2.

To compensate for pipette variations, and for loss of liquid on the interior walls of the tubes, we recommend preparing an additional 10% of the mix.

2.2 Mix the *PCR-I Mix* by pipetting up and down a few times, avoiding bubble formation.

Table 2: *PCR-I Mix*

No. of cDNA reactions	**1**		**2**	
No. of PCR-I reactions	**2**		**4**	
10x PCR buffer (μL)*	5		10	
dNTP mix (μL)*	1		2	
HemaVision DNA Polymerase (μL) *	0.8		1.6	
H_2O (μL)	23.2		46.4	
Total volume (μL):	**30**		**60**	
	↙	↘	↙	↘
	15	**15**	**30**	**30**
M6B PCR-I primers	5		10	
M8F PCR-I primers		5		10
Total volume *PCR-I Mix* (μL):	**20** "M6B *PCR-I Mix*"	**20** "M8F *PCR-I Mix*"	**40** "M6B *PCR-I Mix*"	**40** "M8F *PCR-I Mix*"

***** Supplied with the HemaVision® HV06-RMP Reagent Module.

Note: *Transfer PCR tubes with PCR-I Mix from the Pre-amplification room to the PCR-I set-up area. Similarly transfer the cDNA tube(s) to the PCR-I set-up area.*

2.3 Label two 0.2mL PCR tube for each patient sample and one PCR tube for the negative reaction control – "PCR-I M6B" and "PCR-I M8F" respectively. Transfer 20 μL of the PCR-I Mix into each PCR tube.

2.4 Add 5 μL of cDNA sample to each patient PCR tubes containing 20 μL PCR-I Mix. Similarly add 5 μL of the negative reaction control cDNA to the negative reaction control PCR tubes containing 20 μL PCR-I Mix.

2.5 Place the PCR tubes into the Perkin-Elmer GeneAmp 9700 thermal cycler and immediately start the PCR amplification using the PCR cycling parameter given in **Table 3**.

Table 3: PCR-I Amplification Parameters

Step	Time/Temperature	Cycles
1	15 minutes at 95°C	1
2	30 seconds at 95°C 30 seconds at 58°C 1 minute 30 seconds at 72°C	25
3	Hold at 4°C	1

Step 3 PCR-II (Nested PCR Amplification)

Note: *PCR-II Mix must be prepared in the Pre-amplification room.*

3.1 Prepare the ***PCR-I Mix (M6B PCR-II Mix and M8F PCR-II Mix)*** for the nested PCR-II reactions according to Table 4.

3.2 Use the M6B PCR-II and M8F PCR-II primers in separate tubes. Mix by pipeting up and down a few times. Avoid the formation of bubbles.

Note: *To compensate for pipette variations and for loss of mix during pipetting we recommend preparing an additional 10% of the mix.*

Table 4: *PCR-II Mix*

No. of cDNA reactions	**1**		**2**	
No. of PCR-I reactions	**2**		**4**	
10x PCR buffer (µL)*	5		10	
dNTP mix (µL)*	1		2	
HemaVision DNA Polymerase (µL) *	0.8		1.6	
H_2O (µL)	31.2		62.4	
Total volume (µL):	**38**		**76**	
	↙	↘	↙	↘
	19	**19**	**38**	**38**
M6B PCR-II primers	5		10	
M8F PCR-II primers		5		10
Total volume *PCR-I Mix* (µL):	**24** "M6B *PCR-II Mix*"	**24** "M8F *PCR-II Mix*"	**48** "M6B *PCR-I Mix*"	**48** "M8F *PCR-I Mix*"

***** Supplied with the HemaVision® HV06-RMP Reagent Module.

3.3 Label two 0.2 mL PCR tube for each patient and negative control.

3.4 Transfer 24 µL PCR-II Mix to each PCR-II tubes.

Note*: Transfer the PCR tubes with PCR-II Mix for PCR-II from the Pre-amplification room to the PCR-II set-up area. Similarly transfer the PCR tubes with amplified PCR-I into the PCR-II set-up area.*

3.5 Add 1 µL of each PCR-I reaction to each of the corresponding PCR-II tubes resulting in a final volume of 25 µL in each PCR reaction.

3.6 Perform PCR-II by the following program:

Table V: PCR-II Parameters

Step	Time/Temperature	Cycles
1	15 minutes at 95°C	1
2	30 seconds at 95°C 30 seconds at 58°C 1 minute 30 seconds at 72°C	20
3	10 minutes at 72°C	1
4	Hold at 4°C	1

Step 4 Agarose Gel Electrophoresis

4.1 Prepare a 1.5% (w/v) agarose gel, at least 10 centimeters long, in 1x TBE buffer. Add ethidium bromide to a final concentration of 0.5 μg/mL.

4.2 Add 3 μL of 10X loading buffer to each PCR-II reaction. Load 14 μL in the gel. For convenient interpretation, we recommend loading all PCR reactions from one sample followed by molecular weight marker.

4.3 Run the gel in 1x TBE buffer until the Bromophenol blue dye has migrated approximately 3/4 of the gel.

4.4 Examine the gel under UV illumination and document by photography.

7. INTERPRETATION

The **reaction control fragment of 911 bp** must be present in all lanes except the negative reaction control lane. The 911 bp reaction control band may only be weak or missing when the lane contains an intense translocation specific band. The reaction control will only be present when non-degraded RNA is used and all reactions have been done correctly.

Weak or no amplification of the reaction control in any lane most likely is caused by: degraded RNA, low initial RNA concentration or the presence of contaminating genomic DNA in the RNA preparation. PCR can also be inhibited if the blood is collected in heparin tubes.

The presence of one of the following band sizes in either of the patient lanes shows that the RNA sample contains the t(9;22)(q34;q11)(BCR-ABL1) fusion transcript .

Note: *You may see PCR products of a different size as a consequence of the amplification of an unpublished breakpoint or splice variant.*

PRIMER MIX	CHROMOSOMAL ALTERATION	GENES INVOLVED	FUSION GENE	PCR-II AMPLICONS (bp)
M6B	t(9;22)(q34;q11)	BCR(22q11) ABL1(9q34.1)	M-bcr, P210: BCR ex12 - ABL1 ex3 (b1a3) BCR ex13 - ABL1 ex3 (b2a3) BCR ex12 - ABL1 ex2 (b1a2) BCR ex14 - ABL1 ex3 (b3a3) BCR ex13 - ABL1 ex2 (b2a2) BCR ex14 - ABL1 ex2 (b3a2) μ-bcr, P230: BCR ex19 - ABL1 ex3 (c3a3) BCR ex20 - ABL1 ex3 (c4a3) BCR ex19 - ABL1 ex2 (c3a2) BCR ex20 - ABL1 ex2 (c4a2)	M-bcr, P210: 118 bp 223 bp 292 bp 298 bp 397 bp 472 bp μ-bcr, P230: 838 bp 973 bp 1012 bp 1147 bp
M8F	t(9;22)(q34;q11)	BCR(22q11) ABL1(9q34.1)	m-bcr, P190: BCR ex1 – ABL1 ex3 (e1a3) BCR ex1 – ABL1 ex2 (e1a2) BCR ex6 – ABL1 ex3 (e6a3) BCR ex6 – ABL1 ex2 (e6a2)	m-bcr, P190: 146 bp 320 bp 788 bp 962 bp

Note: *Gene abbreviations in the table above have been updated according to the HUGO Gene Nomenclature Committee (HGNC) system. The HGNC approves a unique and meaningful name for every known human gene (read more at www.genenames.org). Below list of relevant genes for the HemaVision®-9;22N kit, with the old abbreviation and the corresponding present HGNC abbreviation.*

Old Abbreviation	HGNC Abbreviation	Chromosome	HGNC ID
ABL	ABL1	9q34.1	HGNC:76
BCR	BCR	22q11	HGNC:1014

8. REFERENCES

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2. Cross N.C., Melo J.V., Feng L., and Goldman J.M.: An optimized multiplex polymerase chain reaction (PCR) for detection of BCR-ABL fusion mRNAs in haematological disorders. Leukemia **8**: 186, 1994.
3. Hochhaus, A., Reiter A., Skladny H., Melo J.V., Sick C., Berger U., Guo J.Q., Arlinghaus R.B., Hehlmann R., Goldman J.M., and Cross N.C.P.: A novel BCR-ABL fusion gene (e6a2) in a patient with Philadelphia chromosome-negative chronic myelogenous leukemia. Blood **88**: 2236, 1996.
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5. Song MJ., Kim HJ., Park CH., Kim SK., Ki CS., Kim JW., Kim SH**.:** Diagnostic utility of a multiplex RT-PCR assay in detecting fusion transcripts from recurrent genetic abnormalities of acute leukemia by WHO 2008 classification. Diagn mol pathol. 2012 Mar;21(1):40-4.

REVISION HISTORY

REVISION NUMBER	SECTION CHANGED	DATE
5	Updated intended use to more precisely describe. Updated 5. Precautions with more details on specimen collection and RNA extraction. Updated 6. procedure with more details on RNA extraction.	2019.09.19
6	Corrected mistakes in precautions where qPCR was mentioned and it should be PCR	2020.09.15
7	Minor editions in precautions and RNA preparation section	2020.10.19
8	Changed from User Manual to Instruction For Use	2021.04.26

Symbols used on tubes and boxes

CE	"Conformité Européenne" ("European Conformity")	IVD	In vitro Diagnostic Medical Device	i	Consult instructions for use
REF	Catalogue Number	LOT	Lot number	**CONT**	Contents

	Storage temperature		Expiry Date		Manufacturer

DNA
DIAGNOSTIC

Availability / questions
Our team and distributors are always at hand
to answer all your questions.
Contact us to find your nearest HemaVision® partner.

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DNA Diagnostic A/S was established in 1992.
DNA Diagnostic A/S is an ISO 13485 certified
developer, manufacturer, and worldwide supplier
of PCR based CE IVD marked in vitro diagnostic kits.