ZytoLight® SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe

CE IVD

Background

The ZytoLight® SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe is designed to detect the specific translocation involving the chromosomal region 21q22.12 harboring the RUNX1 (a.k.a. AML1) gene and the chromosomal region 8q21.3 harboring the RUNX1T1 (a.k.a. ETO, CBF2T1) gene.

The balanced chromosomal translocation t(8;21) is found in about 90% of acute myeloid leukemia (AML) patients. AML is a heterogeneous clonal disorder of hematopoietic progenitor cells and one of the most common malignant myeloid disorders in adults.

The runt related transcription factor 1 gene (RUNX1) and RUNX1 translocation partner 1 (RUNX1T1) gene are both involved in the transcriptional regulation of genes during normal hematopoiesis.

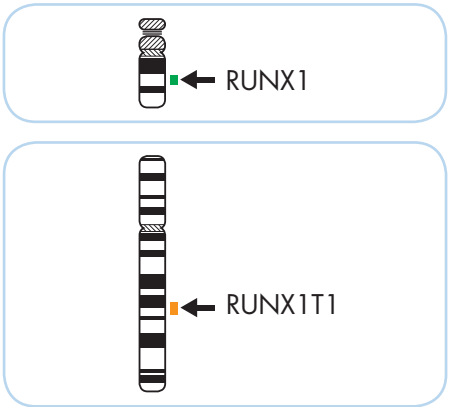
The non-random translocation t(8;21)(q21.3;q22.1) is strongly associated with the French-American-British (FAB) phenotype M2 (AML-M2) and produces a chimeric gene consisting of the 5′-region of the RUNX1 gene fused to the 3′-region of the RUNX1T1 gene. The chimeric protein is thought to be associated with the nuclear corepressor/histone deacetylase complex to block hematopoietic differentiation. fluorescence *in situ* hybridization (FISH) can provide important information for the management of patients with hematologic disorders.

References
Dayyani F, et al. (2008) Blood 111: 4338-47.
Estey E & Döhner H (2006) Lancet 368: 1894-907.
Gmidène A, et al. (2011) Med Oncol 28 Suppl 1: 509-12.
Licht D (2001) Oncogene 20: 5560-79.
Vangala RK, et al. (2003) Blood 101: 270-7.

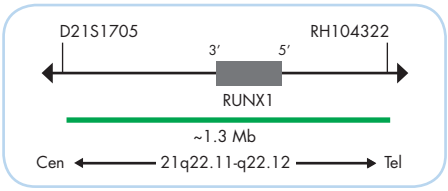
Probe Description

The ZytoLight® SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe is composed of:

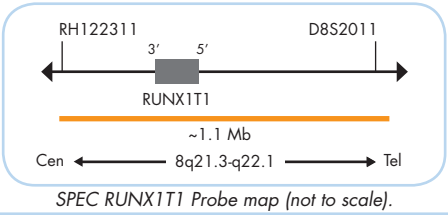
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12 ng/µl), which target sequences mapping in 21q22.11-q22.12** (chr21:35,530,283-36,855,548) harboring the RUNX1 gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6 ng/µl), which target sequences mapping in 8q21.3-q22.1** (chr8:92,632,490-93,746,043) harboring the RUNX1T1 gene region.
- Formamide based hybridization buffer



Ideograms of chromosomes 21 (above) and 8 (below) indicating the hybridization locations.



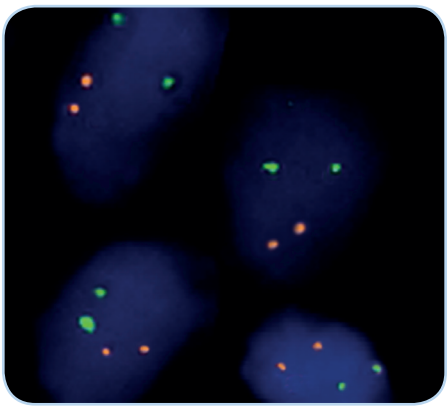
SPEC RUNX1 Probe map (not to scale).



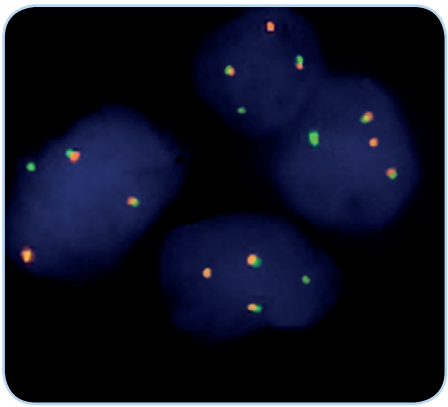
SPEC RUNX1T1 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. A reciprocal translocation involving two breakpoints splits the two signals and generates a fusion signal on each of the chromosomes involved. The chromosomal regions which are not translocated are indicated by the single orange and green signal, respectively.



SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Bone marrow biopsy section with translocation affecting the RUNX1/RUNX1T1 locus as indicated by one separate orange signal, one separate green signal, and two orange/green fusion signals.

Prod. No.	Product	Label	Tests* (Volume)
Z-2112-50	ZytoLight SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe CE IVD	●/●	5 (50 µl)
Z-2112-200	ZytoLight SPEC RUNX1/RUNX1T1 Dual Color Dual Fusion Probe CE IVD	●/●	20 (200µl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x $MgCl_2$, 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

** Using 10 µl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

***According to Human Genome Assembly GRCh37/hg19*