ZytoLight® SPEC KMT2A Dual Color Break Apart Probe

CE IVD

Background

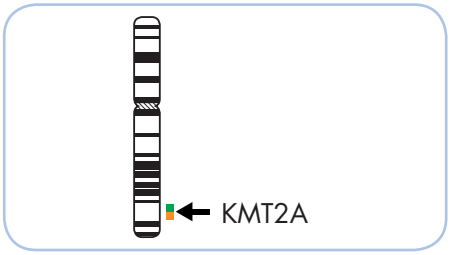
The ZytoLight® SPEC KMT2A Dual Color Break Apart Probe is designed to detect translocations involving the chromosomal region 11q23.3 harboring the KMT2A gene. The KMT2A (a.k.a. MLL: mixed-lineage leukemia or myeloid-lymphoid leukemia) gene encodes a histone lysine N-methyltransferase and is involved in a variety of cellular processes, including hematopoiesis, DNA damage response, and cell cycle control.

Translocations involving the KMT2A gene are identified in 5-6% of all acute myeloid leukemias (AML) and 5-10% of all acute lymphoblastic leukemias (ALL). The frequency of translocations involving the KMT2A gene is significantly higher in infants with AML (50%) as well as with ALL (80%). More than 30 fusion partners are documented for KMT2A, the most common translocations are t(4;11) and t(11;19) in ALL, and t(6;11), t(9;11), and t(11;19) in AML patients.

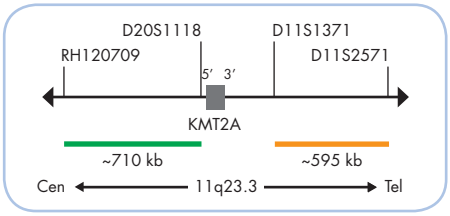
Between 1-15% of cancer patients treated with DNA topoisomerase II inhibitor develop therapy-related leukemia (t-AML) associated with KMT2A translocations. Generally, the presence of KMT2A rearrangements in patients with acute leukemia indicates a less favorable prognosis. However, recent studies suggest that the specific KMT2A translocation partner may influence response to therapy and overall prognosis depending on the clinical context. Hence, detection of KMT2A translocations by Fluorescence *in situ* Hybridization may be of diagnostic and prognostic relevance.

Probe Description

The SPEC KMT2A Dual Color Break Apart Probe is a mixture of two direct labeled probes hybridizing to the 11q23.3 band. The green fluorochrome direct labeled probe hybridizes proximal to the KMT2A gene, and the orange fluorochrome direct labeled probe hybridizes distal to the KMT2A gene region.



Ideogram of chromosome 11 indicating the hybridization locations.

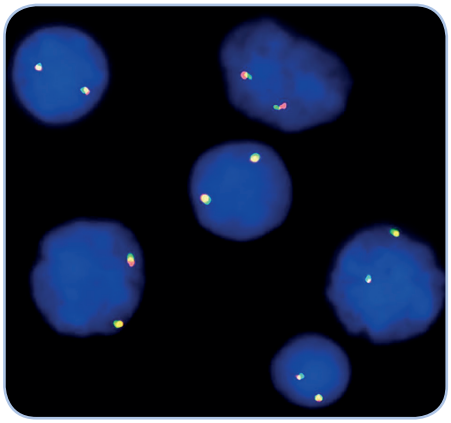


SPEC KMT2A Probe map (not to scale).

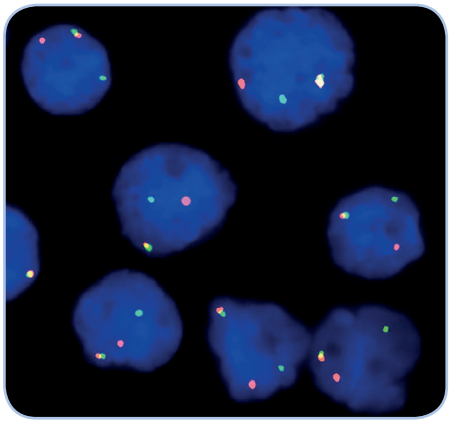
References
Broeker PL, et al. (1996) Blood 87: 1912-22.
De Braekeleer M, et al. (2005) Anticancer Res 25: 1931-44.
Ford DJ & Dingwall AK (2015) Cancer Genet 208: 178-91.
Gindin T, et al. (2014) Hematol Oncol [Epub ahead of print].
Keefe JG, et al. (2010) J Mol Diagn 12: 441-52.
Langer T, et al. (2003) Genes Chromosomes Cancer 36: 393-401.
Wechsler DS, et al. (2003) Genes Chromosomes Cancer 36: 26-36.

Results

In an interphase nucleus lacking a translocation involving the 11q23.3 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 11q23.3 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 11q23.3 locus and one 11q23.3 locus affected by a translocation.



SPEC KMT2A Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Bone marrow tissue section with translocation of the KMT2A gene as indicated by one non-rearranged orange/green fusion signal, one orange signal, and one separate green signal indicating the translocation.

Prod. No.	Product	Label	Tests* (Volume)
Z-2193-200	ZytoLight SPEC KMT2A Dual Color Break Apart Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 500 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml		20
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x MgCl2, 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoLight® FISH probes are direct labeled using the unique ZytoLight® *Direct Label System II* providing improved signal intensity. Advanced specificity of the single copy SPEC probes is obtained by the unique ZytoVision® *Repeat Subtraction Technique.*

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