

ZytoLight® SPEC MALT1/IGH Dual Color Dual Fusion Probe



Background

The ZytoLight® SPEC MALT1/IGH Dual Color Dual Fusion Probe (PL279) is intended to be used for the qualitative detection of the translocation t(14;18)(q32.3;q21.3) involving the human MALT1 gene at 18q21.32 and the human IGH locus at 14q32.33 in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-20).

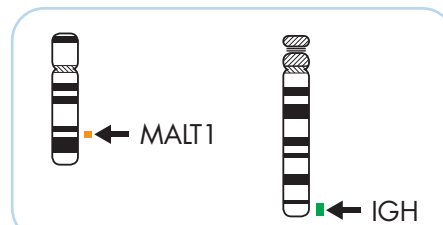
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

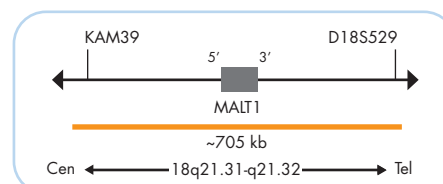
Probe Description

The ZytoLight® SPEC MALT1/IGH Dual Color Dual Fusion Probe is composed of:

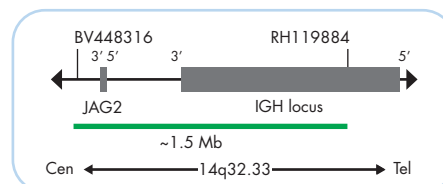
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6 ng/μl), which target sequences mapping in 18q21.31-q21.32** (chr18:56,021,766-56,724,408) harboring the MALT1 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12 ng/μl), which target sequences mapping in 14q32.33** (chr14:105,462,169-106,995,000) harboring the IGH locus.
- Formamide based hybridization buffer



Ideograms of chromosomes 18 (left) and 14 (right) indicating the hybridization locations.



SPEC MALT1 Probe map (not to scale).

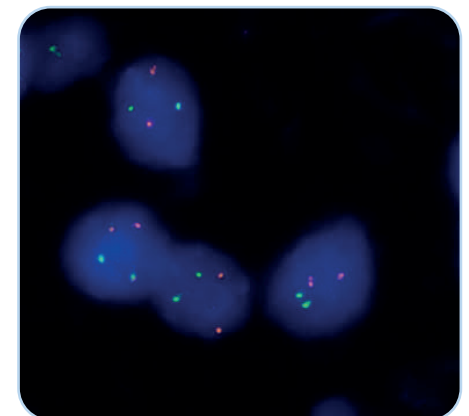


SPEC IGH Probe map (not to scale).

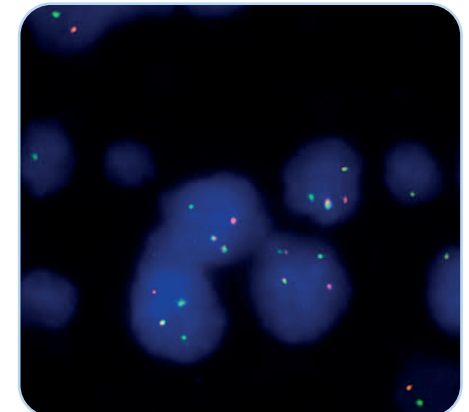
Results

In a normal interphase nucleus, two green and two orange signals are expected.

A reciprocal translocation involving the chromosomal regions of MALT1 and IGH is indicated by one separate green signal, one separate orange signal, and two green/orange fusion signals.



SPEC MALT1/IGH Dual Color Dual Fusion Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Example of an aberrant signal pattern: SPEC MALT1/IGH Dual Color Dual Fusion Probe hybridized to MALT lymphoma tissue section with t(14;18) as indicated by one separate orange signal, one separate green signal and two orange/green fusion signals indicating the MALT1/IGH translocation.

Prod. No.	Product	Label	Tests* (Volume)
Z-2325-50	ZytoLight SPEC MALT1/IGH Dual Color Dual Fusion Probe CE 0124 IVD	Orange/Green	5 (50 μl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD		5
Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTest-Solution, 0.2 ml			

* 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