

ZytoLight® SPEC MAML2 Dual Color Break Apart Probe



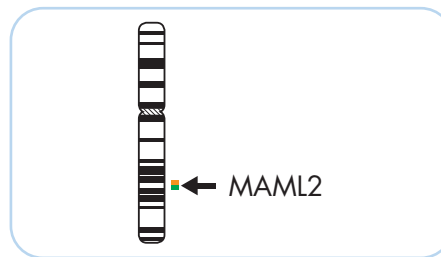
Background

The ZytoLight® SPEC MAML2 Dual Color Break Apart Probe (PL5) is intended to be used for the qualitative detection of translocations involving the human MAML2 gene at 11q21 in formalin-fixed, paraffin-embedded specimens, such as mucoepidermoid carcinoma (MEC), 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 MEC and therapeutic measures should not be initiated based on the test result alone.

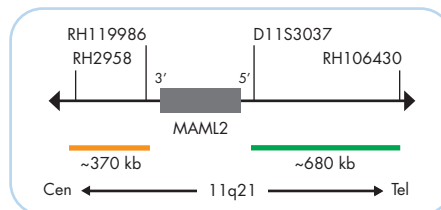
Probe Description

The ZytoLight® SPEC MAML2 Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/μl), which target sequences mapping in 11q21** (chr11:96,115,829-96,797,136) distal to the MAML2 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/μl), which target sequences mapping in 11q21** (chr11:95,296,828-95,668,215) proximal to the MAML2 breakpoint region.
- Formamide based hybridization buffer



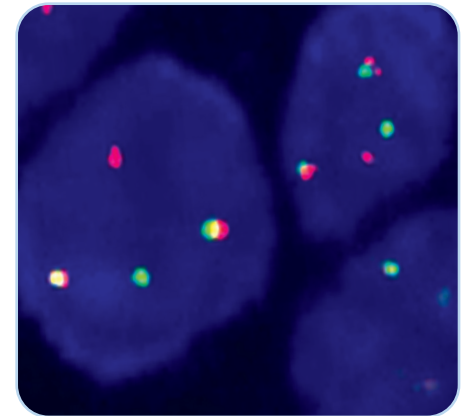
Ideogram of chromosome 11 indicating the hybridization locations.



SPEC MAML2 Probe map (not to scale).

Results

In an interphase nucleus lacking a translocation involving the 11q21 band two orange/green fusion signals are expected representing two normal (non-rearranged) 11q21 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 11q21 locus and one 11q21 locus affected by the translocation specific for mucoepidermoid carcinomas.



Mucoepidermoid carcinoma section with translocation affecting the 11q21 locus as indicated by one separate orange and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2014-50	ZytoLight SPEC MAML2 Dual Color Break Apart Probe CE 0124 IVD	●/●	5 (50 μl)
Z-2014-200	ZytoLight SPEC MAML2 Dual Color Break Apart Probe CE 0124 IVD	●/●	20 (200 μl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		5
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 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