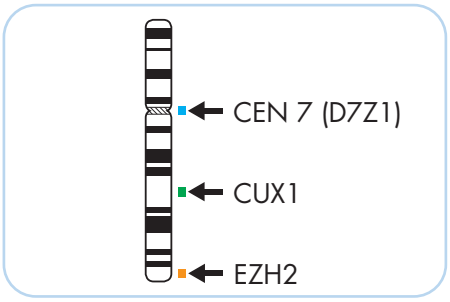
ZytoLight® SPEC CUX1/EZH2/CEN 7 Triple Color Probe

CE 0124
IVD

Background

The ZytoLight® SPEC CUX1/EZH2/CEN 7 Triple Color Probe (PL172) is intended to be used for the qualitative detection of deletions involving the human CUX1 gene and the human EZH2 gene as well as the detection of chromosome 7 alpha satellites in cytological specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Cytology Implementation Kit (Prod. No. Z-2099-20).
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.

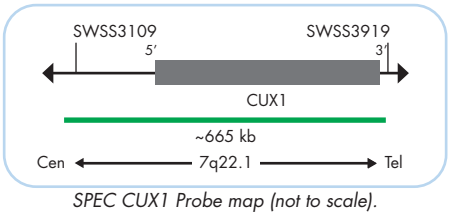


Ideogram of chromosome 7 indicating the hybridization locations.

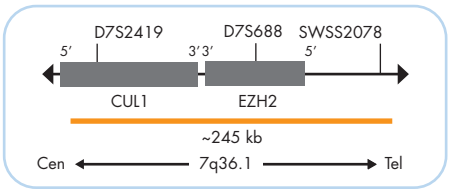
Probe Description

The ZytoLight® SPEC CUX1/EZH2/CEN 7 Triple Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 7q22.1** (chr7:101,270,255-101,934,924) harboring the CUX1 gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 7q36.1** (chr7:148,402,839-148,647,927) harboring the EZH2 gene region.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~12.0 ng/µl), which target sequences mapping in 7p11.1-q11.1 specific for the alpha satellite centromeric region D7Z1 of chromosome 7.
- Formamide based hybridization buffer



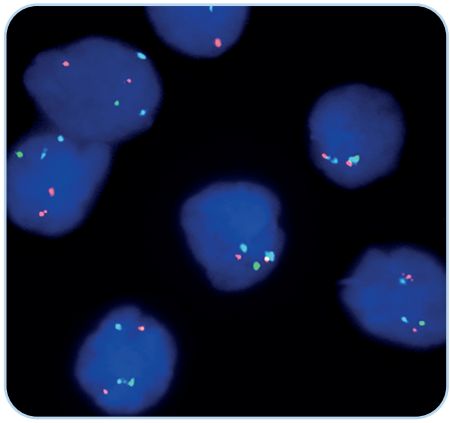
SPEC CUX1 Probe map (not to scale).



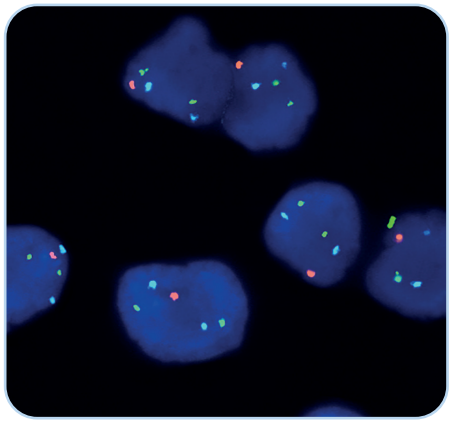
SPEC EZH2 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange, two green, and two blue signals are expected. In a cell with deletions affecting the 7q22.1 and/or 7q36.1 locus, one or no copy of the green and/or orange signal will be observed. Monosomy 7 will result in a loss of a green, orange, and blue signal.



Example of an aberrant signal pattern: Bone marrow smear with deletion of the CUX1 gene as indicated by one green signal in each nucleus.



Example of an aberrant signal pattern: Bone marrow smear with deletion of the EZH2 gene as indicated by one orange signal in each nucleus.

Specimens kindly provided by Paediatric Oncology/Haematology, Charité-Universitätsmedizin Berlin, Germany.

Prod. No.	Product	Label	Tests* (Volume)
Z-2214-50	ZytoLight SPEC CUX1/EZH2/CEN 7 Triple Color Probe CE 0124 IVD	●/●/●	5 (50 µl)
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*