ZytoDot® 2C SPEC 19q13/19p13 Probe

CE 0124
IVD

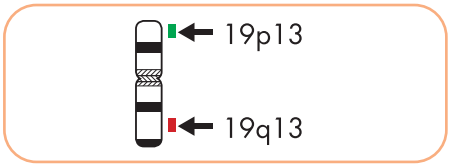
Background

The ZytoDot® 2C SPEC 19q13/19p13 Probe (PD22) is intended to be used for the qualitative detection of deletions involving the human chromosomal region 19q13.32-q13.33 as well as chromosome 19p13.3 specific sequences in formalin-fixed, paraffin-embedded specimens, such as glioma, by chromogenic *in situ* hybridization (CISH). The probes are intended to be used in combination with the ZytoDot® 2C CISH Implementation Kit (Prod. No. C-3044-10/-40).
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 product is intended to be used as an aid to the differential diagnosis of glioma and therapeutic measures should not be initiated based on the test result alone.

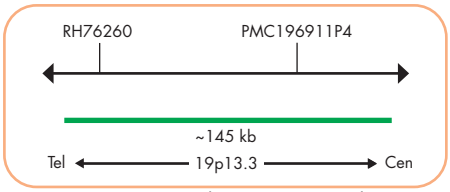
Probe Description

The ZytoDot® 2C SPEC 19q13/19p13 Probe is composed of:

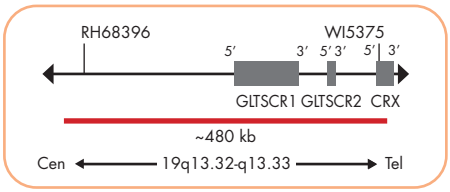
- Dinitrophenyl-labeled polynucleotides (~0.8 ng/µl), which target sequences mapping in 19q13.32-q13.33** (chr19:47,857,776-48,339,398).
- Digoxigenin-labeled polynucleotides (~0.8 ng/µl), which target sequences mapping in 19p13.3** (chr19:815,938-962,244).
- Formamide based hybridization buffer



Ideogram of chromosome 19 indicating the hybridization locations.



SPEC 19p13 Probe map (not to scale).



SPEC 19q13 Probe map (not to scale).

Results

Using the ZytoDot® 2C SPEC 19q13/19p13 Probe in combination with the ZytoDot® 2C CISH Implementation Kit, two red (19q) and two green (19p) signals are expected in a normal interphase nucleus. In a cell with deletions affecting the 19q13 locus, one or no copy of the red signal will be observed.

SPEC 19q13/19p13 Dual Color Probe hybridized to glioma tissue section with 19q13 deletion as indicated by one red signal in each nucleus.

Image kindly provided by Prof. W. Müller, University Leipzig, Germany.

Prod. No.	Product	Label	Tests* (Volume)
C-3037-100	ZytoDot 2C SPEC 19q13/19p13 Probe CE 0124 IVD	DNP/DIG	10 (100 µl)
C-3037-400	ZytoDot 2C SPEC 19q13/19p13 Probe CE 0124 IVD	DNP/DIG	40 (400 µl)
Related Products			
C-3044-10	ZytoDot 2C CISH Implementation Kit CE IVD Incl. Heat Pretreatment Solution EDTA, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 20x Wash Buffer TBS, 50 ml; Anti-DIG/DNP-Mix, 1 ml; HRP/AP-Polymer-Mix,1 ml; AP-Red Solution A, 0.1 ml; AP-Red Solution B, 4 ml; HRP-Green Solution A, 0.2 ml; HRP-Green Solution B, 4 ml; Nuclear Blue Solution, 4 ml; Mounting Solution (alcoholic), 1 ml		10
C-3044-40	ZytoDot 2C CISH Implementation Kit CE IVD Incl. Heat Pretreatment Solution EDTA, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 20x Wash Buffer TBS, 2x 50 ml; Anti-DIG/DNP-Mix, 4 ml; HRP/AP-Polymer-Mix, 4 ml; AP-Red Solution A, 0.4 ml; AP-Red Solution B, 15 ml; HRP-Green Solution A, 0.8 ml; HRP-Green Solution B, 15 ml; Nuclear Blue Solution, 20 ml; Mounting Solution (alcoholic), 4 ml		40

** 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*