ZytoDot® 2C Glioma 1p/19q Probe Set

Intended Purpose

The ZytoDot 2C Glioma 1p/19q Probe Set is intended to be used for the qualitative detection of deletions involving the human chromosomal region 1p36.31 as well as deletions involving the human chromosomal region 19q13.32-q13.33 in formalin-fixed, paraffin-embedded specimens, such as glioma, by chromogenic *in situ* hybridization (CISH). The probe is 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 probe 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 Glioma 1p/19q Probe Set is a set comprising two separate probes:

- ZytoDot 2C SPEC 1p36/1q25 Probe (Prod. No. C-3036-100/-400)
- ZytoDot 2C SPEC 19q13/19p13 Probe (Prod. No. C-3037-100/-400)

The ZytoDot 2C SPEC 1p36/1q25 Probe (PD21) is composed of:

- Digoxigenin-labeled polynucleotides (~1.7 ng/µl), which target sequences mapping in 1q25.3* (chr1:184,562,510-184,752,938) (see Fig. 1).
- Dinitrophenyl-labeled polynucleotides (~1.7 ng/µl), which target sequences mapping in 1p36.31* (chr1:5,808,946-6,176,336) (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

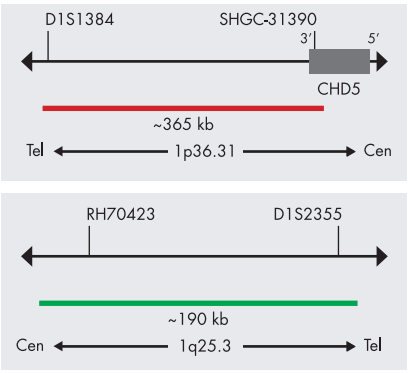


Fig. 1: Top: SPEC 1p36 Probe map; Bottom: SPEC 1q25 Probe map (not to scale)

The ZytoDot 2C SPEC 19q13/19p13 Probe (PD22) is composed of:

- Digoxigenin-labeled polynucleotides (~1.7 ng/µl), which target sequences mapping in 19p13.3* (chr19:815,938-962,244) (see Fig. 2).
- Dinitrophenyl-labeled polynucleotides (~1.7 ng/µl), which target sequences mapping in 19q13.32-q13.33* (chr19:47,857,776-48,339,398) (see Fig. 2).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

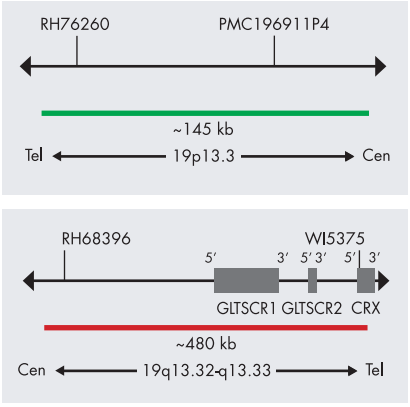
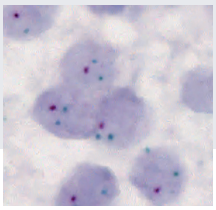


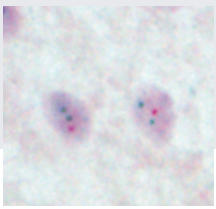
Fig. 2: Top: SPEC 19p13 Probe map; Bottom: SPEC 19q13 Probe map (not to scale)

Results

Normal situation: Using the SPEC 1p36/1q25 Probe or the SPEC 19q13/19p13 Probe in a normal interphase nucleus, two red and two green signals are expected.
Aberrant situation: In a cell with deletions affecting the 1p36 or 19q13 locus, one or no copy of the red signal will be observed.



SPEC 1p36/1q25 Probe hybridized to glioma tissue section with 1p36 deletion as indicated by one red signal in each nucleus.



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

Labels	Contents	Reg. Status	Tests	Order No.
DNP/DIG	ZytoDot 2C SPEC 1p36/1q25 Probe, 0.1 ml; ZytoDot 2C SPEC 19q13/19p13 Probe, 0.1 ml	CE/IVD	10	C-3076-10
	ZytoDot 2C SPEC 1p36/1q25 Probe, 0.4 ml; ZytoDot 2C SPEC 19q13/19p13 Probe, 0.4 ml		40	C-3076-40

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