ZytoDot [®]2^C Products for CISH analysis

ZytoDot ® 2C SPEC EGFR/CEN 7 Probe

Background

The ZytoDot [®] 2C SPEC EGFR/CEN 7 Probe (PD18) is intended to be used for the qualitative detection of amplifications involving the human EGFR gene as well as the detection of chromosome 7 alpha satellites in formalin-fixed, paraffin-embedded specimens 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 various cancers and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoDot®2C SPEC EGFR/CEN 7 Probe is composed of:

- Digoxigenin-labeled polynucleotides (~1.1 ng/µl), which target sequences mapping in 7p11.2** (chr7:55,082,262-55,278,647) harboring the EGFR gene region.
- Dinitrophenyl-labeled polynucleotides (~1.1 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

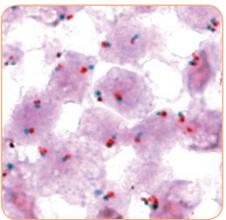
EGFR EGFR CEN 7 (D7Z1) Ideogram of chromosome 7 indicating the hybridization locations. SHGC-148394 3' EGFR 200 lb



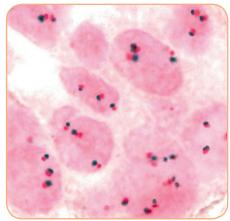
SPEC EGFR Probe map (not to scale).

Results

In a normal interphase nucleus, using the ZytoDot[®] 2C CISH Implementation Kit two green and two red signals are expected. In a cell with amplification of the EGFR gene locus, multiple copies of the green signal or green signal clusters will be observed.



Normal nuclei each with two EGFR (green) and two centromere 7 (red) signals.



Trisomy of chromosome 7 as indicated by three EGFR (green) and three CEN 7 (red) signals in each nucleus.

$\left(\right)$	Prod. No.	Product	Label	Tests* (Volume)
	C-3033-100	Zyto <i>Dot</i> 2C SPEC EGFR/CEN 7 Probe C € IVD	DIG/DNP	10 (100 µl)
	C-3033-400	Zyto <i>Dot</i> 2C SPEC EGFR/CEN 7 Probe C € IVD	DIG/DNP	40 (400 µl)
	Related Prod	ucts		
	C-3044-10	Zyto <i>Dot</i> 2C CISH Implementation Kit C € ™D		10
		Ind. 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		
	C-3044-40	Zyto <i>Dot</i> 2C CISH Implementation Kit C € IVD		40
		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		
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* Using 10 µl probe solution per test. [ND] labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.



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