ZytoDot® 2C SPEC CDK4/CEN 12 Probe

Intended Purpose

The ZytoDot 2C SPEC CDK4/CEN 12 Probe (PD42) is intended to be used for the qualitative detection of amplifications involving the human CDK4 gene as well as the detection of chromosome 12 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 CDK4/CEN 12 Probe is composed of:

- Digoxigenin-labeled polynucleotides (~1,1 ng/µl), which target sequences mapping in 12q13.3-q14.1* (chr12:58,004,553-58,313,271) harboring the CDK4 region (see Fig. 1).
- Dinitrophenyl-labeled polynucleotides (~1,1 ng/µl), which target sequences mapping in 12p11.1-q11 specific for the alpha satellite centromeric region D12Z3 of chromosome 12.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

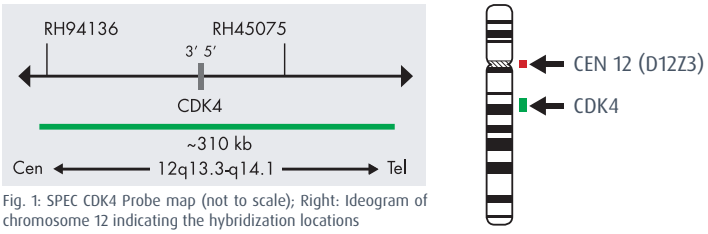
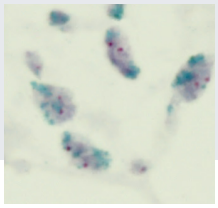


Fig. 1: SPEC CDK4 Probe map (not to scale); Right: Ideogram of chromosome 12 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the CDK4 gene region, two distinct dot-shaped green and two distinct dot-shaped red signals appear.
Aberrant situation: In cells with an amplification of the CDK4 gene region, an increased number of green signals or green signal clusters will be observed.



Example of an aberrant signal pattern: Liposarcoma tissue section with CDK4 amplification as indicated by large green clusters.

Labels	Chromosome	Reg. Status	Tests	Order No.
DIG/DNP	12	CE/IVD	40 (400 µl)	**C-3062-400**

ZytoDot® SPEC MDM2 Probe

Intended Purpose

The ZytoDot SPEC MDM2 Probe (PD9) is intended to be used for the qualitative detection of amplifications involving the human MDM2 gene in formalin-fixed, paraffin-embedded specimens, such as atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLPS) and dedifferentiated liposarcoma (DDLPS), by chromogenic *in situ* hybridization (CISH). The probe is intended to be used in combination with the ZytoDot CISH Implementation Kit (Prod. No. C-3018-40).

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 ALT/WDLPS and DDLPS and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoDot MDM2 Probe is composed of:

- Digoxigenin-labeled polynucleotides (~1,8 ng/µl), which target sequences mapping in 12q15* (chr12:69,190,708-69,430.185) (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

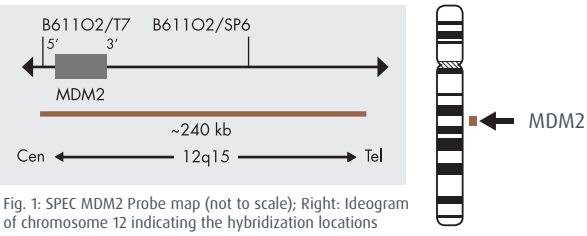
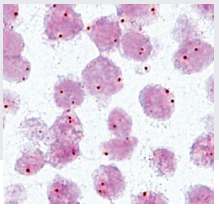


Fig. 1: SPEC MDM2 Probe map (not to scale); Right: Ideogram of chromosome 12 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the MDM2 gene region, two distinct dot-shaped brown signals appear.
Aberrant situation: In cells with an amplification of the MDM2 gene region or aneuploidy of chromosome 12, an increased number of the brown signal or brown signal clusters will be observed.



Normal nuclei each with two MDM2 signals.

Labels	Chromosome	Reg. Status	Tests	Order No.
DIG	12	CE/IVD	40 (400 µl)	**C-3012-400**