

ZytoDot® 2C SPEC CDK4/CEN 12 Probe



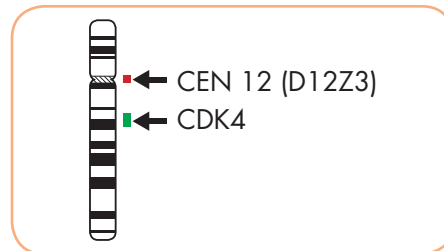
Background

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.

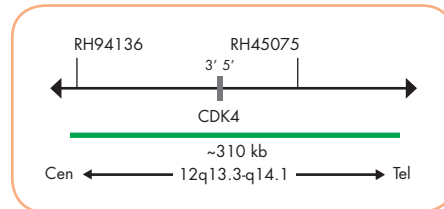
Probe Description

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 gene region.
- 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



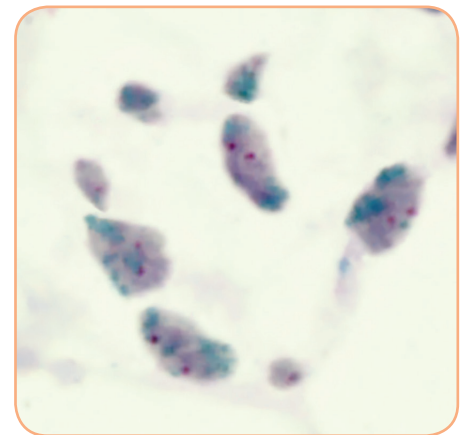
Ideogram of chromosome 12 indicating the hybridization locations.



SPEC CDK4 Probe map (not to scale).

Results

In a normal interphase nucleus, using the ZytoDot® 2C CISH Implementation Kit, two green (CDK4) and two red (CEN 12) signals are expected. In a cell with amplification of the CDK4 gene locus or polysomy of chromosome 12, multiple copies of the green signal or green signal clusters will be observed.



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

Prod. No.	Product	Label	Tests* (Volume)
C-3062-400	ZytoDot 2C SPEC CDK4/CEN 12 Probe CE IVD	DIG/DNP	40 (400 μl)
Related Products			
C-3044-40	ZytoDot 2C CISH Implementation Kit CE 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			

* 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