

ERBB2 Control Slide Set

REF E-4007-2

Σ 2 slides

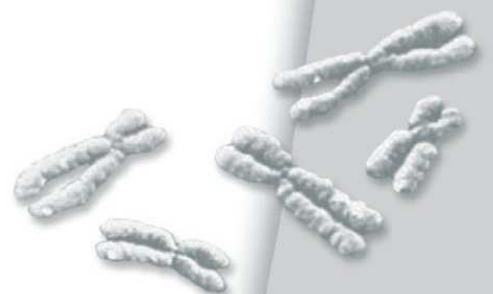
For the detection of ERBB2 gene amplification by
chromogenic *in situ* hybridization (CISH)



IVD

In vitro diagnostic medical device

according to EU directive 98/79/EC



Product Description

- Content:** ERBB2 Control Slide (SC2), consisting of four different cell lines affected by different levels of ERBB2 gene amplification, and one tissue (canine myocardial muscle).
- Product:** E-4007-2 (2 slides)
- Specificity:** The ERBB2 Control Slide (SC2) is designed to be used as a positive control for the detection of ERBB2 gene amplification by chromogenic *in situ* hybridization (CISH).
- Storage/Stability:** The ERBB2 Control Slide (SC2) must be stored at 2...8°C and is stable through the expiry date printed on the label.
- Use:** This product is designed for *in vitro* diagnostic use (according to EU directive 98/79/EC). Interpretation of results must be made within the context of the patient's clinical history with respect to further clinical and pathologic data of patient by a qualified pathologist!
- Safety Precautions:** Read the operating instructions prior to use!
- Although the fixation process renders the slides non-infectious, the user is advised to observe the same safety precautions as for handling/disposing potentially infectious agents!
- Avoid any direct contact with the slides. Take appropriate protective measures (use disposable gloves, protective glasses, and lab garments).

Slide Description

The ERBB2 Control Slide (SC2) consists of four different cell lines, affected by different levels of ERBB2 gene amplification, and one tissue (canine myocardial muscle).

The ERBB2 Control Slide (SC2) should be used for monitoring the correct performance of a CISH experiment for the detection of ERBB2 gene amplification in formalin-fixed, paraffin-embedded tissues. For use as an on-slide control simply mount a tissue sample of interest next to the cell lines of the ERBB2 Control Slide (SC2) before baking the slide.

Source: Mammalian cell lines containing human ERBB2 gene sequences, and canine myocardial muscle tissue

Fixative: 10% neutrally buffered formalin (24 h, pH 7.0)

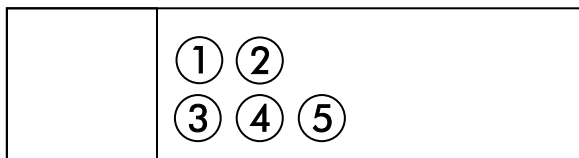
Embedding: Paraffin, red-colored

Thickness: 4 μm

Mounting: Positively charged slides

Pretreatment: Pre-baked for 15 min at 58°C

Design:



1: no ERBB2 amplification, 1-2 gene copies per nucleus

2: no ERBB2 signals

3: no ERBB2 amplification, 1-2 gene copies per nucleus

4: low level ERBB2 amplification, 3-6 gene copies per nucleus

5: high level ERBB2 amplification, large cluster per nucleus

Instructions

- 1.** Remove label of the ERBB2 Control Slide (SC2) and label slide with a pencil
- 2.** For on-slide control mount tissue sample of interest
- 3.** Bake slide at 60°C for a minimum of 2 h up to 16 h

Pre-treatment (dewaxing, proteolysis, post-fixation) should be carried out according to the needs of the user.

For a particularly user-friendly performance, we recommend the use of a *ZytoDot* CISH system by ZytoVision.

Results

When using appropriate ERBB2 probes, a positive staining can be obtained on the different spots of the ERBB2 Control Slide (SC2), as for example two dot-shaped ERBB2 signals in a nucleus of a cell line not affected by an ERBB2 gene amplification. If the cells on the ERBB2 Control Slide (SC2) fail to show a positive staining, results of test samples should be considered as being invalid. In case of cross-reaction using an ERBB2 probe please alter washing steps and/or increase stringency of hybridization/washing.

Our experts are available to answer your questions.

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Trademarks:

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ZytoVision GmbH · Fischkai 1
D - 27572 Bremerhaven · Germany
Phone: +49 (0) 471/4832 - 300
Fax: +49 (0) 471/4832 - 509
www.zytovision.com
info@zytovision.com



Your local distributor