ZytoFast® Ig-kappa/Ig-lambda CISH System

Intended Purpose

The Zyto*Fast* Ig-kappa/Ig-lambda-CISH System is intended to be used for the qualitative detection of human Ig-kappa (κ) and Ig-lambda (λ) light chain mRNA in formalin-fixed, paraffin-embedded specimens, such as multiple myeloma, by chromogenic *in situ* hybridization (CISH).

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 product is intended to be used as an aid to the differential diagnosis of multiple myeloma and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Fast* human Ig-kappa Probe (PF30) is composed of:

- Digoxigenin-labeled oligonucleotides (~ 0.2 ng/µl), which target mRNA sequences encoding Ig-kappa light chain constant regions.

The Zyto*Fast* human Ig-lambda Probe (PF31) is composed of:

- Digoxigenin-labeled oligonucleotides (~ 0.2 ng/µl), which target mRNA sequences encoding Ig-lambda light chain constant regions.

The Zyto*Fast* human Ig-kappa/Ig-lambda Probe (PF22) is composed of:

- Digoxigenin-labeled oligonucleotides (~ 1 ng/µl), which target mRNA sequences encoding Ig-kappa light chain constant regions.
- Biotin-labeled oligonucleotides (~ 1ng/µl), which target mRNA sequences encoding Ig-lambda light chain constant regions.

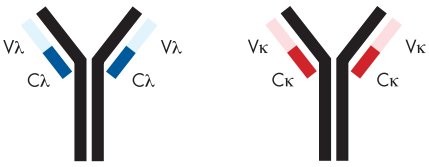


Fig. 1: Basic immunoglobulin structure indicating the heavy chains (black), l (blue) and k (red) lights chains. The light chain constant regions (C) whose encoding mRNA sequences are targeted by Zyto*Fast* Ig-lambda and Ig-kappa probes are indicated in dark blue and red respectively, the variable regions (V) in light blue and red.

Results

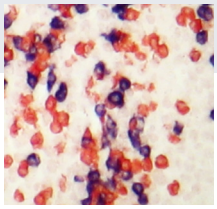
A positive reactivity in the target cells is indicated by cytoplasmic staining. Depending on the detection chemistry that is used, colored precipitates, which can be clearly distinguished from the background, will be dark violet-blue when using NBT/BCIP as substrate, strong red when using AEC, dark brown when using DAB, green when using HRP-Green, or strong red when using Permanent Red.

Using the Zyto*Fast* human Ig-kappa Probe, B-cells expressing antibodies with κ light chains will result in cytoplasmic staining whereas IGL expressing B-cells are not stained.

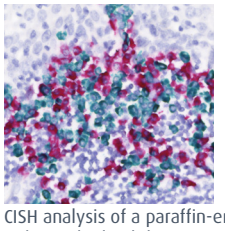
Using the Zyto*Fast* human Ig-lambda Probe, B-cells expressing antibodies with λ light chains will result in cytoplasmic staining whereas IGK expressing B-cells are not stained.

Using the Zyto*Fast* human Ig-kappa/Ig-lambda CISH Kit, B-cells expressing antibodies with κ light chains will result in a red cytoplasmic staining and simultaneously IGL expressing B-cells will result in a dark violet-blue cytoplasmic staining.

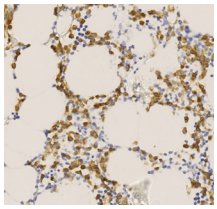
Using the Zyto*Fast* human Ig-kappa/Ig-lambda Permanent CISH Kit, B-cells expressing antibodies with κ light chains will result in a green cytoplasmic staining and simultaneously IGL expressing B-cells will result in permanent red cytoplasmic staining.



CISH analysis of a paraffin-embedded bone marrow biopsy specimen using the Zyto*Fast* human Ig-kappa/Ig-lambda CISH Kit.



CISH analysis of a paraffin-embedded tonsil tissue using the Zyto*Fast* human Ig-kappa/Ig-lambda Permanent CISH Kit.



Multiple myeloma tissue with B-cells expressing Ig-kappa hybridized with Zyto*Fast* human Ig-kappa Probe, detected with Zyto*Fast* PLUS CISH Implementation Kit HRP-DAB.

Digoxigenin-labeled Probes

Product Name	Reg. Status	Tests	Order No.
Zyto*Fast* human Ig-kappa Probe	CE/IVD	40 (400 µl)	**T-1115-400**
Zyto*Fast* human Ig-lambda Probe	CE/IVD	40 (400 µl)	**T-1116-400**

Biotin-/Digoxigenin-labeled Probes and Probe Kits

Product Name	Reg. Status	Tests	Order No.
Zyto*Fast* human Ig-kappa/Ig-lambda Probe	CE/IVD	40 (400 µl)	**T-1017-400**
Zyto*Fast* human Ig-kappa/Ig-lambda CISH Kit Incl.: Ig-kappa/Ig-lambda Probe (DIG/Biotin-labeled), 0.4 ml; Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 2x 50 ml; Anti-Biotin/DIG-Mix, 4 ml; AEC Solution, 4 ml; NBT/BCIP Solution, 4 ml; Nuclear Green Solution, 20 ml; Mounting Solution (aqueous), 4 ml	CE/IVD	40	**T-1005-400**
Zyto*Fast* human Ig-kappa/Ig-lambda Permanent CISH Kit Incl: Ig-kappa/Ig-lambda Probe (DIG/Biotin-labeled), 0.4 ml; Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 2x 50 ml; Anti-Biotin/DIG-Mix, 4 ml; HRP-Green-Solution A, 0.8 ml; HRP-Green-Solution B, 15 ml; Permanent Red Solution A, 0.25 ml; Permanent Red Solution B, 15 ml; Nuclear Blue Solution, 20 ml; Mounting Solution (alcoholic), 4 ml	CE/IVD	40	**T-1105-400**