# ZytoLight® SPEC ERG/TMPRSS2 TriCheck™ Probe

CE IVD

## Background

The ZytoLight® SPEC ERG/TMPRSS2 TriCheck™ Probe (PL92) is intended to be used for the qualitative detection of rearrangements involving the human ERG gene at 21q22.2 and the human TMPRSS2 gene at 21q22.3 in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-20).

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.

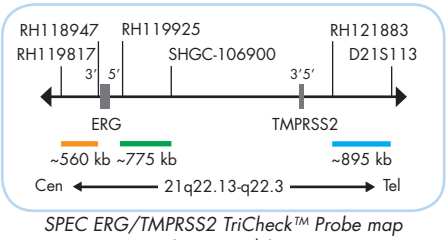
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.


*Ideogram of chromosome 21 indicating the hybridization locations.*

## Probe Description

The ZytoLight® SPEC ERG/TMPRSS2 TriCheck™ Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 21q22.2** (chr21:40,078,039-40,850,582) distal to the ERG breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 21q22.13-q22.2** (chr21:39,171,790-39,733,849) proximal to the ERG breakpoint region.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~37.0 ng/µl), which target sequences mapping in 21q22.3** (chr21:43,301,411-44,195,531) distal to the TMPRSS2 breakpoint region.
- Formamide based hybridization buffer




*SPEC ERG/TMPRSS2 TriCheck™ Probe map (not to scale).*

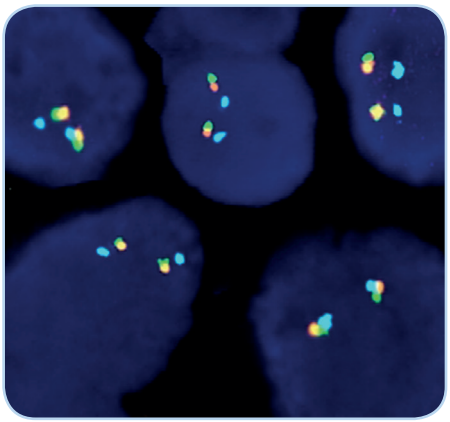
## Results

In a normal interphase nucleus, two orange/green fusion signals and two blue signals in close proximity of the respective fusion signals are expected representing two normal (non-rearranged) 21q22.13-q22.3 loci.

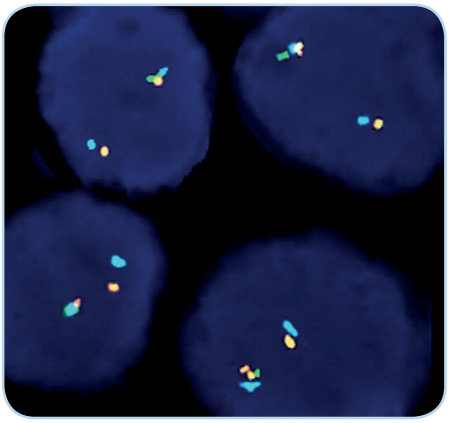
One 21q22 locus affected by a 21q22.2 deletion resulting in the TMPRSS2-ERG fusion is indicated by one separate orange signal co-localizing with one blue signal, and the loss of one green signal.

An ERG translocation without involvement of TMPRSS2 is indicated by a separated orange signal and a blue signal co-localizing with the separate green signal.

A non-ERG translocation affecting TMPRSS2 is indicated by a separated blue signal not co-localizing with the ERG fusion signal.



*SPEC ERG/TMPRSS2 TriCheck™ Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals and two blue signals in close proximity of the respective fusion signals.*



*Example of an aberrant signal pattern: Prostate cancer tissue section with one 21q22 locus affected by an interstitial deletion of the chromosomal region 21q22.2 resulting in the TMPRSS2-ERG fusion as indicated by one separate orange signal co-localizing with one blue signal, and the loss of one green signal.*

| Prod. No. | Product | Label | Tests* (Volume) |
|---|---|---|---|
| Z-2135-200 | ZytoLight SPEC ERG/TMPRSS2 TriCheck Probe CE IVD | ●/●/● | 20 (200 µl) |
| **Related Products** | | | |
| Z-2028-20 | ZytoLight FISH-Tissue Implementation Kit CE IVD<br>Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml | | 20 |

** 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*