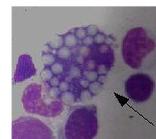


## 2. LIPSGENE® – GENE EXPRESSION QUANTIFICATION



### LIPSGENE® Survivin Kit

#### Intended use

The LIPSGENE® Survivin cDNA Quantification Kit is intended for *in vitro* quantification of total *survivin* transcripts (Inhibitor of Apoptosis [IAP] family), including all known splice variants, in total RNA/mRNA samples. *Survivin* is undetectable in terminally differentiated adult tissues and normal peripheral blood mononuclear cells, whereas it becomes prominently expressed in transformed cell lines and in all the most common human cancers of lung, colon, pancreas, prostate, breast and adult T-cell leukaemia *in vivo*. *Survivin* expression was shown to be a new unfavourable prognostic factor of *de novo* AML and soft tissue sarcoma (STS). An inverse correlation between the level of *survivin* mRNA (ratio >2 zmol *survivin*/amol GAPDH) in STS and the rate of overall survival was found associated with a 2.7-fold increased risk to die of the tumour. Co-expression of *survivin* and human *telomerase reverse transcriptase (TERT)* has been shown to be a significant negative prognostic factor for patients with stage I to stage IV soft tissue sarcoma with a 20-fold increased relative risk to die of the tumour.

#### Kit contents

- ✓ Lyophilized oligonucleotide mix containing *survivin* cDNA specific primers and probes, PCR vessels containing stabilized synthetic *survivin* standard DNA (ready-to-use reference curves), sample PCR tubes (shipped at room temperature or together with taq polymerase on dry ice).
- ✓ Taq Polymerase, 10x PCR buffer, 50 mM Mg-chloride solution, PCR grade water, 10x ROX (shipped on dry ice).
- ✓ Sufficient to run 120 tests.

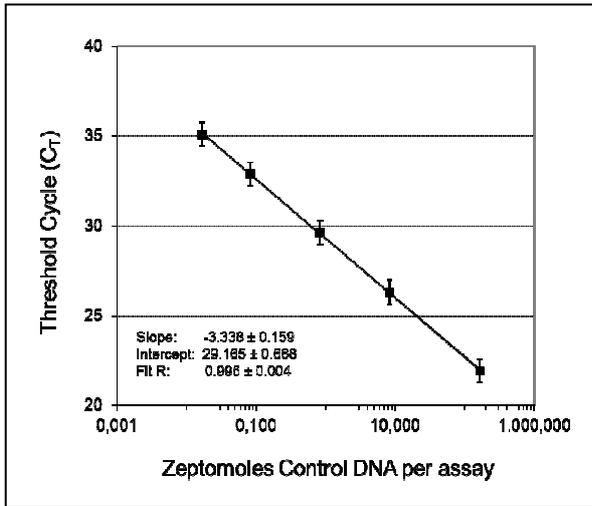
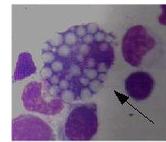
*Note: Reverse transcription reagents available with a separate kit (M-MLV Reverse Transcription Kit, Cat.no. 1050001XX-050).*

#### Performance assessment

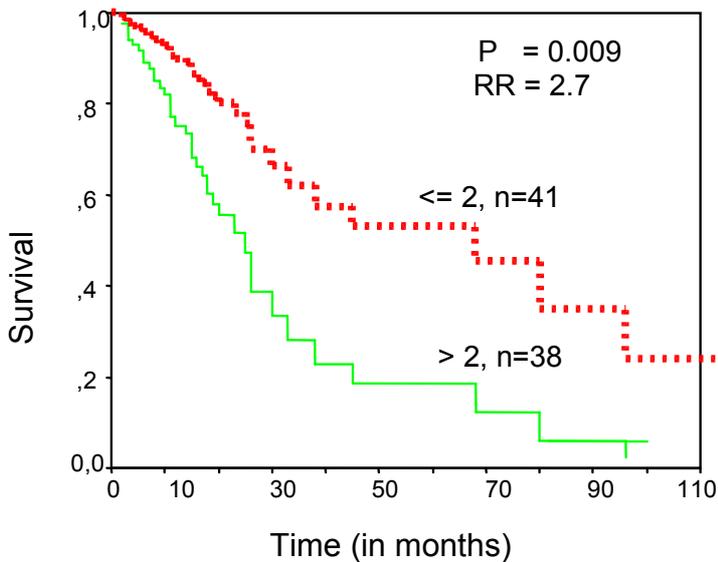
The LIPSGENE® Survivin Kit was evaluated together with cDNA obtained from 76 frozen primary tumour samples of 79 adult soft tissue sarcoma (STS) patients (before an adjuvant treatment was initiated). The kit was evaluated according to the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic <i>survivin</i> DNA	≥5 copies/run
Linear range	Synthetic <i>survivin</i> DNA	>5 logs

## 2. LIPSGENE<sup>®</sup> – GENE EXPRESSION QUANTIFICATION



**Figure 2.15:** Repeatability of *survivin* cDNA quantification assay. The study was performed with synthetic *survivin* DNA specimen and 67 replicates for each concentration (ready-to-use *survivin* DNA standards; 166.113, 8.306, 0.831, 0.083, 0.017 zmol per tube) on ABI PRISM SDS. The mean run data are included in the figure.



**Fig. 2.16:** Multivariate Cox model for *survivin* mRNA overexpression and survival in STS patients. Curves of patients with a *survivin* mRNA expression  $\leq 2$  (zmol *survivin*/amol *GAPDH*) (dashed line; n=41) and patients with a *survivin* mRNA expression  $> 2$  (zmol *survivin*/amol *GAPDH*) (solid line; n=38) are significantly different (P=0.009). A relative hazard of 2.7 is associated with *survivin* mRNA expression  $> 2$  (zmol *survivin*/amol *GAPDH*) in a multivariate Cox model adjusted to staging, to tumour entity, tumour localization and type of tumour. Data kindly provided by M. Kappler & T. Köhler, results published in Int. J. Cancer 2001, 95: 360-363.

### Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	-	-	-	-
120 tests	1030111RP-120	1030111ST-120	1030111LP-120	-	-	-	-

**RP** = 0.2 ml regular profile 8-well/strip PCR tubes and cap strips (e.g. ABI PRISM<sup>®</sup> 7000/7300/7700 SDS [Applied Biosystems/Life Technologies], iCycler IQ<sup>™</sup>; IQ5 [Bio-Rad], MX3000P, Mx3005P [Stratagene]; Mastercycler<sup>®</sup> ep realplex [Eppendorf]); **ST** = Single 0.2 ml PCR Tube with attached cap (e.g. Rotor-Gene<sup>™</sup> 3000/6000, Rotor-Gene Q [Qiagen]; LineGene K [Bioer]); **LP** = 0.1 ml low profile 8-well/strip PCR tubes and cap strips (e.g. , 7500 Fast [Applied Biosystems/Life Technologies], MiniOpticon<sup>™</sup>, CFX-96 [Bio-Rad]); **LC** = 20 µl LightCycler glass capillaries (LightCycler 2.x, Roche); **SC** = 25 µl SmartCycler tubes (e.g. SmartCycler<sup>®</sup> [Cepheid]); **SP** = 20 µl DX-12 reaction tubes (Spartan Dx-12); **RS** = 0.1 ml 4-well tube/strips (Rotor-Gene<sup>™</sup> 3000/6000, Rotor-Gene Q [Qiagen]).