Clinical implications

Chronic lymphocytic leukemia (CLL) occurs mostly in elderly people (median age 65 years) and is the most common leukemia in Europe and North America where CLL comprises of about 30 % of leukemic diseases of adults. The frequency of CLL is approximately two-times higher in men than in women. IGHV mutational status analysis helps to better predict disease progression and patient survival. Somatic hypermutation of IGHV is the physiological process that leads to an increase in antibody diversity. In patients with mutated IGHV, better prognosis with a slower progression of disease and a longer patient´s survival can be observed. In those with unmutated IGHV a worse clinical course and prognosis can be expected.

Principle of detection

Kit is intended for prognosis assessment in CLL patients by analysis of cDNA (reverse transcribed RNA) samples of human B lymphocytes obtained from peripheral blood. The kit is based on **reverse transcription together with quantitative real-time polymerase chain reaction (qRT-PCR) using fluorescently labelled probes**. The kit contains all components necessary for analysis of gene expression. Two of six genes are housekeeping genes (*B2M, HPRT1*) and three of them are target genes *(LPL, ZAP70* and *COBLL1*). The remaining gene *CD3D* serves as contamination marker (sample contamination by T lymphocytes).

CE IVD

Available products

Cat. No.	Product	Number of tests
3240-010	gb ONCO CLL	10

1 kit contains reagents to provide 30 PCR reactions (20 µl volume of each reaction) – test for 10 patients.

Parameters of the diagnostic kit

- ***in vitro* diagnostics**
- **CE IVD marked**
- **ready-to-use assays**
- **RNA input 500–1000 ng**
- **reverse transcription reagents included**
- **negative and positive controls included**
- **FAM channel detection**

Content of the diagnostic kit

*	Component	Conc.	Purpose
●	Mix 1 – Rev transcription	2×	RNA transcription
●	Mix 2 – Rev transcription	2×	RNA transcription
●	Assay qPCR B2M	1.25×	Detection assay
●	Assay qPCR HPRT1	1.25×	Detection assay
●	Assay qPCR CD3D	1.25×	Detection assay
●	Assay qPCR LPL	1.25×	Detection assay
●	Assay qPCR ZAP70	1.25×	Detection assay
●	Assay qPCR COBLL1	1.25×	Detection assay
●	Positive control G		Positive Control
●	Positive control B		Positive Control
●	Deionized water		Negative Control

** Lid colour*

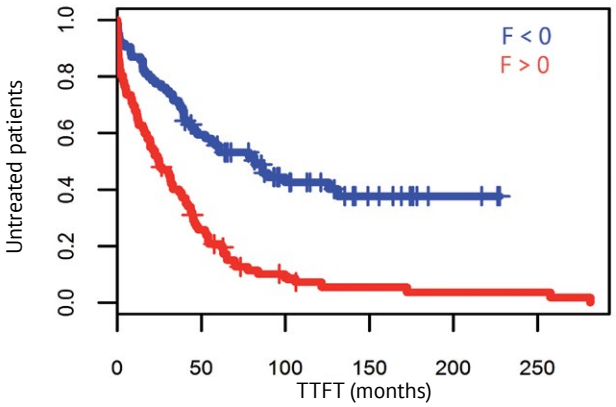

Fig. 1 - The efficiency of the method was experimentally verified on a set od 187 patients with CLL. The success rate of the inclusion of patients in the favorable or unfavorable prognosis is depending on the time until the first treatment (TTFT) is evaluated. the final patient differention (using the RT qPCR method) into the group with favorable or unfavorable prognosis of the disease is shown in the figure.

Validated for cyclers

- Rotor-Gene 3000/6000/Q (Corbett Research, Qiagen)
- iCycler iQ5/CFX96/CFX96 Touch (Bio-Rad)
- ABI 7300/7900HT (Applied Biosystems)
- AriaMx (Agilent Technologies)
- MIC (Bio Molecular Systems)

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