RESULTS

The level of sensitivity was established on mutated RNA from positive patients diluted into negative cell line RNA (HL-60).

Level of sensitivity bcr1: 10^-3

Level of sensitivity bcr3: 10^-4

Level of sensitivity bcr2: 10^-5

SENSITIVITY

The assays specificity was established on negative PML-RARα RNA extracted from 8 cell lines.

Specificity

COMPARISON ON STANDARD RT-PCR ON CLINICAL SAMPLES

The PML-RARα RT-LAMP assays were validated on RNA obtained from 34 clinical samples previously diagnosed at Ospedali Riuniti di Bergamo by using conventional RT-PCR (Biomed) [10].

RT-LAMP RESULTS

RT-PCR RESULTS

References:

CONCLUSIONS

The fluorescent RT-LAMP assays for PML-RARα fusion transcripts detection is highly specific, sensitive and rapid. The isothermal single-step format, starting from patients RNA and monitorable in real-time, simplifies the entire reaction set-up and makes the assay cost-effective and applicable in not highly specialized laboratories.

RT-LAMP could shorten the time to diagnosis for patient affected by APL thus reducing the risk of hemorrhagic complications by an early treatment administration.

100% specificity on 300 replicates, validated through IC

100% agreement with conventional RT-PCR on 96 clinical samples