A Novel Method to Predict the Outcome of Chronic Lymphocytic Leukemia

A simple and robust in vitro DNA-based diagnostic assay to aid in determining the prognosis of patients with chronic lymphocytic leukemia (CLL).

Problem Solved by This Technology
CLL is the most common lymphoid malignancy and its prognosis is highly variable. Currently, several parameters are used to suggest prognosis, such as CD 38, ZAP-70, and the immunoglobulin (IGH) genes; however, each method has its inherent drawbacks, such as unreliability or impracticability in most clinical laboratories.

Applications
This assay developed at the University of Rochester assesses the mutation status of the IGH intronic regions, in addition to the typically sampled IGH coding regions. It comprises amplifying the IGH regions by multiplex PCR and sequencing the PCR products. The primer system allows expressed (productively rearranged) and non-expressed IGH alleles to be easily distinguished. Further, the PCR products can be directly used for sequencing. This assay has been successfully performed on 55 CLL patients and demonstrated that the presence of mutations in the intronic regions serves as a robust discriminator of coding region mutation, and thus are prognostic.

Unlike the existing tests, this test is reliable, robust, fast, and very feasible in a clinical lab setting. In contrast to most other assays which use RNA as the analyte, this test uses genomic DNA and so is reliable when used on a very wide range of specimen types ranging from fresh/frozen, formalin-fixed paraffin-embedded, to even air dried smears. The test result is unambiguous and easy to interpret. A diagnostic test kit can be readily assembled and distributed.

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