



A Novel and Quantitative Diagnostic Assay for Nucleic Acid-Based Markers

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Technology Summary

There is a current need for fast, easy, and precise ways to diagnose patients in order to give them the most effective and appropriate treatments for their disease. One particular method of diagnosis is to detect and measure the abundance of a specific segment of genetic material in an accessible biological sample, i.e. DNA or RNA, which would serve as a marker of disease status. This would allow one to identify the genetic basis of disease, identify pathogens, and monitor the effectiveness of therapies for both infectious and non-infectious diseases. Typically, most DNA or RNA-based detection methodologies utilize nucleic acid amplification procedures such as the polymerase chain reaction (PCR), with various means for detecting specific amplified sequences, including the use of labeled probes that hybridize to the sequence of interest.

Our investigators have developed a rapid and sensitive assay using real-time PCR and molecular beacons to detect and measure the copy number of a specific nucleic acid sequence and another sequence that is determined to be its genomic equivalent. The ratio of the target sequence to its genomic equivalent allows one to quantitatively measure the abundance of the target sequence per cell. This methodology allowed our scientists to quantify residual viral replication in HIV-infected patients with undetectable viremia after antiviral therapy, thus allowing them to determine future management strategies for their treatment. This technology could be easily applied to the diagnosis of any disease where the markers are nucleic acid sequences.

Advantage

This technology allows for the development of a test that is rapid, sensitive, quantitative and accurate. These attributes are highly desirable in a clinical diagnostic test.

Area of Application

Diagnostics tests for the status of any disease where the diagnostic markers are based on a particular DNA or RNA sequence of interest.

Stage of Development

This methodology has been successfully tested on viral mRNAs isolated from peripheral blood mononuclear cells (PBMCs) from humans.

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Patent Information

U.S. Patent 6,235,504 B1 (issued May 22, 2001)

References

Lewin, *et al.* 1999. Use of real-time PCR and molecular beacons to detect virus replication in human immunodeficiency virus type-1-infected individuals on prolonged effective anti-retroviral therapy. *J. Virol.* 73:6099-6103.

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