



## LabCorp's National Genetics Institute Receives FDA Approval for Nucleic Acid Tests for HCV and HIV-1

September 21, 2001

BURLINGTON, N.C., Sep 21, 2001 /PRNewswire/ -- Laboratory Corporation of America(R) Holdings (NYSE: LH) (LabCorp(R)) today announced that its National Genetics Institute Inc. (NGI) had its Biologics License Applications for the UltraQual(TM) HCV RT-PCR and UltraQual(TM) HIV-1 RT-PCR assays approved by the U. S. Food and Drug Administration (FDA). NGI's UltraQual(TM) assays for HCV and HIV-1 are the first nucleic acid amplification tests (NAT) to be approved by the FDA for donor screening and will result in earlier detection of HCV or HIV-1 infection in plasma donors as well as increase the overall safety of plasma derived products. The FDA has also approved the use of the NGI UltraQual(TM) HIV-1 RT-PCR assay in combination with approved pooling algorithms as an alternative to currently licensed HIV-1 p24 antigen tests for the screening of Source Plasma.

When used in combination with FDA approved pooling and resolution algorithms, NGI's UltraQual(TM) HCV RT-PCR and UltraQual(TM) HIV-1 RT-PCR assays are indicated for the qualitative detection of Hepatitis C Virus (HCV) and Human Immunodeficiency Virus, type 1 (HIV-1) nucleic acids in pools of human Source Plasma comprised of equal aliquots of not more than 512 individual plasma samples respectively.

"Our NGI laboratory team has once again demonstrated outstanding scientific leadership by becoming the first clinical laboratory to have these important assays approved by the FDA," said Myla P. Lai-Goldman, M.D., executive vice president, chief scientific officer and medical director. "These tests represent a totally new and innovative approach to screening plasma donations. In addition to enhanced product safety, these extremely sensitive assays allow us to test large numbers of donations in a very efficient manner when used in combination with complex pooling algorithms. We look forward to employing these assays with Alpha Therapeutic Corporation, which has simultaneously received approval by the FDA to combine its pooling and resolution algorithms with LabCorp/NGI's newly approved assays."

The first national clinical laboratory to fully embrace genomic testing, Laboratory Corporation of America(R) Holdings (LabCorp(R)) has been a pioneer in commercializing new diagnostic technologies. As a national laboratory with annual revenues of \$1.9 billion in 2000 and over 18,000 employees, the company offers more than 4,000 clinical tests ranging from simple blood analyses to sophisticated molecular diagnostics. Serving over 200,000 clients nationwide, LabCorp leverages its expertise in innovative clinical testing technology with its Centers of Excellence. The Center for Molecular Biology and Pathology, in Research Triangle Park, North Carolina, offers state-of-the-art molecular gene-based testing in infectious disease, oncology and genetics. Its National Genetics Institute in Los Angeles is an industry leader in developing novel, highly sensitive polymerase chain reaction (PCR) methods for testing hepatitis C and other blood borne infectious agents. LabCorp's Minneapolis-based Viro- Med offers molecular microbial testing using real time PCR platforms, while its Center for Esoteric Testing in Burlington, North Carolina, performs the largest volume of specialty testing in the network. LabCorp's clients include physicians, state and federal government, managed care organizations, hospitals, clinics, pharmaceutical and Fortune 1000 companies, and other clinical laboratories.

Each of the above forward-looking statements is subject to change based on various important factors, including without limitation, competitive actions in the marketplace and adverse actions of governmental and other third-party payors. Further information on potential factors that could affect LabCorp's financial results is included in the Company's Form 10-K for the year ended December 31, 2000 and subsequent SEC filings.

MAKE YOUR OPINION COUNT - [Click Here](http://tbutton.prnewswire.com/prn/11690X04068992)  
<http://tbutton.prnewswire.com/prn/11690X04068992>

### SOURCE Laboratory Corporation of America Holdings

CONTACT: Pamela Sherry of Laboratory Corporation of America Holdings,  
+1-336-436-4855, or [Investor@labcorp.com](mailto:Investor@labcorp.com), or shareholder direct,  
+1-800-LAB-0401