



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

May 7, 2007

Donald Rex Simpson, M.D., Ph.D.
National Genetics Institute
2440 So Sepuleveda #130
Los Angeles, CA 90064

PFI 5828 & 7184

Dear Dr. Simpson:

Thank you for submitting portions of your standard operating procedure manual and validation data needed to evaluate your method to test for HIV - 1 RNA in pooled plasma from clinical patients for diagnostic purposes using RT PCR. After carefully evaluating all the information provided, the department's reviewer has found your validation data for this test acceptable. You may offer this assay under your current permit in the category of Human Immunodeficiency Virus - Viral Identification. The patient report must include information on any limitations of the assay as evidenced by the validation studies and if applicable, the disclaimer required by the FDA for the use of analyte specific reagents (ASR).

Since this method currently does not require oversight by the Food and Drug Administration, please retain this letter to verify that the procedure for this test has been submitted to and approved by this department. Please note that any modifications of your present test methods must be immediately forwarded to this office for evaluation by the program's professional staff. You will be informed if additional validation studies are required to support the modifications of your procedure. This approval is for an indefinite period, subject to successful completion of any on-site surveys and compliance of your laboratory with regulatory requirements.

If you have any questions or require further information, please contact either Beth Johansen at 518-402-4064 or Michael Neal at 518-402-4110. Additionally, they can be contacted by e-mail at CLEPCERT@health.state.ny.us

Sincerely,

Adam N. Nagy, Ph.D.
Head, Technical Development Unit
Clinical Laboratory Evaluation Program

BAC

cc: Reviewer
A Roque
Geri Cox