



January 11, 2013

National Genetics Institute
Attention: Ms. Geri Cox
2440 S. Sepulveda Blvd., Suite 235
Los Angeles, CA 90064-1748

Dear Ms. Cox:

We have approved your request to supplement your biologics license applications to include a proposal for a new method to detect HCV- and HIV-1-specific amplicons generated by NGI's UltraQual HCV and HIV-1 RT-PCR Assays. The proposed change in detection method is to discontinue Southern blotting combined with immunoblotting and employ a detection method based on probe-coupled bead technology using the Bio-Rad Bio-Plex Suspension Array System. The following biologics license application supplements are included:

STN	Name of Biological Product
BL 103868/5094	Hepatitis C Virus (Hepatitis C Virus/Nucleic Acid Pooled Testing/Synthetic)
BL 103902/5089	Human Immunodeficiency Virus Type 1 (HIV-1/Nucleic Acid Pooled Testing/Synthetic)

We will include information contained in the above-referenced supplements in your biologics license application files.

Sincerely yours,

Hira L. Nakhasi

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics
Evaluation and Research