Development of a Genotyping Assay for HIV-1 Integrase Compatible with Globally Available IVD Platforms

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Abstract

Background: With recent regulatory approval of the first INI, a genotyping application to detect HIV-1 proviral IN polymorphisms is sought. IN polymorphism analysis is an emerging technique that can provide additional drug resistance information beyond that of conventional protease and reverse transcriptase assays. Applicability to other platforms, based on dideoxynucleotide sequencing, was also demonstrated. In this study, we report use of Primer Sets Optimized for Specific Platforms and Uses. Complete IN sequences were generated for 100% of the samples. Subtype and Clinical Subtyping tool analysis is provided for complete IN sequence data. The GenoType® Gold IN assay is currently used for research.

Materials and Methods: Oligonucleotide primers were designed to produce a 1.2 kb RT-PCR product and to amplify a 1.5 kb RT-PCR product. Three primer sets were used: Primers 1 (v1.5) amplify a 1.5 kb region that includes protease and portions of HIV-1 gag and env genes. The current TRUGENE HIV-1 Assay (for in vitro diagnostic use) RT-PCR primers amplify a 1.2 kb region. The AmpliChip® HIV-1 Assay commercially available from Illumina uses primers that span the gag, pol, and env regions. Alternatively, a single pair covering the majority of mutations considered clinically significant. Data were generated from 50–400 RNA copies/mL. The data were generated from 50–400 RNA copies/mL. The data were generated from 50–400 RNA copies/mL. The data were generated from 50–400 RNA copies/mL.

Results: 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated. 96 plasma samples from primary collection tubes and was demonstrated.

Conclusions: With recent regulatory approval of the first INI, a genotyping application to detect HIV-1 proviral IN polymorphisms is sought. IN polymorphism analysis is an emerging technique that can provide additional drug resistance information beyond that of conventional protease and reverse transcriptase assays. Applicability to other platforms, based on dideoxynucleotide sequencing, was also demonstrated. In this study, we report use of Primer Sets Optimized for Specific Platforms and Uses. Complete IN sequences were generated for 100% of the samples. Subtype and Clinical Subtyping tool analysis is provided for complete IN sequence data. The GenoType® Gold IN assay is currently used for research.

References: