Comparison of Trofile® and ViroTectTropism Assays in Treatment-Experienced Subjects
Regis Vilchez, Julie Strizki, Jorge Quiroz, Lisa Dunkle, and Wayne Greaves
Schering-Plough Research Institute, Kenilworth, NJ, USA

Methods: Comparative tropism was determined independently using the standard ‘Trofile®’ (Monogram Biosciences) and ViroTectTropism™ (Invirion Diagnostics) assays on plasma and whole blood samples obtained from 300 treatment-experienced subjects within 1-2 days of sample collection. Whole blood and plasma samples were tested in duplicate. Flow cytometry was performed on frozen whole blood samples, and on 100% plasma using prediluted reagents expressing predetermined dilutions. The monoclonal antibodies used were specific for expression of the coreceptors used by the two assays. The results of the ViroTectTropism assay were not subject to any dilution. The determination of the homogeneity of the marginal distributions of two assays to compare the results of tropism determinations by the Trofile® and ViroTectTropism™ assays is an ongoing study.

Results: Among the 300 samples tested, 58 (19%) inconclusive results were reported by Trofile® and 50 (17%) by ViroTectTropism™. The number of inconclusive results using the Trofile® assay was related to R5 RNA load (r = 0.51, <0.01). The number of samples that were positive for CCR5 expression by Trofile® varied from 10 to 90% with 95% confidence intervals of 15.3-25.6. The ViroTectTropism assay had a reported sensitivity to detect minor populations of X4-tropic viruses present in plasma at 5% with about 85% certainty.1

Summary:
- The different characteristics of the two assays are described in Table 1.
- The number of discordant D/M results detected by the Trofile® assay was highest in samples with HIV RNA <1000 copies/mL.
- Trofile® reported a greater number of inconclusive results with HIV RNA >1000 copies/mL.

Conclusion:
- The standard Trofile® assay showed discordant results between the two assays in 48% of samples yielding results.
- In this treatment-experienced population, the Trofile® assay detected 51% of X4 viruses in 51% of samples, compared with ViroTectTropism™ which reported 33% of samples with X4 virus.
- Inconclusive results emerged from 14% of samples tested by Trofile®, compared with 8% by ViroTectTropism™.
- Viral load, CD4 count and sample quality may influence the performance of either test.
- Clinical outcome studies are needed to determine the predictive value of different tropism assays with respect to long-term benefit of CCR5 antagonists.

References: