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Poster Presentation

## MULTI-SITE STUDY OF THE PROCLEIX® ULTRIO® ASSAY USING THE ENHANCED SEMI-AUTOMATED SYSTEM COMPARED WITH THE TIGRIS® AUTOMATED SYSTEM (SP227)

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### Background:

The investigational PROCLEIX® ULTRIO® (ULTRIO) and associated discriminatory assays use Transcription Mediated Amplification (TMA) to detect HIV-1, HCV and HBV in donated blood. A multi-site study was performed to compare the performance of the ULTRIO assays using the enhanced semi-automated PROCLEIX® System (eSAS) and the fully automated PROCLEIX® TIGRIS® System (TIGRIS).

### Methods:

Performance was evaluated using 410 negative and 317 positive commercially obtained panel members. Each panel member was tested in triplicate on TIGRIS at three blood centers; eSAS testing was performed at Gen-Probe. For each platform, the data were analyzed by comparing the percent correct detection of positive and negative replicates and 95% confidence intervals (CI); non-overlapping 95% CIs were considered significantly different.

### Results:

For ULTRIO, 2,180 eSAS and 6,497 TIGRIS valid results were obtained. 13 positive panel members had low viral loads (<100 copies/mL for HIV-1 and HCV; <15 IU/mL for HBV). Including these 13 samples, eSAS correctly identified 99.5% (CI: 98.8%-99.8%) and TIGRIS identified 99.0% (CI: 98.5%-99.3%). Excluding these 13 samples, eSAS and TIGRIS identified 100% (CI: 99.6%-100%) and 99.9% (CI: 99.7%-100%), respectively. For negative samples, eSAS and TIGRIS identified 98.8% (CI: 98.0%-99.3%) and 99.5% (CI: 99.2%-99.7%), respectively. Within all samples tested, there were 33 negative samples with discordant results: 15 of 1,232 (1.2%) eSAS and 20 of 3,672 (0.54%) TIGRIS replicate tests were falsely reactive. Within all samples tested, there were 8 positive samples with discordant results: 5 of 948 (0.84%) eSAS and 29 of 2,825 (1.06%) TIGRIS replicate tests were falsely negative. 7 of these 8 positive panel members had low viral loads. The percent detection of positive samples, excluding 13 low-level positives was better for eSAS by 0.1% (CI: -0.1% to 0.3%) and in negative samples by 0.7% with TIGRIS (CI: -1.4% to 0.0%). Similar results were observed for the discriminatory assays.

### Conclusions:

Within the scope of the study, equivalence was demonstrated between the two test platforms. Positive sample detection for all markers was higher using eSAS. Fewer false positives occurred using TIGRIS.