Plain English Summary of Results

Urine drug testing can be used as a tool for detecting illicit drug users and for monitoring the compliance of subjects in recovery programs. The study aimed to evaluate the performance of a multidrug device (Evidence MultiSTAT Drugs of Abuse (DOA) ToxPlex Urine Array EV4505) for detecting 23 drugs as well as a marker for sample dilution in urine samples.

The study used de-identified leftover pooled samples (100) from routine diagnostic testing and leftover known positive samples (30) sourced from the US, ran blinded. Results using the device were compared to another testing device to demonstrate equivalent clinical performance. No positive samples detected in the 100 leftover pooled samples from routine diagnostic testing on both devices. The 30 confirmed positive samples all reported positive for the drugs of abuse expected.

A known limitation of the study was that the alternative testing device was not able to detect all 23 drugs detected and that positives were not available for all 23 drugs. All study primary outcomes were achieved where positives were available and were tests were measured by the reference device. No failures were observed with the device.

The study demonstrated the successful use of the device in a clinical setting by the intended user to meets its intended use. No further studies are envisaged for this device.