Plain English Summary of Results

Sexually transmitted infections (STIs) are a considerable threat to public health worldwide. They can cause acute urogenital conditions such as cervicitis, urethritis, vaginitis and genital ulceration, with some of the etiological agents also infecting the rectum and pharynx. Many STIs are generally asymptomatic in the early stages of infection, which increases the potential for undetected transmission. If left undiagnosed and untreated, common STIs may cause complications and long-term health problems. Randox has developed a sensitive, multitarget approach for detecting nine common STIs with the STI-fleX qPCR device family, which comprises four diagnostic assays. This study aimed to assess the performance of the Randox STI-fleX qPCR device family for potential use in routine STI testing.

Remnant samples (leftover or archived) taken for purposes of routine STI diagnostic testing through a swab or urine sample from male and female subjects were assessed (n=1163). Subjects were persons aged ≥18 years who were suspected of having an STI infection, at increased risk of STI, have a known exposure to any STI, or contact tracing. A viable result for at least one of the four assays within the STI-*fle*X qPCR device family was found for 1131 samples tested. Excluded samples (n=32) were voided as per assays' instructions for use (IFU) recommendations. The study confirmed detection of all STIs covered by the assays within the STI-*fle*X qPCR device family and showed high correlation with a reference method. All study primary outcomes were measured with the device family showing overall good test performance. The study demonstrated that, under the anticipated conditions of use, the STI-*fle*X device family met the intended use and labelling claims.