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# **HIV-1** incidence biomarkers

#### Background

Measures of HIV incidence are used to help public health officials, researchers, and policy makers monitor the epidemic, evaluate the impact of interventions, and assist in the identification of sites for HIV prevention trials. Traditional HIV surveillance methods use changes in HIV prevalence to estimate incidence rates, which is challenging and expensive. Thus, the World Health Organization has identified a need for cost-effective blood based assays that provide accurate incidence estimates.

#### Technology

The technology is a four-antibody blood test used to distinguish those with recently-acquired HIV infections from those with chronic infections, which, when used in a sample from a population of interest, allows researchers to monitor population-level incidence and effectively target treatment and prevention strategies.

#### Utility

- · Monitoring incidence in specific locations, and in key or high-risk populations
- Selecting clinical trial sites and adequately powering efficacy studies
- Determining the impact and efficacy of vaccines and other interventions

#### Advantages over other assays

- Improved discrimination of recent versus chronic HIV
- Comparable or decreased false recent rate when used in anti-retroviral-naïve patients, with a longer mean duration of recent infection (MDRI).
- Significantly decreased false recent rate (<11%, without use of confirmatory viral load test) when used in anti-retroviral-treated patients, one of the difficult to classify patient groups, that also encompasses 59% of all HIV-infected patients
- Reduced patient sample sizes needed for accurate HIV-1 incidence estimates due to improved accuracy and increased MDRI
- Accurately classifies samples from multiple HIV-1 subtypes (A, A/E, B, C and CRF01\_AE) with a single test and no adjustment for subtype specific false recent rate or MDRI

#### Intellectual Property

Patent Pending