

**The Procleix<sup>®</sup> Advantage!**

Helps protect against false-negative results<sup>1,2</sup>

Provides optimal clinical sensitivity<sup>1,2</sup>

Protects against HIV-1 mutations and reduces the risk of missed HIV-1 infections<sup>1,2</sup>

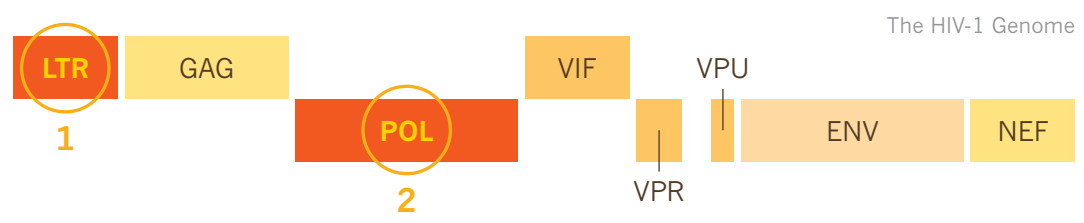
Two-region detection to protect against HIV-1 mutations and reduce the risk of missed HIV-1 infections.<sup>1,2</sup>

Highly diverse and rapidly mutating HIV-1 genome can escape amplification and detection with NAT assays that target only one region of the HIV-1 genome.<sup>2,3</sup> In blood screening, this can lead to missed window period cases.<sup>1,2,3</sup>

The Procleix Ultrio Assay is the only FDA approved, CE Marked NAT blood screening assay to target two highly conserved HIV-1 regions.<sup>3,4</sup>

**How two region amplification and detection helps prevent false negative results and improve clinical sensitivity**

HIV-1 is a virus with high rates of mutation. If one of the targeted regions mutate or change, an assay that targets just that one region would not recognize a target for amplification and detection and would therefore “miss” a positive sample. Targeting two regions of the genome increases the chances of reliably detecting positive samples.<sup>1,2,3</sup>



**Dual Region HIV-1 Targets:**

Illustration of an assay that targets two HIV-1 regions (i.e. Ultrio):

**Capture of Target Nucleic Acid**



**Amplification**

Mutation in LTR  
↓  
No Amplification

No Mutation in pol  
↓  
Amplification

**Hybridization with Probe**

No Hybridization

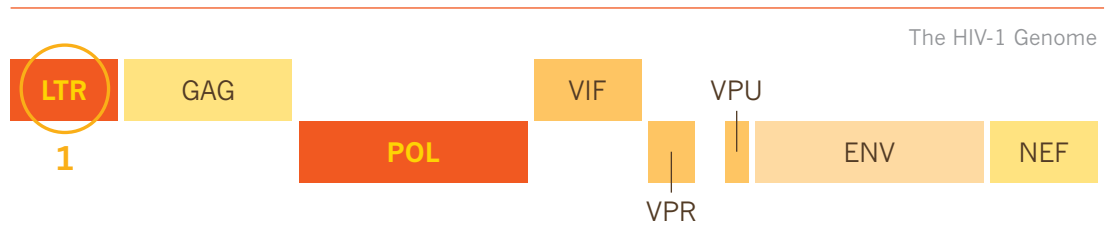
Hybridization

**Detection and Result**

No Signal

Signal => Reactive

Highly diverse and rapidly mutating HIV-1 genome can escape amplification and detection with NAT assays that target only one HIV-1 region. In blood screening, this can lead to false negative results and missed window period cases.



**Single Region HIV-1 Target:**

Illustration of an assay that targets one HIV-1 region:



**Capture of Target Nucleic Acid**

Mutation in LTR

**Amplification**

No Amplification

**Hybridization with Probe**

No Hybridization

**Detection and Result**

No Signal

**Only Procleix!**

Procleix Ultrio is the only NAT blood screening assay to target two HIV-1 regions. 2-region detection protects against HIV-1 mutations and reduces the risk of missed HIV-1 infections.

**References**

1. Korn K et al. Journal of Clin Microbiology, Apr. 2009, p. 1238–1240.
2. Edelmann A et al. Transfusion. 2010 Mar;50(3):685-92.
3. Gen-Probe letter, dated April 11, 2011.
4. Chudy M et al. Transfusion 2011.

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