

# ELECSYS® HIV COMBI PT 4TH GENERATION (AG+AB TEST)

## Detect HIV early across groups and subtypes

### *Don't let HIV elude capture*

HIV remains a deadly virus that continues to evolve at a rapid rate. To ensure HIV doesn't go undetected, it's critical that screening assays recognize all variant forms of HIV.

### *Control starts with earlier detection*

With the Elecsys® HIV combi PT assay, the HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 can be detected simultaneously in one determination. This leads to improved sensitivity and therefore a shorter diagnostic window as compared to anti-HIV assays. Initiating therapy earlier may lead to a better control of the disease and improved survival rates.<sup>1</sup>

### *Improve patient management*

- 100% clinical sensitivity for HIV-1
- 99.94% specificity in clinical routine, pregnancy and pediatrics testing

### *Reliably diagnose HIV infection from all over the world*

- Recognition of all known HIV groups and subtypes
- High sensitivity for HIV-2 antibodies in positive populations and HIV-2 endemic regions

### **HIV continues to impact lives**

More than **1.2 million**  
Americans live with HIV.<sup>2</sup>

**40,000** HIV infections are diagnosed  
in the U.S. every year.<sup>2</sup>

**13%** of HIV-infected Americans don't  
even know they are infected.<sup>2</sup>

# High sensitivity and specificity to accurately identify HIV

## Individuals positive for antibodies positive to HIV-1<sup>3</sup>

HIV-1 antibody positive cohorts	Clinical sensitivity
Adults (n=1225)	100%
Pediatrics (n=50)	100%
Pregnant (n=60)	100%
HIV Group M subtypes (n=75)	100%
Antibody positive adults (n=50)	100%

## Low-risk population<sup>3</sup>

Cohort	Overall specificity
Adults (n=6050)	99.94%
Pediatrics (n=591)	
Pregnant women negative for HIV (n=202)	

## Ability to detect a wide range of HIV-1 Group M subtypes<sup>3</sup>

Subtype (n=15)	Elecsys <sup>®</sup> HIV combi PT	Reference method
A	15/15	15/15
B	15/15	15/15
C	15/15	15/15
D	15/15	15/15
CRF01_AE	15/15	15/15
CRF02_AG	10/10	10/10

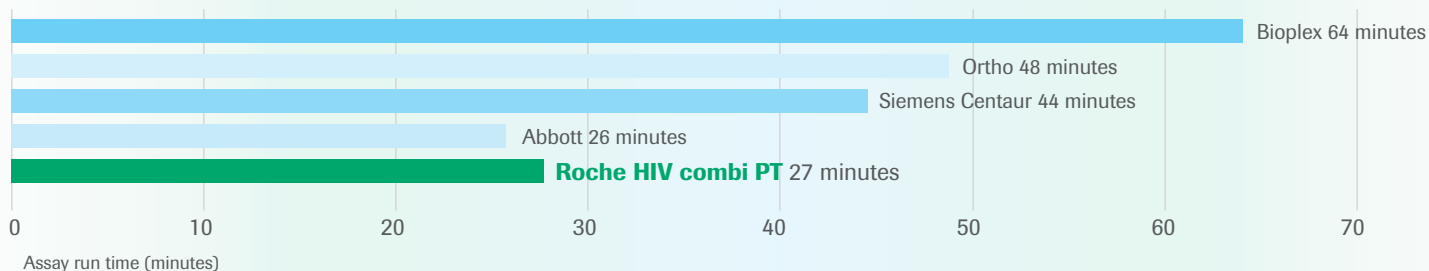
## Individuals positive or at high risk for HIV-2<sup>3</sup>

Specimen population	Clinical sensitivity
Known positive for antibodies to HIV-2	100% (211/211)
HIV-2 endemic regions	99.64% (705/706)

## Ability to detect HIV-1 group O<sup>3</sup>

Cohort sensitivity	Sensitivity
Group O (n=42)	100%

## Fast turnaround time. Run time is one of the fastest in the industry.<sup>4,5,6,7</sup>



For more information, contact your laboratory or visit [www.usdiagnostics.roche.com](http://www.usdiagnostics.roche.com)

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### SOURCES

<sup>1</sup>Jonsson M. et al. HAART initiation and clinical outcomes: insights from the CASCADE cohort of HIV-1 seroconverters on "When to Start." XVIII International AIDS Conference (AIDS 2010), Vienna, July 18-23, 2010. Abstract THLB201.  
<sup>2</sup>Trends in U.S. HIV Diagnoses, 2005-2014, CDC Fact Sheet, February 2016.  
<sup>3</sup>Elecsys<sup>®</sup> HIV combi PT, package insert.  
<sup>4</sup>Advia Centaur and Centaur XP 1.697136 rev B (downloaded June 8, 2017), <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm450386.htm>.  
<sup>5</sup>Architect HIV AG/Ab/combo insert FDA clearance <https://www.cdc.gov/hiv/pdf/testing/hiv-tests-laboratory-use.pdf> (downloaded June 8, 2017).  
<sup>6</sup>Ortho Anti-HIV 1+2 package insert <http://apps.orthoclinical.com/TechDocs/TechDocSearch.aspx?c%CE%BCulture=en-us&tID=0&region=US>.  
<sup>7</sup>BioPlex<sup>®</sup> 2200 System HIV Ag-Ab, Instructions for Use, Ref 665-3455, <https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM455847.pdf> (accessed August 2, 2017); supplemental form, the next-generation HIV testing, bio-rad.com.

