



Blood screening for patient safety

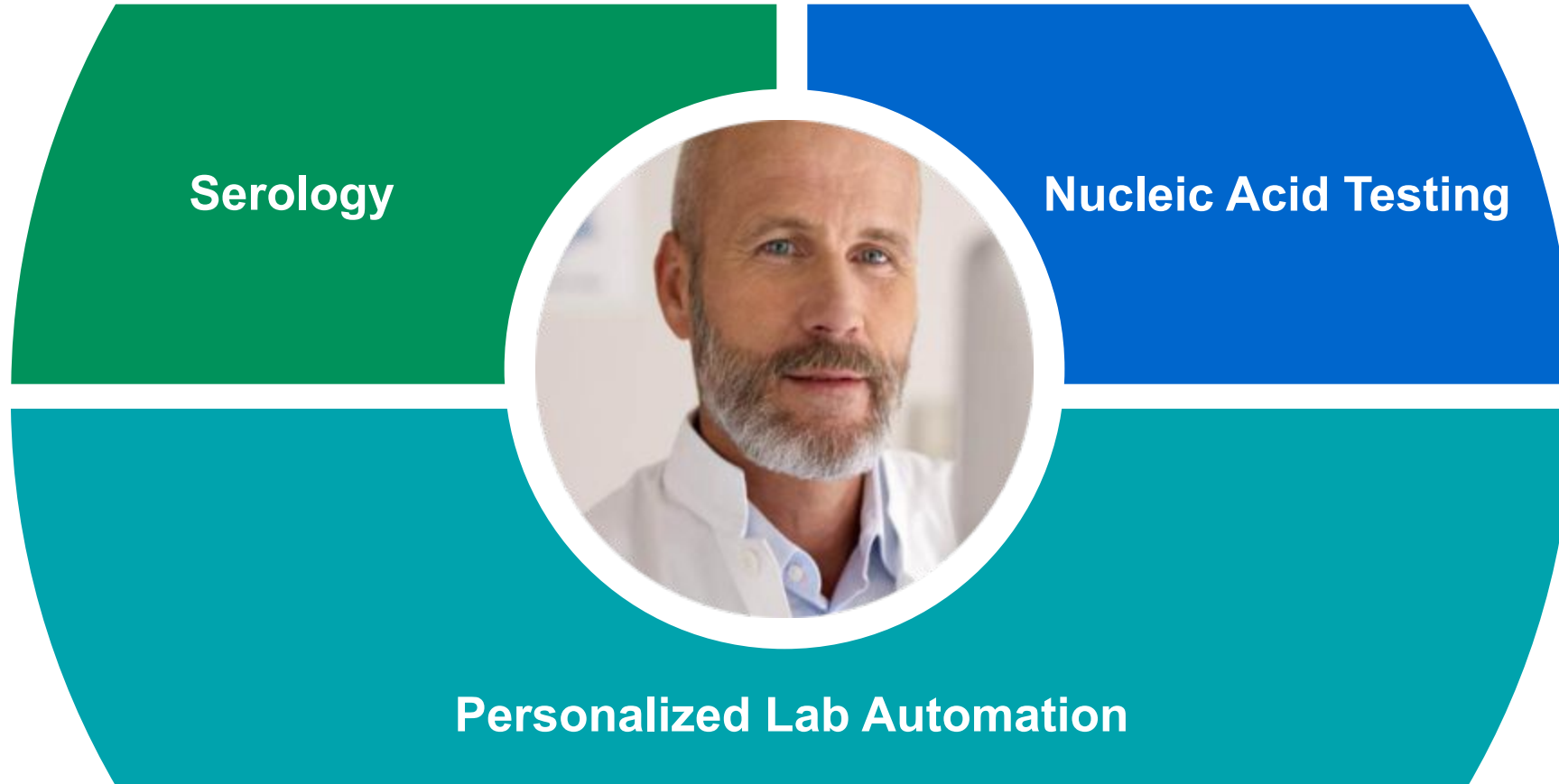
Kiev, October 30th 2018

Joanna Bućko

*Product Manager RMS for Export Markets
Management Center Poland & East Europe*

RBSS - Roche Blood Safety Solutions

Designed to work together and tailored to your needs



RBSS - Roche Blood Safety Solutions

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Serology

Nucleic Acid Testing

Personalized Lab Automation

cobas e 411, e 601, e 602, e 801

cobas s 201, 6800, 8800

cobas p 312, p 512, p 612

cobas® IT solutions

RBSS - Comprehensive state-of-the-art portfolio

Investing to deliver a complete solution

<h3>Serology</h3>	<h3>NAT</h3>
<h4>Bloodscreening assays</h4> <ul style="list-style-type: none"> HIV combi PT anti-HCV II HBsAg II anti-HBc II anti-HBs II HTLV-I/II Syphilis CMV IgG HIV Duo¹ Chagas 	<h4>Bloodscreening assays</h4> <ul style="list-style-type: none"> TaqScreen MPX 2.0 TaqScreen WNV TaqScreen DPX cobas[®] MPX cobas[®] WNV cobas[®] DPX cobas[®] HEV cobas[®] CHIKV/DENV cobas[®] Zika² cobas[®] Babesia³

Note: Serology assays are CE marked according to Directive 98/79/EC. ¹For cobas e801 ²US-IVD ³US-IND. Test performance has been established according to the Common Technical Specifications (CTS) for diagnostic use and for screening of blood donations;

RBSS - Comprehensive state-of-the-art portfolio

Investing to deliver a complete solution

Serology		NAT
Bloodscreening assays	Additional serology assays	Bloodscreening assays
HIV combi PT	anti-HAV	TaqScreen MPX 2.0
HIV Duo [†]	anti-HAV-IgM	TaqScreen WNV
anti-HCV II	anti-HBc IgM	TaqScreen DPX
HBsAg II	anti-HBe	cobas [®] MPX
anti-HBc II	HBeAg	cobas [®] WNV
anti-HBs II	HBsAg II quant II	cobas [®] DPX
HTLV-I/II	HIV-Ag	cobas [®] HEV
Syphilis	CMV IgM	cobas [®] CHIKV/DENV
CMV IgG	HCV Duo ¹	cobas [®] Zika ²
Chagas	-	cobas [®] Babesia ³

*Note: Serology assays are CE marked according to Directive 98/79/EC. ¹For cobas e801 ²US-IVD ³US-IND ⁴Under development
 Test performance has been established according to the Common Technical Specifications (CTS) for diagnostic use and for screening of blood donations;*

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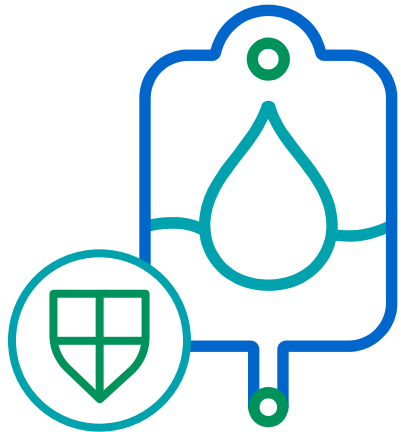
Safety is key



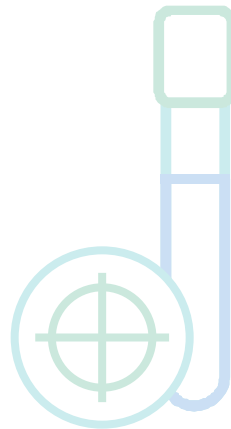
Dedication



Safety



Reliability



Efficiency



Safety – RBSS NAT assays

Comprehensive genotype coverage and excellent sensitivity

Combined assay for 4 CHIKV genotypes and main geographical serotypes of DENV.

Dual target approach for HIV-1 group M, detection of HIV-2; dual probes for HCV

Real-time detection and discrimination of HIV, HCV, and HBV in a single test.

Protects blood and plasma from new virus variants.



Provides **sensitive detection** of both WNV lineages 1 and 2.

Provides coverage for multiple genotypes of B19V (1, 2, 3) and HAV (I, II, III).

Provides **broad coverage** of all 4 major HEV genotypes.

**In development. Products of the Roche Blood Safety Solutions portfolio are not commercially available in all regions.*

Please contact your local Roche representative regarding availability. cobas® DPX test is designed for use in process testing of plasma intended for further manufacture.

Safety – RBSS Serology assays

Comprehensive genotype coverage and excellent sensitivity

Specific assay design ensures **detection of all major groups and subtypes of HIV-1 and HIV-2** found worldwide and providing an extra level of safety

Best in class seroconversion sensitivity¹ allows the earliest possible detection of infectious samples



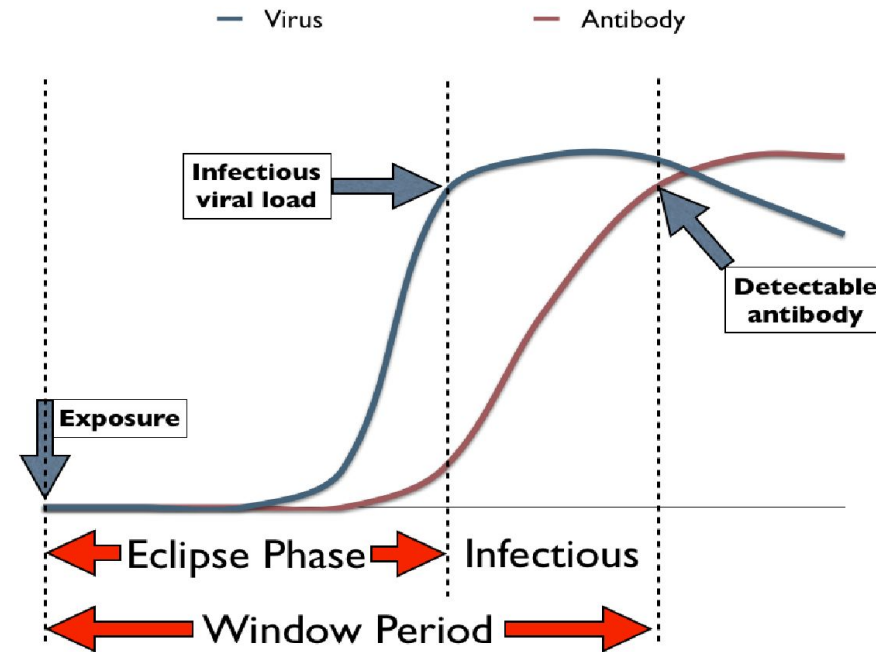
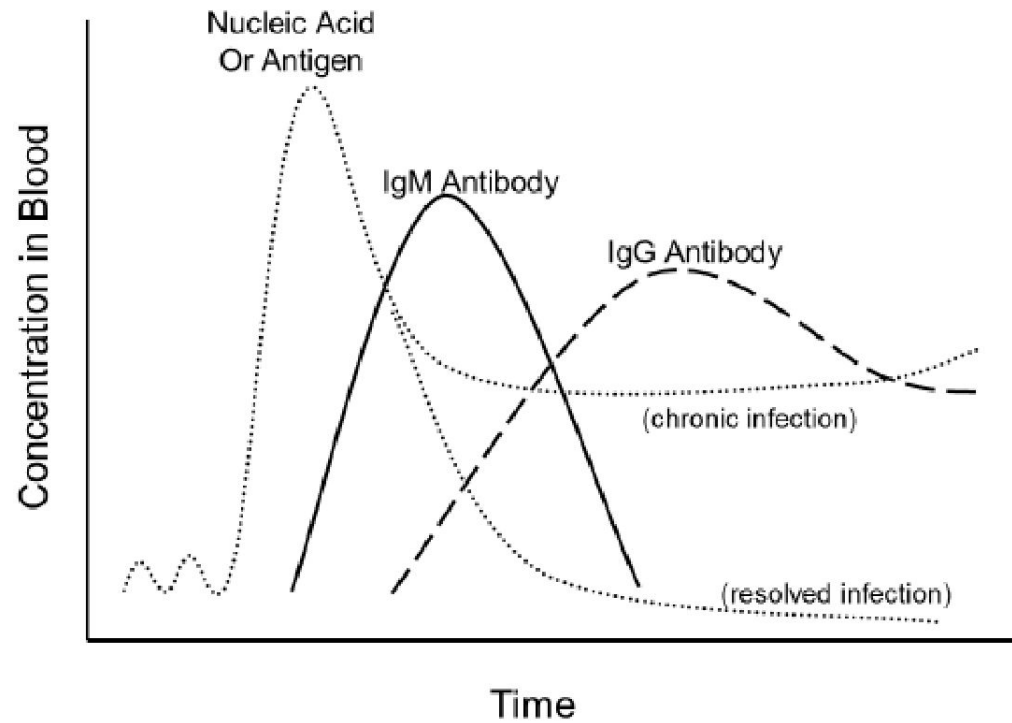
Excellent analytical sensitivity and comprehensive mutant coverage allows **reliable detection** of infectious samples.

High clinical sensitivity in all stages of infection for **safe product supply**

Sources: HTLV I/II Elecsys cobas e method sheet, Elecsys HBsAg II cobas e method sheet, Elecsys Syphilis cobas e method sheet, Elecsys HIV combi PT cobas e method sheet, Elecsys anti-HCV II method sheet, 1. Esteban JI et al. (2013). Multicenter Evaluation of the Elecsys® Anti-HCV II Assay for the Diagnosis of Hepatitis C Virus Infection *Journal of Medical Virology* 85:1362–1368.

NAT & serology

Closing the window period



Galel SA in AABB Technical Manual (18th ed) 2014, p. 193.

From Chaffin, J. The Blood Bank Guy. 2011

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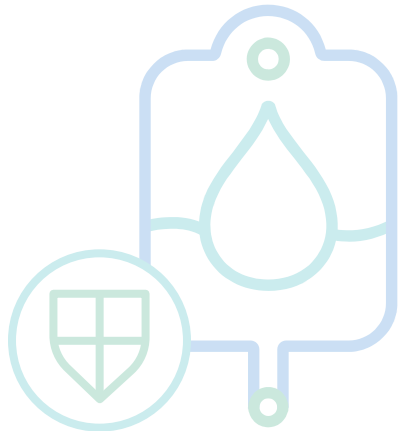
Supporting a consistent and dependable blood supply



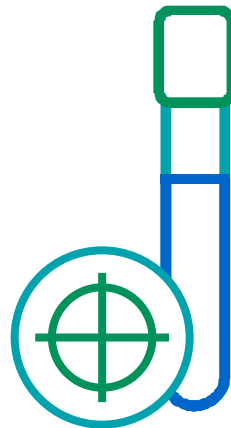
Dedication



Safety



Reliability



Efficiency



Reliability - Confidence in results

Validated workflows minimize risk of cross-contamination

Disposable tips across all systems

Cross-contamination studies on cobas p 512/612*



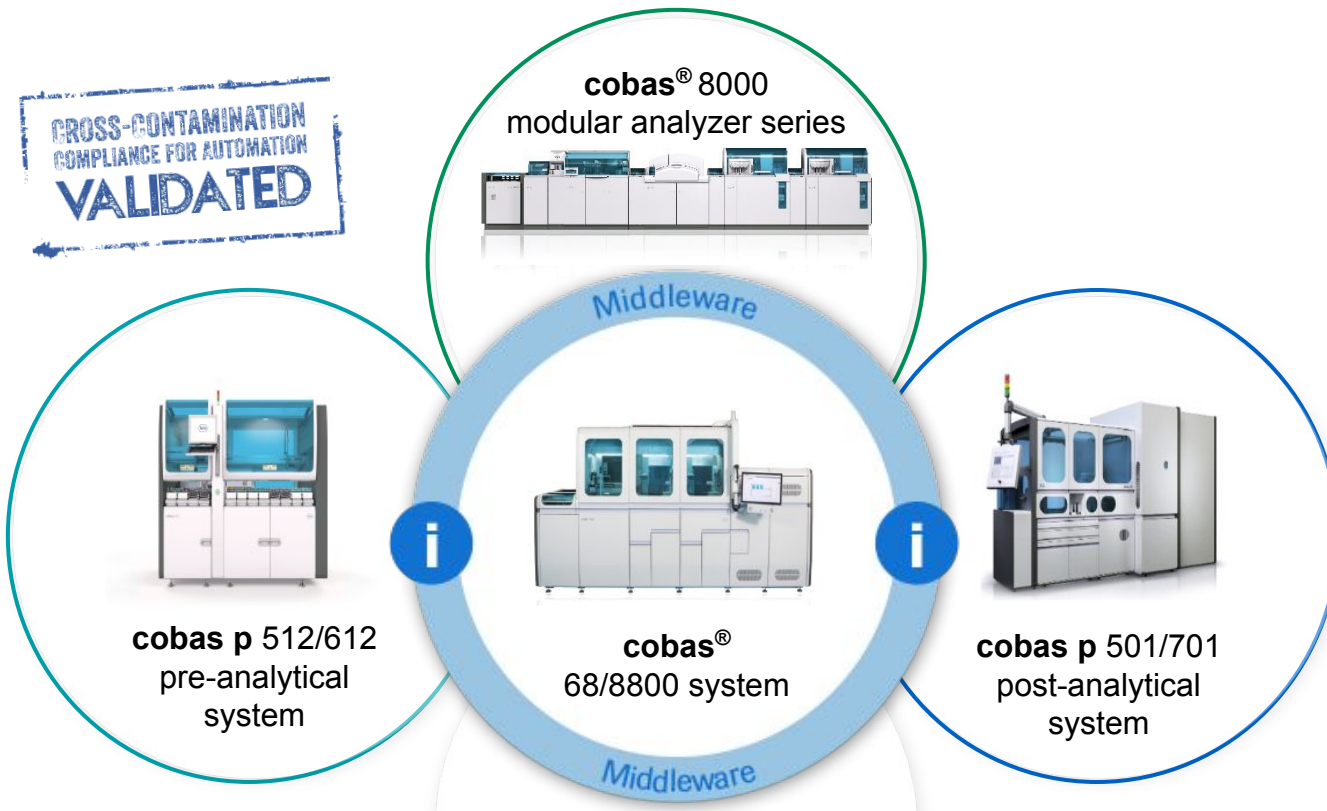
- Total of 832 samples tested
- 208 HBV high titer samples at 1.00E+08IU/mL per workflow
- 624 negative samples per workflow
- Negative samples tested on **cobas**® 6800/8800 using cobas MPX NAT test
- Result: 0 cross contamination detected

Minimizing risk of cross-contamination

*Roche. (2016). Declaration of Serology and NAT testing compliance. | Iordanoaia, N., et al. (2016 September). Cross-contamination Compliance of cobas p 612 pre-analytical system in use with cobas® 6800/8800 Systems. Poster presented at ISBT, Dubai, UAE. Disposable tips used for sample pipetting



Roche has validated all systems in RBSS portfolio for cross contamination compliance with NAT environments providing end-to-end automation for Blood Screening workflows



End-to-end RBSS SOLUTIONS VALIDATED for cross-contamination compliance

cobas® 6800/8800 Systems, cobas p 501 system and cobas® connection modules are not available in all markets. Roche. (2016). Declaration of Serology and NAT testing compliance. | Iordanoaia, N., et al. (2016 September). Cross-contamination Compliance of cobas p 612 pre-analytical system in use with cobas® 6800/8800 Systems. Poster presented at ISBT, Dubai, UAE.

cobas[®] 6800/8800 Systems - Absolute Automation

Integrated & fully automated workflow to guarantee safety



cobas[®] 6800 System

Fully Automated Contamination Prevention

Ensures confidence in sample & result integrity

Physical

Chemical



Hydraulic doors & airlock screens

Maintains “clean room” environment



Separation of sample & reagent pipetting

Dedicated, filtered tips maintain sample integrity



Automatic heat sealing of amplification plate

Isolates wells to ensure result integrity

AmpErase
Enzyme

AmpErase incorporated into every reaction

Protection against carry-over amplicon

RBSS - Roche Blood Safety Solutions

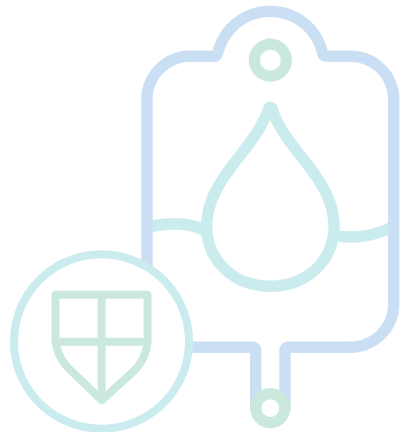
Realize efficiency gains



Dedication



Safety



Reliability



Efficiency



Efficiency through high specificity

Less retesting and minimized loss in donations

Pathogen	Roche NAT offering		Roche Serology offering	
HIV	cobas® MPX	99.98% ^a (n=19,643)	Elecsys® HIV combi PT	99.88% ^c (n=7,343)
HCV			Elecsys® Anti-HCV II	99.85% ^c (n= 6,850)
HBV			Elecsys® HBsAg	99.98% ^c (n=6,360)
HEV	cobas® HEV	100% ^a (n=1,500)		
HAV	cobas® DPX	100% ^b (n=284)		
Parvo B19				
Flaviviruses	cobas® WNV	100% ^a (n=8,203)		
Syphilis			Elecsys® Syphilis	99.93% ^c (n=4,579)
HTLV-I/II			Elecsys® HTLV-I/II	99.95% ^c (n=11,575)

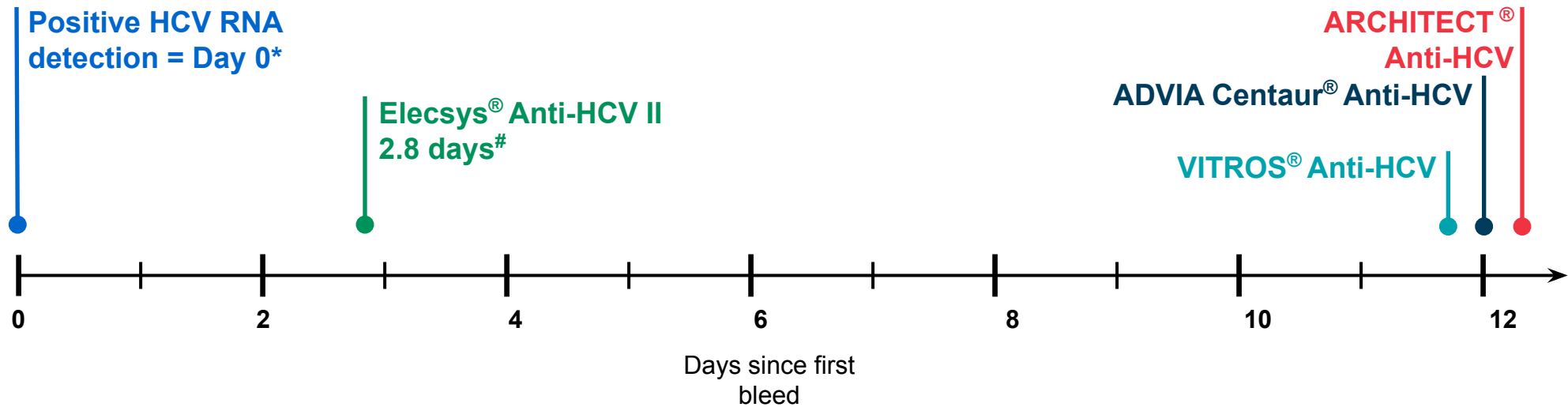
a. Malhotra, K., et al. 2014 Poster presentation 33rd International Congress of the ISBT, Seoul. b. cobas® DPX Package Insert. c. HTLV I/II Elecsys cobas e method sheet, Elecsys HBsAg II cobas e method sheet, Elecsys Syphilis cobas e method sheet, Elecsys HIV combi PT cobas e method sheet, Elecsys anti-HCV II method sheet, Products of the Roche Blood Safety Solutions portfolio are not commercially available in all regions. Please contact your local Roche representative regarding availability. Serology portfolio in addition is not available in USA, Canada and Philippines due to patent and license restrictions

Elecsys® Anti-HCV II - Seroconversion Sensitivity

Time matters when diseases can spread

Elecsys® Anti-HCV II is more sensitive in recognizing early HCV infection than comparator assays

Early detection of antibodies to HCV: 2.8 days after HCV RNA



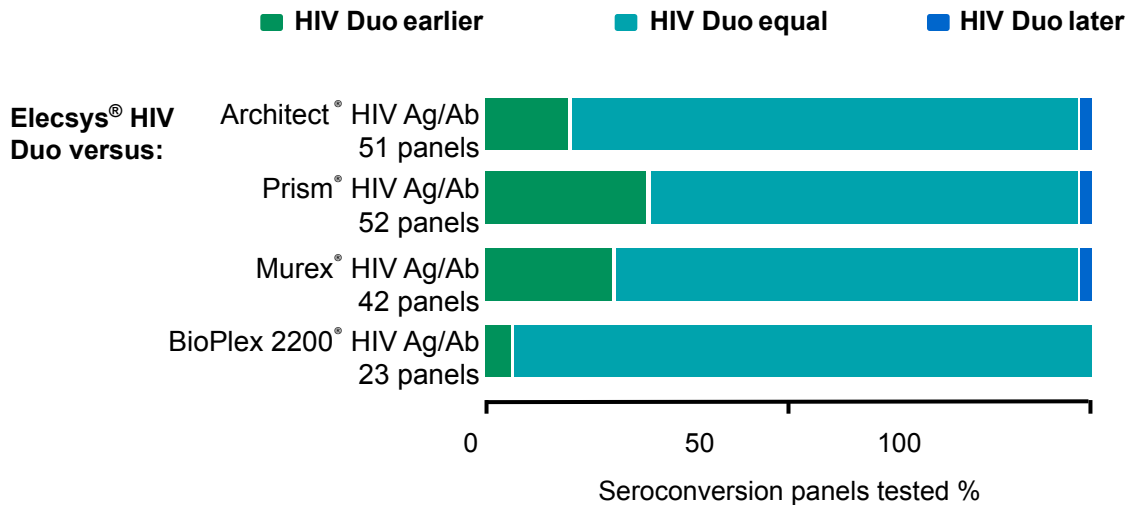
Antibody detection compared with the detection of HCV RNA for the same 6 seroconversion panels (comprising a total of 39 samples)

Yoo, SJ et al. J Clin Virol, 64, 20-7 (2015). *Positive nucleic acid test result considered Day 0; #Mean difference vs. HCV RNA test

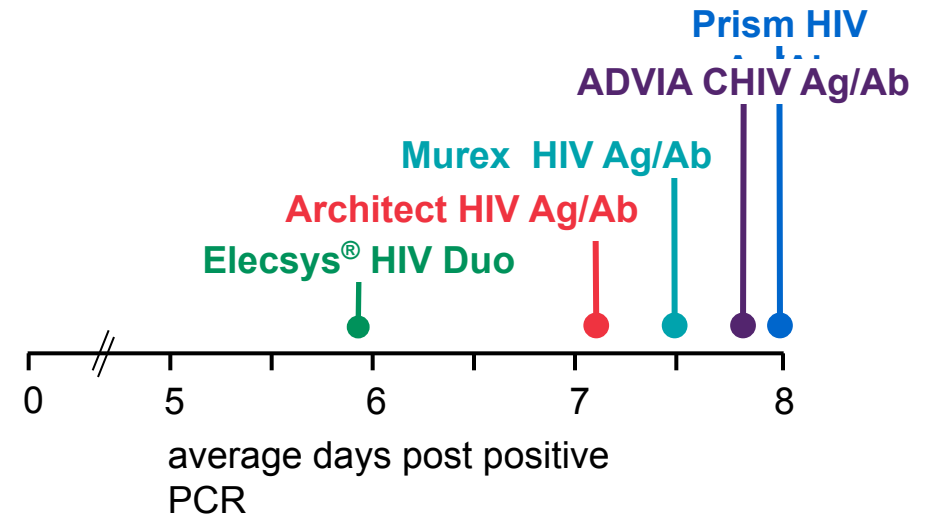
Elecsys® HIV Duo- seroconversion sensitivity

Time matters when diseases can spread

Seroconversion panel comparison



Head-to-head comparison of the same seroconversion panels (n=20)



In both analyses the Elecsys® HIV Duo demonstrated overall higher seroconversion sensitivity when compared with other providers

Roche Diagnostics study report, Performance Evaluation CE Elecsys HIV Duo on cobas e 801 RD002525. Roche R&D Penzberg

Elecsys[®] Anti-HBc II – The new generation Anti-HBc test

Unique design for higher specificity

	Sensitivity*	Specificity*
Elecsys[®] Anti-HBc II	100%	99.88-100%**
Abbott Architect	100%	99.61-100%
Abbott Alinity i	100%	99.85-100%
Abbott Prism	99.49%	96.85-99.88%
Siemens Centaur	100%	98.09-99.82%
Siemens Immulite	98.9%	99.7-99.9%
DiaSorin Liaison	100%	99.7-100%

The best sensitivity/specificity combination driven by unique dual recombinant antigen (patented) design

* Source: manufacturer's package inserts assessed November 2016. The specificity ranges cover blood donors, hospitalized patients and routine testing.

** Dialysis patients not included due to missing data from competitors

Elecsys[®] HBsAg II assay

100% reliable detection of all relevant HBV mutants

HBV mutants	Elecsys [®]
R1 (F8L/R24K/N40R/G43R/L94S/M103I/113A114/M133T/P142L/D144G)	✓
R2 (I110L/S113T/T114S/T126I/N131T/F134Y/T143S/G145R)	✓
R3 (S132Y/P142S/G145R)	✓
R4 (Q129P/F134R/P142L/D144E/G145K/S171F/L175S)	✓
R5 (R122I)	✓
R6 (R122T)	✓
R7 (C124R)	✓
R8 (E122I)	✓
R9 (T123N)	✓
R10 (G145K)	✓
R11 (I22RA123)	✓
R12 (P142L/G145R)	✓
R13 (D144G)	✓

Mühlbacher, et al. (2008). *Med Microbiol Immunol.*; Jia, et al. (2009). *Med Microbiol Immunol.*; Louisirirochanakul, et al. (2010). *J Med Virol*

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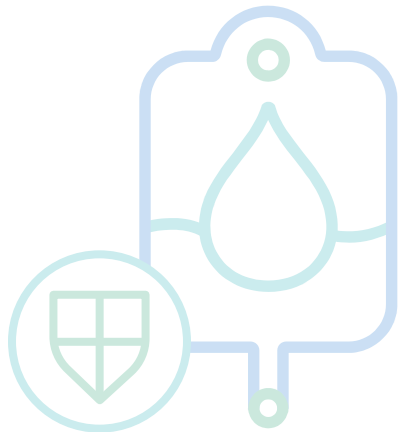
Dedicated to blood screening since 1998



Dedication



Safety



Reliability



Efficiency



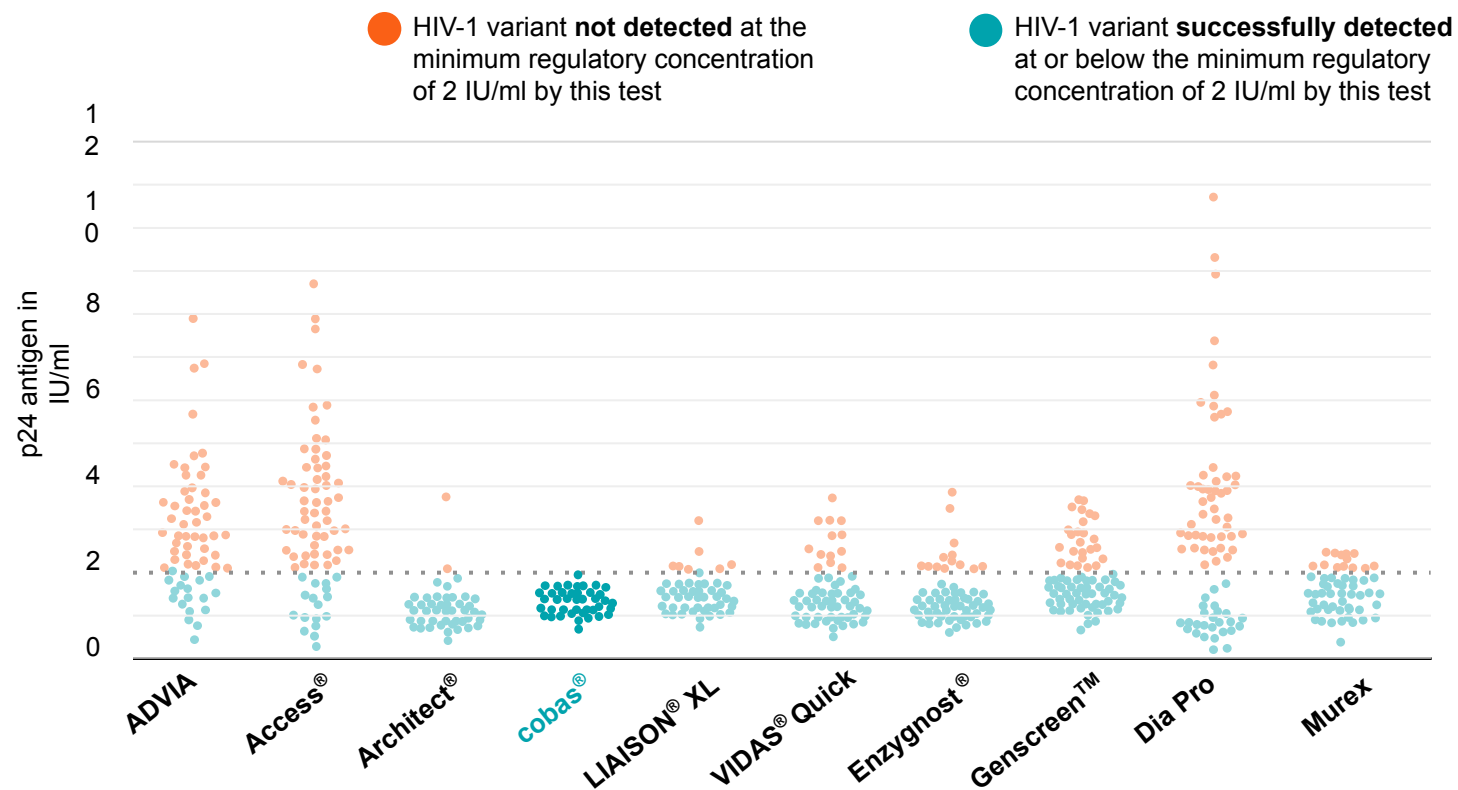
Doing now what patients need next

Elecsys[®] HIV combi PT– best in class antigen sensitivity

Stay on the safe side. Avoid false negative results

Elecsys[®] HIV combi PT exceeds requirements of analytical sensitivity.

Minimal impact of HIV-1 genetic variation on performance of Elecsys[®] HIV combi PT in a study evaluating the detection of p24 antigen from different HIV-1 variants with respect to the minimum regulatory requirements of 2 IU/ml.



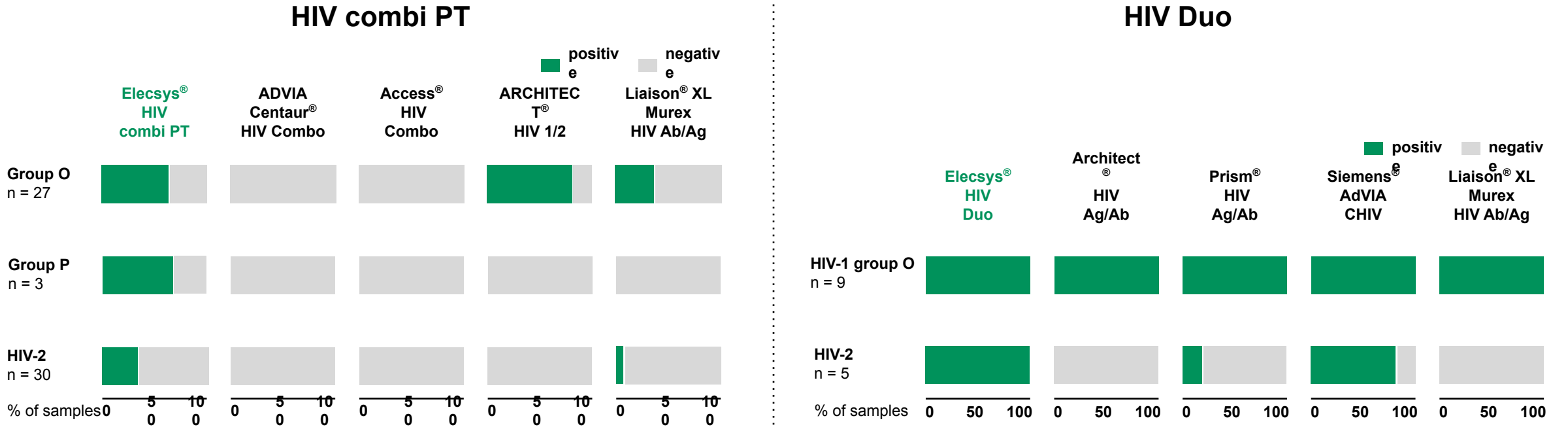
Simplified picture - Ly et al. (2012). J. Clin. Virol

Product names and trademarks are the property of their respective owners.



Elecsys[®] HIV tests – best in class inclusivity for HIV antigen

Reassurance when faced with rare serotypes



Elecsys[®] HIV combi PT and Elecsys[®] HIV Duo showed higher overall capability to detect the HIV antigen of rare serotypes

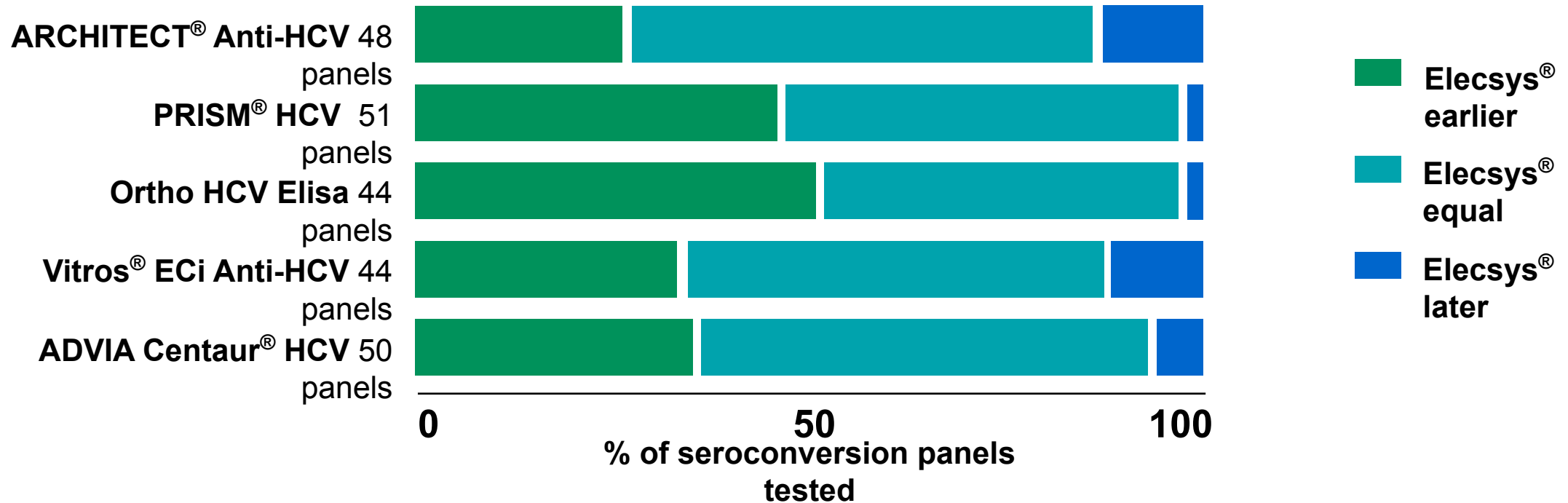
Ly et al. (2012). J Clin Virol Product names and trademarks are the property of their respective owners.



Elecsys[®] Anti HCV II - seroconversion sensitivity

Earlier detection enabled by best in class sensitivity

Elecsys[®] Anti-HCV II versus:

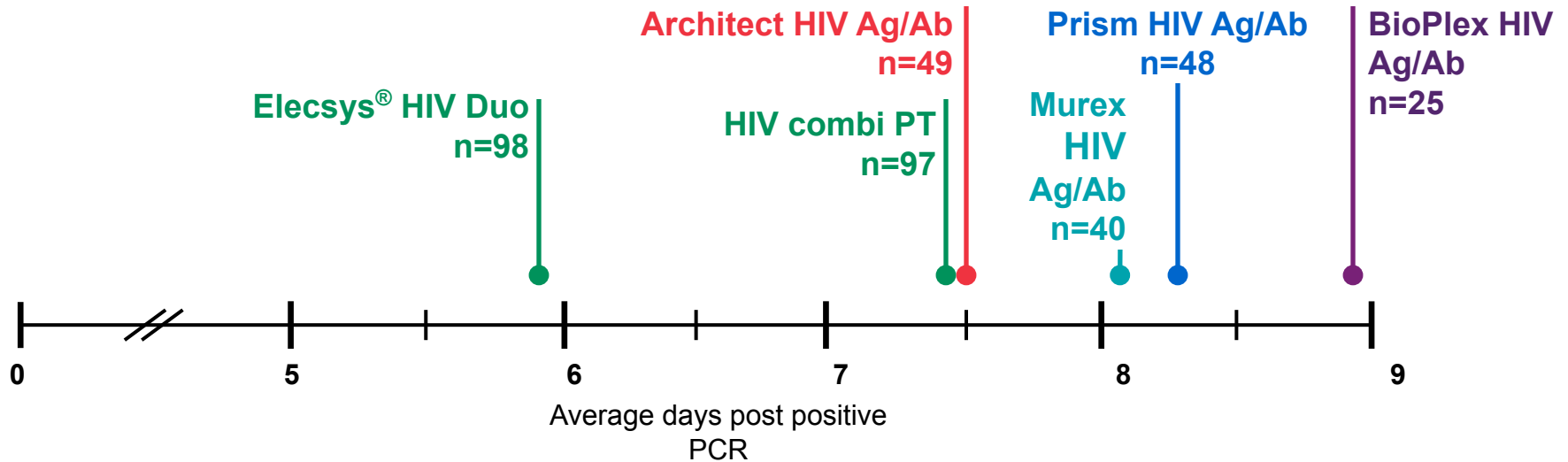


Combined data from "Study report: Performance evaluation CE: Elecsys Anti-HCV II; 20 Feb. 2012, Version2; Study Number: CIM RD 001230/B10P010" Penzberg, Germany and Esteban, et al. (2013). J Med Virol. Product names and trademarks are the property of their respective owners.

Elecsys[®] HIV tests

Excellent seroconversion sensitivity

Individual analysis of seroconversion panels

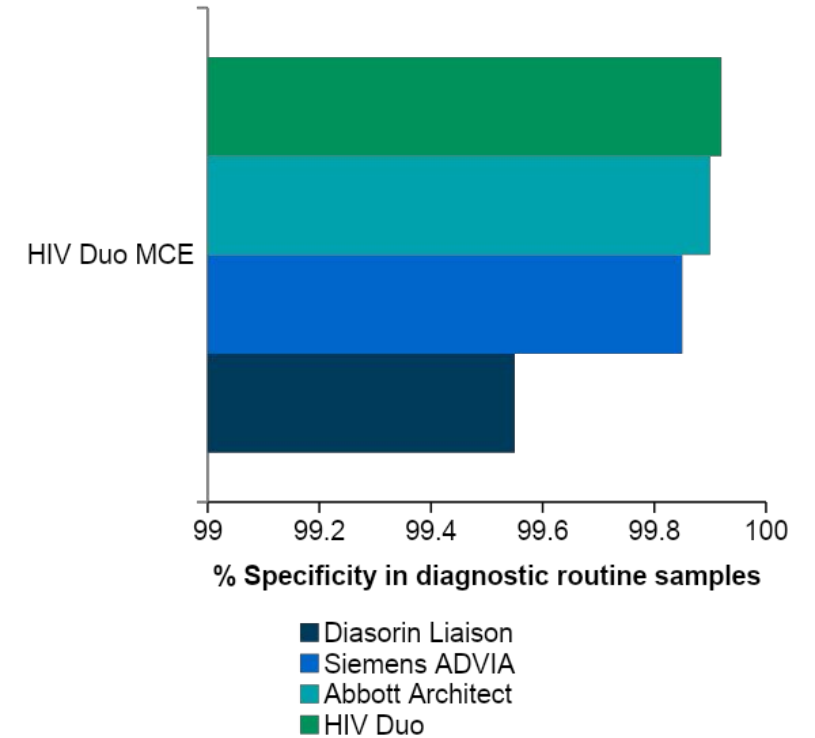
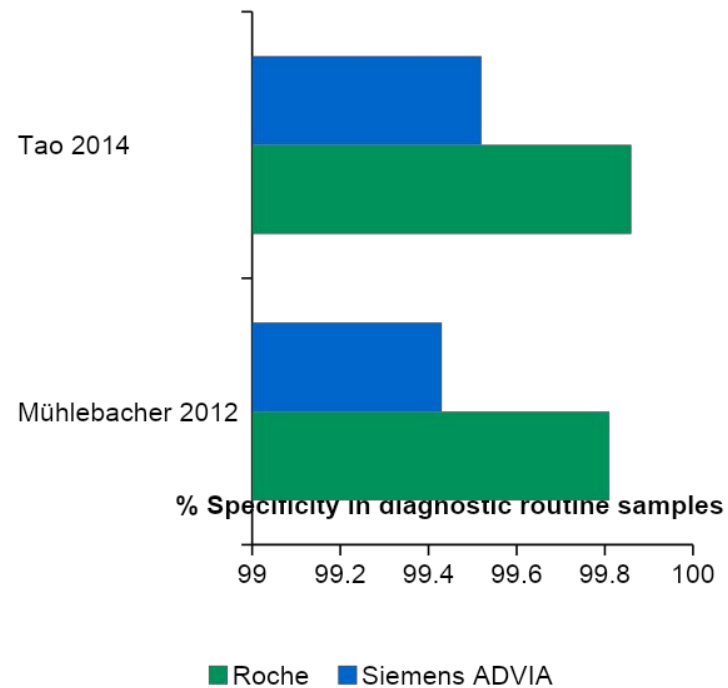


Both the Elecsys[®] HIV combi PT as well as the Elecsys HIV Duo have demonstrated excellent seroconversion sensitivity when compared to other tests

Roche Diagnostics study report, Performance Evaluation CE Elecsys HIV Duo on cobas e 801 RD002525. Roche R&D Penzberg

Elecsys[®] HIV tests – First class specificity

Limiting retests, building confidence



Reliable high specificity as shown in various field studies

Tao CM et al. (2014). *J. Clin. Virol* ; Song EY et al. (2012). *J. Med. Virol*; Mühlbacher A et al. (2012). *Med. Microbiol. Immunol.*

Doing now what patients need next