Leading the way in molecular diagnostic performance

Reinforcing trust with consistent reliability

Trust is an important foundation for relationships. It is based on integrity and mutual respect. Whether from patients and their physicians, HCPs and the laboratory, or between diagnostic professionals and Roche, trust is built by and maintained through many small actions over time.

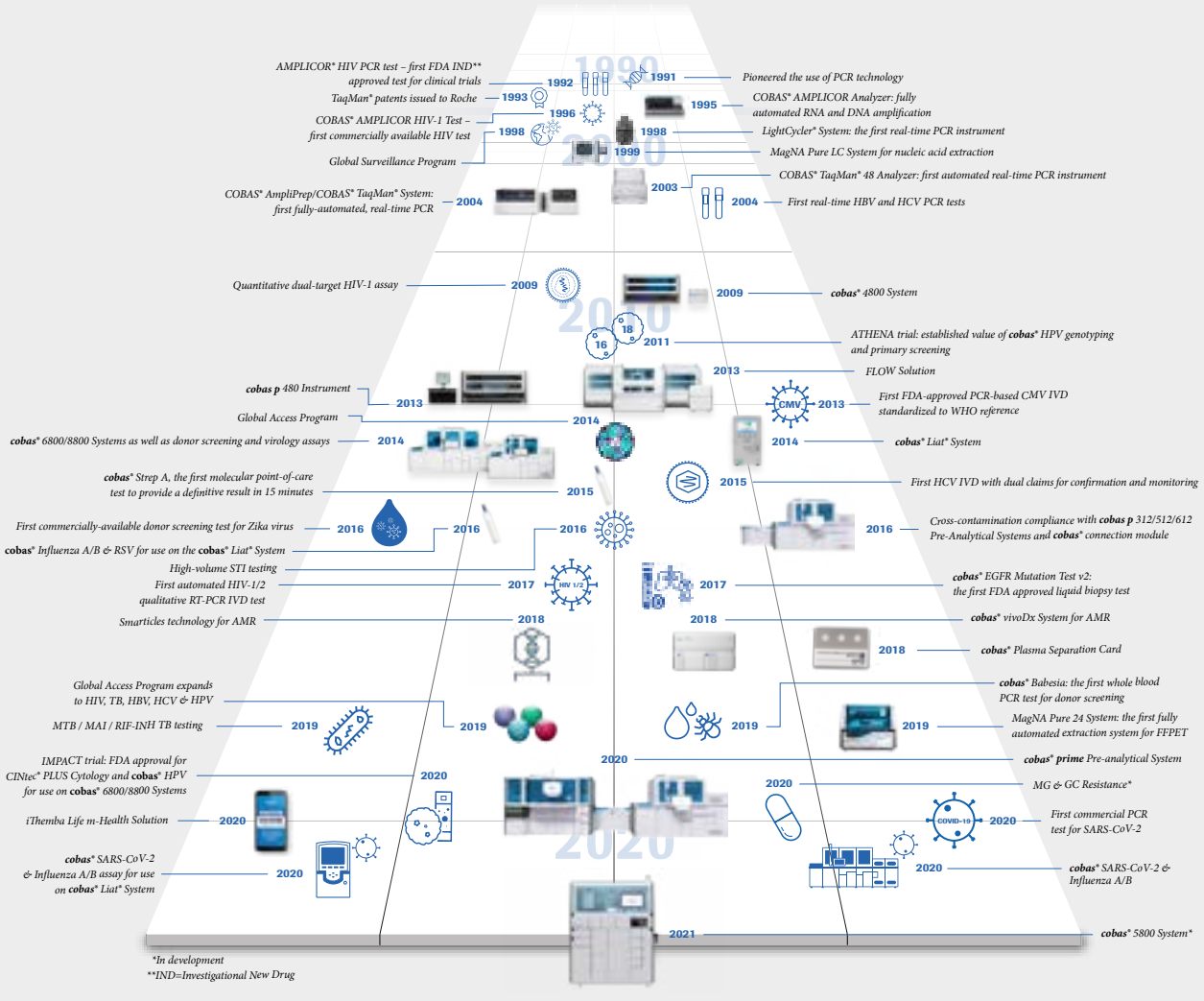
The global healthcare infrastructure is intricate and ever-evolving. However, the one trusted constant through all of this change is Roche's unwavering commitment to health systems and the patients they serve.

Innovation is in our DNA

Roche Molecular Systems is more than molecular testing. Our comprehensive assay portfolio spans the entire continuum, from diagnostics to care. Advancements in screening, diagnosis, treatment and monitoring have allowed us to deliver value to patients and clinicians at every stage to optimise clinical decision-making.

Innovative launches through the decades

Our proven track record of exceptional quality underscores our unwavering commitment to excellence. This reinforces customer trust and amplifies the impact our innovations have on the greater healthcare landscape.



Delivering confidence in clinical decision-making

Today, we sit at the pinnacle of assay research in pharmaceutical and clinical studies. Decades of experience in setting the standard for infectious disease testing makes Roche the partner of choice for clinical trials around the world. Roche assays have been trusted to define treatment cut-offs[1] for some of the world's most burdensome diseases.

HBV HIV HCV

HBV	
HEPSERA®	2002
BARACLUDE®	2005
PEGASYS®	2005
TYZEKA®	2006
VIREAD®	2008
VEMLIDY®	2016

HCV	
PEGASYS®	2002
COPEGUS®	2002
VICTRELIS™	2011
INCIVEK™	2011
OLYSIO™	2013
SOLVADI™	2013
DAKLINZA™	2014
HARVONI™	2014
VIEKIRA PAK™	2014
EPCLUSA®	2016
ZEPATIER®	2016
TECHNIVIE™	2016
MAVYRET™	2017

HIV					
NORVIR®	1996	VIREAD®	2001	VIRAMUNE® XR	2011
CRIXIVAN®	1996	FUZEON®	2003	EDURANT®	2011
VIRAMUNE®	1996	REYATAZ®	2003	COMPLERA®	2011
VIRACEPT®	1997	EMTRIVA®	2003	STRIBILD™	2012
RESCRIPTOR®	1997	LEXIVA®	2003	VITEKA™	2014
COMBIVIR®	1997	EPZICOM®	2004	TYBOST™	2014
FORTOVASE®	1997	TRUVADA®	2004	EVOTAZ™	2015
SUSTIVA®	1998	APTIVUS®	2005	GENVOYA®	2015
ZIAGEN®	1998	PREZISTA®	2006	ODEFSEY®	2016
AGENERASE®	1999	ATRIPLA®	2006	BIKTARVY®	2018
KALETRA®	2000	SELZENTRY®	2007	TROGARZO™	2018
TRIZIVIR®	2000	ISENTRESS®	2007		
VIDEX® EC	2000	INTELENCE®	2008		

[2] Data on file with Roche

Having published all these trials in peer-reviewed journals, the scientific community recognises and trusts in the reliability of Roche assays. Their guaranteed high precision and accuracy, plus traceability to World Health Organisation (WHO) standards, exemplifies Roche's commitment to diagnostic excellence.

What goes in to a Roche result?

Each assay is clinically validated, with comprehensive studies conducted during development and with multiple external clinical sites.

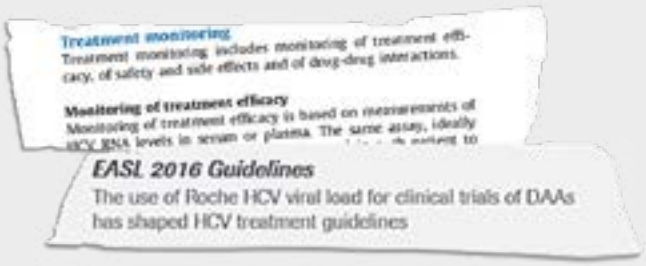
- Extensive customer involvement throughout the process
- Robust testing of assay performance prior to release to the market
- Confidence for customers in assay performance in their laboratories
- Full commitment to quality
- Differentiation from the competitive approaches to CE-mark

Driving standards and informing guidelines

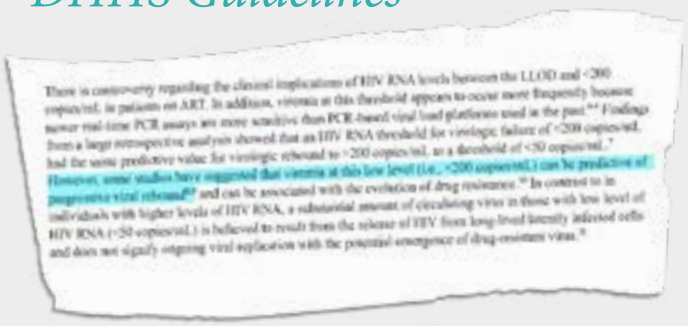
Roche assays have played an integral role in defining and shaping testing guidelines, establishing treatment cut-offs, and as a benchmark for assay performance. Patients, clinicians, laboratories, and global health organisations recognise our industry-leading assay quality, and the WHO uses our HCV test as a reference for their prequalification process.[3]

HIV-1

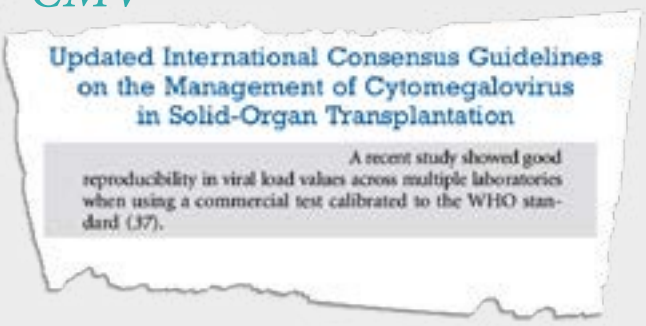
HCV



DHHS Guidelines



CMV



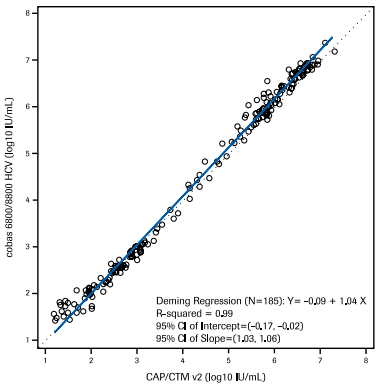
For individual laboratories and laboratory networks, the consistency of a Roche result provides deeper value. Roche studies healthcare data and understands its importance in a modern laboratory. Result data needs to be contextual and Roche solutions are designed with this in mind.

Ensuring confidence with cross-platform consistency

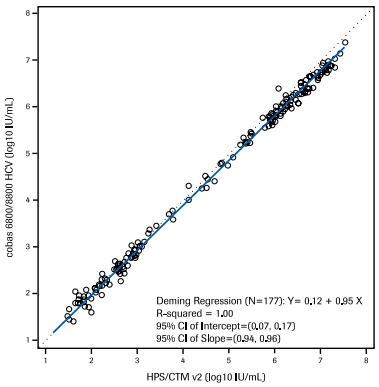
In a series of published multicenter studies across eight international sites, we evaluated the clinical performance and commutability of Roche viral load monitoring assays—HIV-1, HCV and HBV—to demonstrate the consistency and reliability of a result on a Roche system.

Strong correlation across Roche platforms for HCV assays

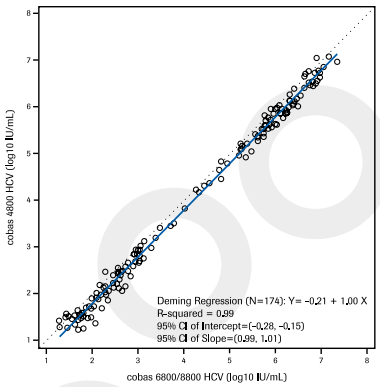
***cobas*® 6800/8800 vs CAP/CTM**



***cobas*® 6800/8800 vs HPS/CTM**



***cobas*® 4800 vs *cobas*® 6800/8800**



Deming regression plots for **cobas**® 6800/8800 HCV versus CAP/CTM v2 (n=185), **cobas**® 6800/8800 versus HPS/CTM v2 (n=177), and **cobas**® 6800/8800 HCV versus **cobas**® 4800 HCV (n=174).*

Across four testing platforms, Roche assays showed consistently high performance. They were proven to have high commutability to support interchangeably in routine clinical practice. These studies confirmed robust and clinically relevant assay performance regardless of disease state, ensuring precision at medically relevant decision points. In other words, “a Roche result is a Roche result” for all assays and platforms.

Several key factors helped to determine the suitability for platform transition, including cross-contamination, linearity, limit of detection, correlation to previous data, and specificity. The data confirmed that the newly established assays are highly sensitive and specific with high cross-platform commutability, and may be used interchangeably in routine clinical practice.

Standardised, clinically validated, and reliable results are important for all laboratories, anywhere in the world. For those areas with the greatest need, Roche is committed to always going the extra mile to deliver world-class diagnostic solutions that support effective healthcare.

*Additional Bland-Altman plots can be found in the following publications:

Adams P, Vancutsem E, Nicolaizeau C, et al. Multicenter evaluation of the **cobas**® HIV-1 quantitative nucleic acid test for use on the **cobas**® 4800 system for the quantification of HIV-1 plasma viral load. J Clin Virol. 2019;114:43–49. doi:10.1016/j.jcv.2019.03.008

Maasoumy B, Bremer B, Lehmann P, et al. Commutability and concordance of four hepatitis B virus DNA assays in an international multicenter study. Therap Adv Gastroenterol. 2017;10(8):609–618. doi:10.1177/1756283X17722745

In times of need, Roche answers the call

As a global leader in diagnostics, we are committed to supporting the world's population. We take this charge seriously and actively work to rapidly develop high-quality products, improve access to testing, and support effective healthcare.

As the world paused during the early stages of the COVID-19 pandemic, Roche's global surveillance team immediately went to work as soon as the novel coronavirus was identified. Free coronavirus tests and instruments were shipped to China to help ease the burden and, a few weeks later, Roche launched the world's first FDA Emergency Use authorised test for SARS-CoV-2 for use on **cobas**® 6800/8800 Systems. Developed in just six weeks, the Roche assay expedited coronavirus testing to meet the urgent medical need. The global install-base of the systems, combined with their high throughput and absolute automation, provided countries with a valuable tool to combat this global outbreak.

In 2016, Zika virus ravaged areas of North and South America, as well as several islands in the Pacific and Southeast Asia. The FDA issued an emergency use authorisation to make Roche's assay the first commercially available test for the detection of Zika—a milestone in the effort to protect the blood supply from the virus. The test is now available globally as an IVD assay.

Improving access to healthcare is embedded in our purpose. Our diagnostic tests are only meaningful if they reach the people who need them when they need them—no matter where they live. In 2017 and 2018, a shortage of supplies in Africa threatened some countries hardest hit by HIV. We responded by chartering Boeing 747/777 aircraft to deliver testing kits to Nigeria, Tanzania, Zambia, Uganda, Ethiopia, and Rwanda in an effort to ease the burden of disease.

Tanzania & Nigeria

6 Boeing 747/777 charters

48 Trucks for transportation

HIV Portfolio & Tonnage

2,500 pallets

490 tons shipped

22 components

132,600 pc

Agile Operating Model

Manufacturing & supply chain teams worked weekends to meet high volume*

"Our innovative medicines and diagnostic tests are only meaningful if they reach the people who need them, when they need them – no matter where they live."

– Severin Schwan, CEO of the Roche Group

Taking on tomorrow together

Today, rapid advancements in healthcare technology, a shortage of skilled workers, industry wide consolidation, and the proven need to be ready for the next outbreak have health systems looking to build a reliable foundation for the future.

While some may view change as a challenge, Roche ensures that transforming your laboratory with the Molecular Work Area allows for a seamless and reliable transition for laboratories of all sizes and disciplines. The Molecular Work Area empowers laboratories to elevate the value they deliver across their organisation to ensure long-term sustainability and success.

As we look for new ways to better support patients and clinicians, you can be confident that new levels of efficiency, flexibility and scalability will help you meet the changing demands of your community, your customers, and the patients they serve.

We invite you to join us in our continued effort to address global and local health needs, while delivering life-changing results to those who need them most.

Doing now what patients need next.

References:

1. Cloherty G, Chevaliez S, Sarrazin C, et al. Hepatitis C RNA assay differences in results: Potential implications for shortened therapy and determination of Sustained Virologic Response. Sci Rep. 2016;6:35410. doi:10.1038/srep35410
2. Data on file with Roche
3. Personal communication with WHO (Ana dos Santos/Ed Marins). July 2018. Imago, Switzerland

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Company Registration Number: 571546.

Document number: MC-IE-01189.
Date of preparation: May 2021.
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