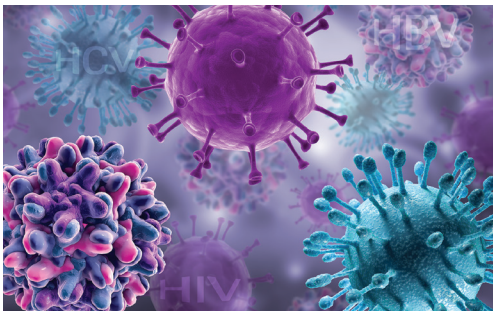


cobas® MPX

*Improve blood and plasma safety:
one test, three results*



*cobas® MPX detects and discriminates
the most critical viral targets in one
easy-to-use assay.*

Potential transmission of viral infections, particularly HIV-1, HIV-2, HCV and HBV is a major concern in the transfusion of blood and blood components. Transmission of these agents primarily occurs by exposure to contaminated blood or blood and plasma products, exposure to certain body tissues or fluids, by sexual contact or by an infected mother to her newborn child.

cobas® MPX is a qualitative *in vitro* nucleic acid test for the detection of HIV, HCV and HBV in serum and plasma specimens from human donors.

Your benefits

Improve blood and plasma supply safety with cobas® MPX



Provides heightened protection from transfusion-transmitted HIV-1, HIV-2, HCV, and HBV infection for recipients of donated blood or blood products

Highly sensitive and specific test with dual target approach for HIV-1 Group M and dual probes for HCV

Increased safety with detection of occult and low viremic HBV infection

Generate trusted, reproducible results with proven performance



Full-process internal control helps ensure result integrity

Stabilised real-time PCR reagents do not require calibration

True external positive controls that have no direct effect on calibration with **cobas® MPX** control kit

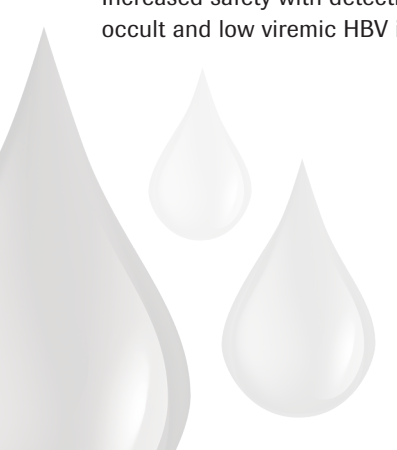
Leverage absolute automation to drive increased efficiency with minimal human interactions



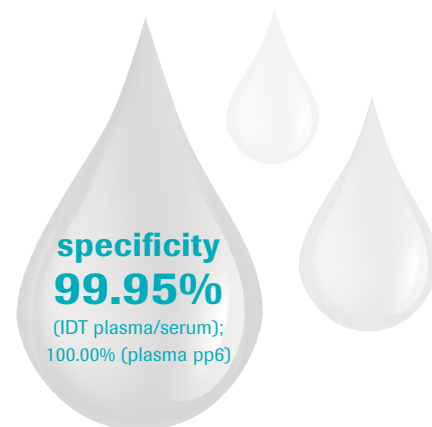
Real-time detection and discrimination of HIV, HCV and HBV

Ready-to-use reagents do not require thawing, mixing or pouring

Flexibility to run simultaneously with other assays on the **cobas®** 5800/6800/8800 Systems



cobas[®] MPX performance



Limit of detection

EDTA Plasma	Units	95% LoD ¹	LCL/UCL
HIV-1 Group M IU/mL	IU/mL	25.7	21.1 -32.8
HIV-1 Group O	copies/mL	8.2	7.0-10.0
HIV-2	IU/mL	4.0	3.3-5.2
HCV	IU/mL	7.0	5.9-8.6
HBV	IU/mL	1.4	1.2-1.7

Key parameters

Parameter	Description
Assay targets	HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV
Sample type	serum, plasma, living and cadaveric donor
Pool sizes	IDT; pools of 1, 6, 24, 96 with cobas[®] Synergy software
Minimum amount of sample required	1000 µL (living donor) 300 µL (cadaveric donor)
Sample processing volume	850 µL (living donor) 150 µL (cadaveric donor)
Testing time	Approximately 3 hours
Open kit stability	
Number of runs	

cobas[®] 5800	cobas[®] 6800/8800
90 days	30 days
40 runs (480T)	10 runs (96T) 20 runs (480T)

Comprehensive NAT menu for blood and plasma screening²

Blood and plasma screening tests

cobas[®] MPX	cobas[®] Zika¹
cobas[®] WNV¹	cobas[®] CHIKV/DENV^{1,4}
cobas[®] DPX^{1,3}	cobas[®] Babesia¹
cobas[®] HEV^{1,4}	

Disclaimers

¹For use on **cobas[®] 6800/8800** systems only

²Not all tests/assays available in all markets

³**cobas DPX** is an in-process test for plasma intended for further manufacture

⁴Not available in the US

Ordering information

Material number	Product name	Tests per unit (cassette)
Current Material Numbers for cobas[®] 6800/8800		
06997708190	cobas[®] MPX-96, CE-IVD	96 tests
06998909190	cobas[®] MPX-96, US-IVD	96 tests
06998917190	cobas[®] MPX-480, US-IVD	480 tests
06997724190	cobas[®] MPX control kit, CE-IVD	4 runs
06999069190	cobas[®] MPX control kit, US-IVD	4 runs
07002220190	cobas[®] NHP negative control kit	16 runs
New Material Numbers for cobas[®] 5800/6800/8800		
09040862190	cobas[®] MPX-480, CE-IVD	480 tests
09040846190	cobas[®] MPX control kit, CE-IVD	4 runs
09051554190	cobas[®] NHP negative control kit	16 runs

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Regulatory Approval	Deanna Koon Regulatory 17-Dec-2021 13:06:07 GMT+0000

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