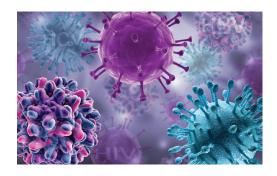


cobas® MPX

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*	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
Assay targets
Sample type
Pool sizes
Minimum amount of sample required
Sample processing volume
Testing time

IDT; pools of 1, 6, 24, 96 with cobas® Synergy software		
1000 μL (living donor) 300 μL (cadaveric donor)		
850 μL (living donor) 150 μL (cadaveric donor)		
Approximately 3 hours		
cobas ® 5800	cobas ® 6800/8800	

HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV

serum, plasma, living and cadaveric donor

Open kit stability		
Number of runs		

cobas ® 6800/8800	
30 days	
 10 runs (96T) 20 runs (480T)	

Comprehensive NAT menu for blood and plasma screening²

Blood and plasma screening tests

cobas® MPXcobas® Zika¹cobas® WNV¹cobas® CHIKV/DENV¹,⁴cobas® DPX¹,³cobas® Babesia¹

cobas® HEV1,4

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

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diagnostics.roche.com

Ordering information

Description

90 days

40 runs (480T)

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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Medical Approval	Jean Stanley Medical 09-Dec-2021 23:09:24 GMT+0000
Other Approval	Kate Suileabhain Business 09-Dec-2021 23:17:09 GMT+0000
Legal Approval	Debra Robinson Legal 10-Dec-2021 12:27:21 GMT+0000
Regulatory Approval	Deanna Koon Regulatory 17-Dec-2021 13:06:07 GMT+0000

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