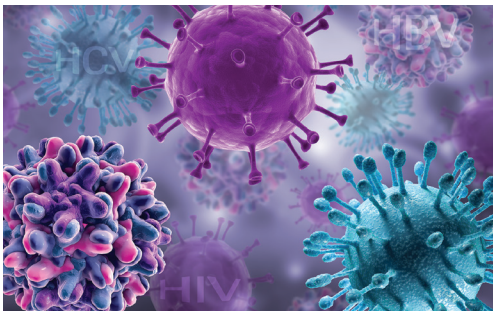


cobas[®] MPX

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

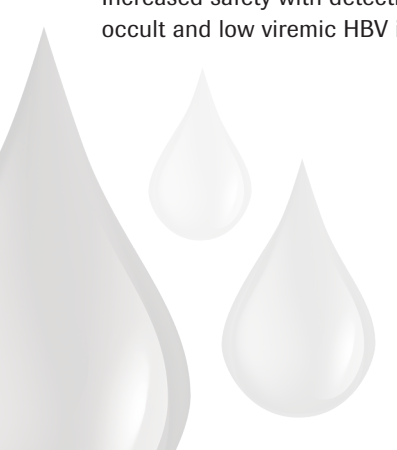
Leverage absolute automation to drive increased efficiency with minimal human interactions



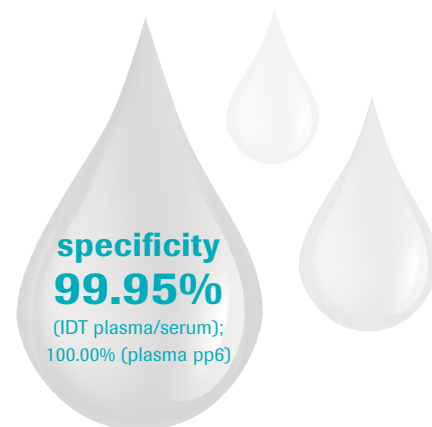
Real-time detection and discrimination of HIV, HCV and HBV

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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| | |
|---------------------|---|
| 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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