Device Schedule:

Intended Purpose as per the Instructions for Use:

The **cobas**® MPX test, for use on **cobas**® 5800/6800/8800 Systems is a qualitative in vitro test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA, and Hepatitis B Virus DNA in human plasma and serum.

This test is intended for use to screen donor samples for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in plasma and serum samples from individual human donors, including donors of whole blood, blood components, and other living donors. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donor's heart is still beating and in testing of cadaveric (non-heart beating) donors. Plasma and serum from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma and serum samples may be tested individually or plasma may be tested in pools comprised of aliquots of individual samples. For donations from cadaveric (non-heart beating) organ and tissue donors, samples may only be screened as individual sample.

For an individual sample, results are simultaneously detected and discriminated for HIV, HCV, and HBV.

The **cobas**® MPX test can be considered a supplemental test that confirms HIV infection for samples that are repeatedly reactive on a CE-IVD test for antibodies to HIV and reactive on the **cobas**® MPX test.

The **cobas**® MPX test can be considered a supplemental test that confirms HCV infection for samples that are repeatedly reactive on a CE-IVD test for antibodies to HCV and reactive on the **cobas**® MPX test.

The **cobas**® MPX test can be considered a supplemental test that confirms HBV infection for samples that are repeatedly reactive on a CE-IVD test for Hepatitis B surface antigen and reactive on the **cobas**® MPX test.

This test may also be used as an aid in the diagnosis of HIV, HCV, or HBV in samples collected from individuals suspected of infection with these viruses by their healthcare provider or to screen individuals whose infection status for HIV, HCV or HBV is unknown.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® MPX - 480	09040862190	IVR 0502	Class D	761333600540AA
cobas® MPX - 192	09288538190	IVR 0502	Class D	761333602493B8
cobas® MPX Control Kit	09040846190	IVR 0502	Class D	761333600541AC
cobas® NHP Negative Control Kit	09051554190	IVR 0502	Class D	761333600542AE