

PROCLEIX[®] ULTRIO[®] Assay – Intended use

The PROCLEIX[®] ULTRIO[®] Assay is a qualitative in vitro nucleic acid assay system to screen for human immunodeficiency virus type I (HIV-1) RNA and hepatitis C virus (HCV) RNA in plasma and serum specimens from individual human donors, including donors of whole blood and blood components, source plasma and other living donors.

It is also intended for use in testing plasma and serum specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens from cadaveric (non-heart-beating) donors.

The assay is not intended for use on cord blood specimens.

The assay is intended for use in testing individual samples from living donors of whole blood, blood components, or source plasma, other living donors and heart-beating organ donors, and for testing individual blood specimens from cadaveric (non-heart-beating) donors. It is also intended for use in testing pools of human plasma comprised of equal aliquots of not more than 16 individual donations from donors of whole blood, blood components, or source plasma.

This assay is intended to be used in conjunction with licensed tests for detecting antibodies to HIV-1 and HCV.

The PROCLEIX[®] ULTRIO[®] Assay is not intended for use to screen donor specimens for HBV DNA.

The assay detects HBV DNA in HBV seroconversion panel specimens that are negative for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B core antigen (anti-HBc). The assay also detects HBV DNA in donor specimens that are positive for HBsAg and/or anti-HBc. However, detection of HBV DNA in donations negative for both HBsAg and anti-HBc has not been demonstrated in the donor setting.