

Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas® DPX – 96:

The **cobas®** DPX test is an in vitro test for the direct quantitation of parvovirus B19 genotypes 1, 2, and 3 DNA and the direct qualitative detection of Hepatitis A virus (HAV) genotypes I, II, and III RNA in human plasma.

This test is intended for use as an in-process test to quantify parvovirus B19 DNA alone or to simultaneously quantify parvovirus B19 DNA and detect HAV RNA in plasma intended for further manufacture collected from donors of whole blood, blood components, or plasma. Plasma from all donors or manufacturing pools may be tested as individual samples or in pools comprised of aliquots of individual samples.

This test is not intended for use on samples of cord blood.

This test is not intended for use as an aid in diagnosis for parvovirus B19 or HAV

cobas® DPX – 192 & cobas® DPX Control Kit:

The **cobas®** DPX test for use on the **cobas®** 5800/6800/8800 systems is an in vitro test for the direct quantitation of parvovirus B19 genotypes 1, 2, and 3 DNA and the direct qualitative detection of Hepatitis A virus (HAV) genotypes I, II, and III RNA in human plasma.

This test is intended for use as an in vitro test to quantify parvovirus B19 DNA alone or to simultaneously quantify parvovirus B19 DNA and detect HAV RNA in plasma collected from donors of whole blood and blood components. Plasma from all donors may be tested as individual samples or in pools comprised of aliquots of individual samples.

This test is not intended for use on samples of cord blood.

This test is not intended for use as an aid in diagnosis for parvovirus B19 or HAV.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
cobas® DPX - 96	07001088190	IVR 0502	Class D	761333600859BE
cobas® DPX - 192	09171126190	IVR 0502	Class D	761333602495BC
cobas® DPX Control Kit	09040749190	IVR 0502	Class D	761333600860AX