

Device Schedule:

Intended Purpose as per the Instructions for Use:

Intended Purpose - cobas® HEV-96

The **cobas®** HEV test for use on **cobas®** 6800 and **cobas®** 8800 Systems is a qualitative in vitro nucleic acid amplification test for the direct detection of hepatitis E virus (HEV) RNA (genotypes 1-4) in human plasma.

This test is intended for use to screen donor samples for HEV RNA in plasma samples from individual human donors, including donors of whole blood, blood components (red cells, platelets, and plasma), and other living donors. Plasma from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma samples may be tested individually or plasma may be tested 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 HEV.

Intended Purpose - cobas® HEV-192

The **cobas®** HEV test for use on **cobas®** 5800/6800/8800 Systems is a qualitative in vitro nucleic acid amplification test for the direct detection of hepatitis E virus (HEV) RNA (genotypes 1-4) in human plasma.

This test is intended for use to screen donor samples for HEV RNA in plasma samples from individual human donors, including donors of whole blood, blood components (red cells, platelets, and plasma), and other living donors. Plasma from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma samples may be tested individually or plasma may be tested in pools comprised of aliquots of individual samples.

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

This test may also be used as an aid in diagnosis of HEV in samples collected from individuals suspected of infection with HEV by their healthcare provider.

Intended Purpose – cobas® HEV Control Kit

The Intended purpose of the control is included in the intended purpose of the reagents.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Basic UDI-DI
cobas ® HEV-96	07001045190	IVR 0502	Class D	761333600850AU
cobas ® HEV-192	09040986190	IVR 0502		761333602496BE
cobas ® HEV Control Kit	09040889190	IVR 0502		761333600851AW