

Device Schedule:

Intended Purpose as per the Instructions for Use:

cobas[®] HBV is an in vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human EDTA plasma or serum of HBV-infected individuals.

This test is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from **cobas**[®] HBV must be interpreted within the context of all relevant clinical and laboratory findings.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
cobas [®] HBV	09040820190	IVR 0504	Class D	761333600845B3