

Genedrive HCV ID Kit



Systemex Asia Pacific is the exclusive distributor for Genedrive point of need molecular diagnostic device and Genedrive HCV ID kit in Asia Pacific region (excluding India). For further enquiries, please email us at systemex@systemex-ap.com.

Genedrive HCV ID Kit, molecular diagnostics at the point of need

Decentralised molecular testing

- Highly accurate results available from smaller laboratories or clinics supporting accelerated treatment decisions and initiation.

Cost effective

- Avoiding the high costs and commitments of central laboratory solutions, Genedrive provides affordable testing for low throughput settings.

Simple & Easy

- Easy to perform HCV test without separate RNA extraction process & therefore can be performed by any lab technician with basic training.

Performance characteristics

In a two site performance evaluation Genedrive HCV ID Kit was compared to Abbott RealTime HCV Assay in 957 frozen samples, with HCV positive samples at levels above 1000 IU/ml.

	Overall
Sensitivity	99.8%
Specificity	100%

		Genedrive HCV ID Kit	
		Positive	Negative
Abbott RealTime HCV Assay	Positive	406	1
	Negative	0	550



Test procedure

Procedure				
Description	Mix 30µl plasma sample with 60µl nuclease free water.	Add sample to the cartridge. Insert cartridge into the Genedrive and start the Plasma Preparation reaction.	Upon completion, add HCV PCR reagents to the cartridge. Insert the cartridge into the Genedrive and start the HCV assay.	Results are displayed within 90 minutes.

Specifications

Test name	Genedrive HCV ID Kit
Technology	Qualitative detection of viral RNA by post PCR melt analysis
Time to result	90 minutes
Hands-on time	<5 minutes
Sample type	Fresh human whole blood derived plasma in K ₂ or K ₃ EDTA anticoagulant
Sample stability	EDTA Whole blood: 6 hours at room temperature (21.5 °C – 25.4 °C) or 72 hours at 4 °C. EDTA plasma : 24 hours at room temperature (25 °C) or 4 days at 4 °C
Analytical sensitivity	2362 IU/ mL (95% CI 1966 – 2758 IU/ mL)
Genotypes	1a, 1b, 2, 3, 4, 5 and 6
RNA extraction	Not required
In built controls	Internal process control
Product code	ID-HCV-03
Pack size	10 tests/ kit
Kit storage	2–30 °C
Materials required but not supplied	Genedrive instrument and calibrated P20 and P100 pipettes