AUTOMATED TESTING FOR HEPATITIS VIRUSES

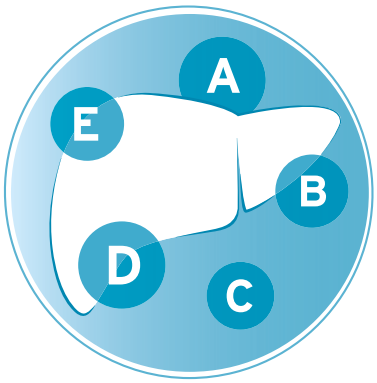
Full hepatitis portfolio from A to E

Hepatitis is an acute or chronic inflammation of the liver. One of the main causes of hepatitis is an infection with one of the five phylogenetically unrelated hepatitis viruses A, B, C, D, and E. While patients usually recover from a transient, acute HAV or HEV infection, over 325 million people worldwide live with a chronic hepatitis B and/or C infection, which can lead to liver cirrhosis and liver cancer. All contributions to positively change this burden are vital.

altona Diagnostics provides five AltoStar® ready-to-use test kits for the detection and/or quantification of DNA/RNA from different hepatitis viruses.

AltoStar® HAV RT-PCR Kit 1.5 (Qualitative detection)
AltoStar® HBV PCR Kit 1.5
AltoStar® HCV RT-PCR Kit 1.5
AltoStar® HDV RT-PCR Kit 1.5
AltoStar® HEV RT-PCR Kit 1.5

These CE-IVD marked AltoStar® kits are intended for use with the AltoStar® Molecular Diagnostic Workflow, which automates your PCR analyses from sample extraction to PCR results with only one extraction chemistry.



AUTOMATED TESTING FOR HEPATITIS VIRUSES

AltoStar® hepatitis portfolio

DISCOVER THE KIT
Hepatitis A

DISCOVER THE KIT
Hepatitis B

	AltoStar® HAV RT-PCR Kit 1.5	AltoStar® HBV PCR Kit 1.5
Order No.	AS0241543	AS0201513
Validated sample type	Human EDTA plasma, Human citrate plasma	Human EDTA plasma
Sample volume	500 µl	1,000 µl
Genotypes detected	HAV genotypes 1a, 1b, 2a, 3a	HBV genotypes A to H
Analytical specificity	≥ 95%	≥ 99%
Limit of detection	6.31 IU/ml (95% confidence interval: 4.17–11.99 IU/ml)	10.2 IU/ml (95% confidence interval: 7.6–15.8 IU/ml)
Linear range	n.a.	20–10,000,000 IU/ml
Quantification standards calibrated against	n.a.	4th WHO International Standard for HBV DNA for NAT (NIBSC code: 10/266)
Temperature profile*	AltoStar® RNA	AltoStar® DNA
Validated real-time PCR instruments	• ABI Prism® 7500 SDS (Applied Biosystems) • CFX96™ Deep Well Dx System (Bio-Rad) • CFX96™ Dx System (Bio-Rad) • LightCycler® 480 Instrument II (Roche) • QuantStudio™ 5 Real-Time PCR System (Applied Biosystems) • Rotor-Gene® Q5/6plex Platform (QIAGEN)	• CFX96™ Deep Well Dx System (Bio-Rad)

*All AltoStar® kits using the same temperature profile can be run in parallel.

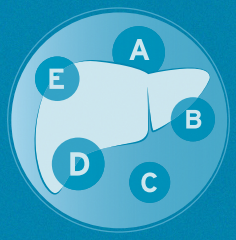
DISCOVER THE KIT
Hepatitis C

DISCOVER THE KIT
Hepatitis D

DISCOVER THE KIT
Hepatitis E

AltoStar® HCV RT-PCR Kit 1.5	AltoStar® HDV RT-PCR Kit 1.5	AltoStar® HEV RT-PCR Kit 1.5
AS0211513	AS0401543	AS0271543
Human EDTA plasma, Human serum	Human EDTA plasma, Human serum	Human EDTA plasma, Human citrate plasma
1,000 µl	500 µl	1,000 µl
HCV genotypes 1 to 6	HDV genotypes 1 to 8	HEV genotypes 1a, 1e, 2a, 3a, 3b, 3c, 3e, 3f, 4c, 4g
≥ 99%	≥ 99%	≥ 95%
11.1 IU/ml (95% confidence interval: 7.8–18.5 IU/ml)	1.12 IU/ml (95% confidence interval: 0.72–2.20 IU/ml)	3.41 IU/ml (95% confidence interval: 2.28–6.37 IU/ml)
25–10,000,000 IU/ml	20–1,000,000 IU/ml	50–1,000,000 IU/ml
6th WHO International Standard for HCV RNA for NAT (NIBSC code: 18/184)	1st WHO International Standard for Hepatitis D Virus RNA for NAT (PEI code: 7657/12)	1st WHO International Standard for Hepatitis E Virus RNA for NAT (PEI code: 6329/10)
AltoStar® RNA	AltoStar® RNA	AltoStar® RNA
• CFX96™ Deep Well Dx System (Bio-Rad)	• CFX96™ Deep Well Dx System (Bio-Rad)	• ABI Prism® 7500 SDS (Applied Biosystems) • CFX96™ Deep Well Dx System (Bio-Rad) • LightCycler® 480 Instrument II (Roche)

powered by integrity



HEADQUARTERS

altona Diagnostics GmbH
Mörkenstr. 12
22767 Hamburg, Germany

phone +49 40 548 0676 0
fax +49 40 548 0676 10
e-mail info@altona-diagnostics.com

www.altona-diagnostics.com

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