RealStar® HEV RT-PCR Kit 1.0

Recent studies have shown the clinical relevance of Hepatitis E virus. The presence of HEV-RNA in plasma samples and the potential of HEV to lead to chronic hepatitis (in immunocompromised or pregnant patients) underline the need for a suitable diagnostic test.

Infections with HEV are a significant public health problem with 2.3 billion infections globally. Particularly HEV genotypes 3 and 4 leading to zoonotic infections are well known in industrialized nations (6).

In Europe mainly HEV subtypes 3c, 3e and 3f are prevalent (6). For immunocompromised patients HEV3 is an emerging concern as it may lead to chronic infection and cirrhosis (6). The fatality rate ranges from 0.2-4.0% in the general population, considerably increasing in pregnant woman to 10-25% (6).

Several studies have reported detecting HEV RNA in pooled plasma samples (3, 4, 5). Using the altona RealStar® HEV RT-PCR Kit 1.0 assay it was found that 0.08% of individual plasma samples or 1.18% of plasma pools were positive for HEV RNA in Germany (4, 7) indicating its relevance in blood safety.

Detected samples had low concentrations between $1.3x10^3$ and $6.3x10^4$ IU/ml (mean 10^4 IU/ml) (4) and $1.3x10^1$ $6.8x10^4$ (7) underlining the need for a highly sensitive HEV RT-PCR assay.

Excellent analytical sensitivity of the altona RealStar® HEV RT-PCR Kit 1.0 was confirmed independently (1).

The RealStar® HEV RT-PCR Kit provides the high analytical sensitivity and reproducibility needed for reliable detection of HEV RNA. The excellent performance allows the safe detection in patient samples with low virus titers.

		Ceeram Tools	altona Diagnostics
HEV strain	**Sample (IU/ml)**	**No. of samples detected**	**No. of samples detected**
3a	2500	6/6	6/6
	500	6/6	6/6
	100	5/6	6/6
	20	0/6	4/6
3c	2500	6/6	6/6
	500	6/6	6/6
	100	6/6	6/6
	20	1/6	6/6
3e	2500	6/6	6/6
	500	6/6	6/6
	100	6/6	6/6
	20	5/6	6/6
3f	2500	6/6	6/6
	500	6/6	6/6
	100	4/6	6/6
	20	2/6	2/6
All samples		**77/96**	**90/96**

Table 1: Data obtained with the Ceeram and the altona Diagnostics assays for the 4 reference strains (modified according to Abravanel et al. 2013, J. Clin. Microbiol.)

1. Abravanel et al. 2013, J Clin Microbiol. 51(6):1913-6; **2.** Abravanel et al. 2012, J Clin Microbiol. 50(3):897-902; **3.** Baylis et al. 2012, Vox Sang. 102:182-3; **4.** Corman et al. 2013, Vox Sang., 104, 179-180; **5.** Ijaz et al. 2011, Vox Sang. 102:272; **6.** Kamar et al. 2012 Lancet; 379(9835):2477-88; **7.** Vollmer et al. 2012, J Clin Microbiol. 50(8):2708-13

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