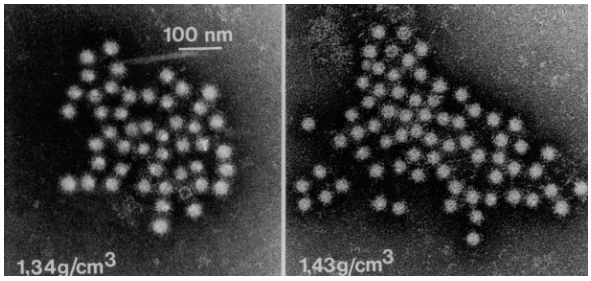
anti-Hepatitis A Virus Antibodies
ELISA E10/E11

Hepatitis A is caused by HAV, a 27-nm ribonucleic acid (RNA) virus that is classified as a picornavirus. Only one serotype has been observed among HAV isolates collected from various parts of the world. HAV causes both acute disease and asymptomatic infection. HAV does not cause chronic infection. Total antibody to HAV develops in response to infection and confers lifelong immunity from future HAV infection.



Electron microscopic picture of HAV particles with bound antibodies.

Antibodies against HAV-Antigen can be used to asses the course of disease as well as the level of immunity.

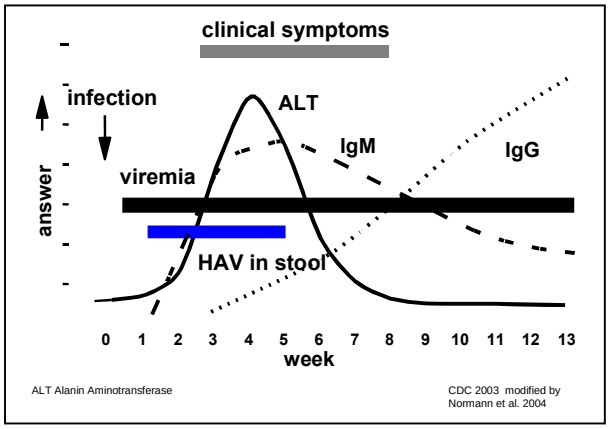
First answer of the immune system regarding a HAV infection is the synthesis of IgM antibodies. These antibodies can only be detected in human serum shortly after infection. Depending on the anti-HAV IgM titre it is possible to differentiate between an acute infection (1 - 3 months after the start of clinical symptoms) and early convalescence (3 - 6 months). In rare cases (approx. 10% of all clinical cases) the anti-HAV IgM response remains positive (6 - 12 months).

Positive detection of antibodies directed against the Hepatitis A virus (anti-HAV) is evidence of immunity to Hepatitis A virus.
The Anti-HAV titers 3 to 6 months after naturally occuring infections are very high, within the range of 100 to more than 300 International Units per ml (IU/ml). Even after more than 10 years the titers usually remain at more than 1 IU/ml. A value of 10 mIU/ml can be considered the minimal protective level.

Mediagnost HAV ELISA E10
HAV – antigen coated microtiterplates are used in this highly specific and sensitive assay. In this competitive assay peroxidase-labelled anti-HAV antibodies compete with antibodies in the sample. Using IgG standard preparations not only qualitative but also quantitative measurement is possible.

Assay Features E10

- ✓ Cut-off sensitivity 100 mIU/ml
- ✓ Calibrated against the World Health Organization (WHO) International Standard NIBSC Code 97/646 - and PEI-IVD anti-HAV IgG
- ✓ Intra-Assay variance of positive and negative control ≤ 10%
- ✓ Inter-Assay variance ≤ 10%.



Mediagnost HAV ELISA E11
The Mediagnost anti-HAV IgM EIA is a "class-capture" enzyme immuoassay. Microtiterplates are coated with µ-chain specific anti-IgM-antibodies. Incubated with HAV-antigen allows the detection of bound IgM antibodies by a peroxidase-labelled monoclonal HAV-antigen specific antibody.

Mediagnost ELISAs E10 and E11 were approved by Paul-Ehrlich Institute, Germany (110a/95; 1529a/89).

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Mediagnost anti-HAV IgG ELISA E10

Dilution of Reagents and Samples		
Conjugat concentrate **KK**	In Dilution Buffer **VP**	1:100
Washing Buffer **WP**	in Aqua dest. (e.g. add 50 ml **WP** in a graduated flask and fill with A.dest to 1000 ml)	1:20
Dilute samples 1:10 with Dilution Buffer **VP** (qualitative Test). For quantitative Antibody determination* dilute at least 1:10 with Dilution Buffer **VP**		

Pipette	Reagents	Position
	Blank	A1/A2
2 x 100 µl	Positive Control **PK**	B1/B2
2 x 100 µl	Negative Control **NK**	C1/C2
* Additonal Protocol for quantitative Determination s. below *		
2 x 100 µl	Sample dilution	Pipette sample in the rest of the wells according the requirements
Cover the wells with the sealing tape.		
Incubation: 2 h at 37°C		
50 µl	1:100 diluted Conjugate Concentrate KK	Beginning with the position B1 in all following wells
Cover the wells with the sealing tape.		
Incubation: 1 h at 37°C		
3 x 300 µl	Aspirate the contents of the wells and wash 3x with 300 µl each Wash Buffer **WP**/well	In all wells
100 µl	Substrate Solution **S**	In all wells
Incubation: 30 min in the Dark at RT		
100 µl	Stopping solution **SL**	In all wells
Measure the absorbance (450/≤ 590nm) during 30 minutes		
*** The quantitative protocol**		
Pipette	Reagents	Position
2 x 100 µl	Standard 1 **STD 1**	D1/D2
2 x 100 µl	Standard 2 **STD 2**	G1/G2
2 x 100 µl	Standard 3 **STD 3**	F1/F2

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