HEV Seroconversion Panel

REF **Catalogue No: SCP-HEV-004a**

The DiaMex GmbH HEV Seroconversion Panel consists of 11 members with each member containing 1.0 mL of human plasma. This panel illustrates the onset and decline of IgM and IgG Hepatitis E virus antibodies from one individual over a period of 47 days.

1. Intended Use

This Seroconversion Panel (SCP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of IgM/IgG antibody test systems and methods. Moreover, it serves as validation tool for diagnostic sensitivity, determination of analytical sensitivity, identification of cut-off values or to study the humoral immune response to this infection.

2. Storage and Stability

Store the SCP at -20°C to -80°C. Thaw samples at room temperature and mix gently by inversion before usage. Avoid foaming, contamination and repeated freeze and thaw cycles. After usage, return immediately to storage conditions.

3. Warnings and Precautions

Potentially infectious materials. Handle the product as if capable of transmitting infectious diseases. Do not pipette by mouth.

Prevention:

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using this product

P273: Avoid the release to the environment

Disposal:

P501: Dispose of waste in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

Declaration of used symbols

REF	LOT			2°C 8°C
Catalog Number	Lot Number	Consult Instructions for Use	Manufactured by	Temperature Limitation

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV 1/2, anti-HCV and HBsAg with CE marked tests.

Donor profile

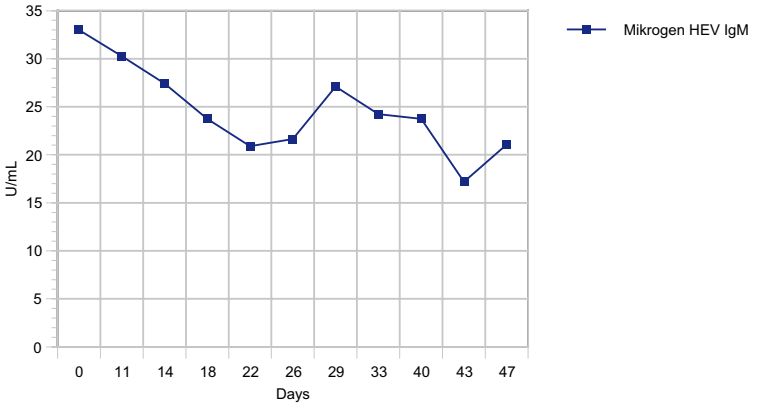
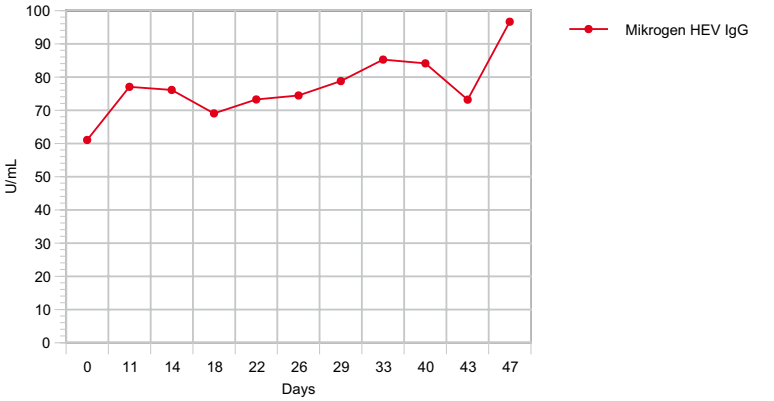
- Sex: Male
- Age: 26
- Ethnicity: Caucasian
- Residence: Germany
- HEV Genotype: 3c

5. Detection Methods

Each panel member has been tested for HEV RNA with RealStar HEV RT-PCR kit by Altona Diagnostic Technologies (ADT). The HEV IgM and IgG antibodies were detected with Mikrogen recomWell. Testing is performed with CE marked test.

6. Limitations and Restrictions

This panel is for Research Use Only and not intended for human or animal diagnostics, or for therapeutic purposes. Each laboratory has the responsibility to ascertain the suitability of the SCP for its particular application and to establish their own guidelines for interpretation of results. Data is provided for informational purposes only. The DiaMex GmbH does not claim that others can duplicate these test results exactly.

HEV Seroconversion Panel, Catalogue No: SCP-HEV-004a

Panel Member	Day	Bleed Date	RealStar HEV RT PCR IU/mL	Mikrogen recomWell HEV IgM U/mL	Mikrogen recomWell HEV IgM Valuation	Mikrogen recomWell HEV IgG U/mL	Mikrogen recomWell HEV IgG Valuation	GLDH U/L	ALT U/L	AST U/L	BiliT mg/dL
				cut off 24 U/mL		cut off 24 U/mL					
1	0	04.08.2011	1.86E+01	33.00	positive	61.05	positive	2.9	12	22	0.16
2	11	15.08.2011	7.72E+00	30.28	positive	77.06	positive	3.2	20	24	0.40
3	14	18.08.2011	negative	27.42	positive	76.10	positive	2.4	15	22	0.26
4	18	22.08.2011	negative	23.75	borderline	69.00	positive	3.3	20	30	0.19
5	22	26.08.2011	negative	20.90	borderline	73.25	positive	<2.0	17	26	0.21
6	26	30.08.2011	negative	21.65	borderline	74.44	positive	3.6	21	30	0.19
7	29	02.09.2011	negative	27.11	positive	78.76	positive	2.9	17	29	0.17
8	33	06.09.2011	negative	24.22	positive	85.26	positive	4.6	27	30	0.26
9	40	13.09.2011	negative	23.74	borderline	84.09	positive	3.9	24	28	0.25
10	43	16.09.2011	negative	17.19	negative	73.18	positive	2.1	15	23	0.23
11	47	20.09.2011	negative	21.05	borderline	96.61	positive	2.7	18	27	0.22