HEV Seroconversion Panel

REF **Catalogue No: SCP-HEV-005a**

The DiaMex GmbH HEV Seroconversion Panel consists of 20 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 140 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: 27
- Ethnicity: Caucasian
- Residence: Germany
- HEV Genotype: 3a

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.

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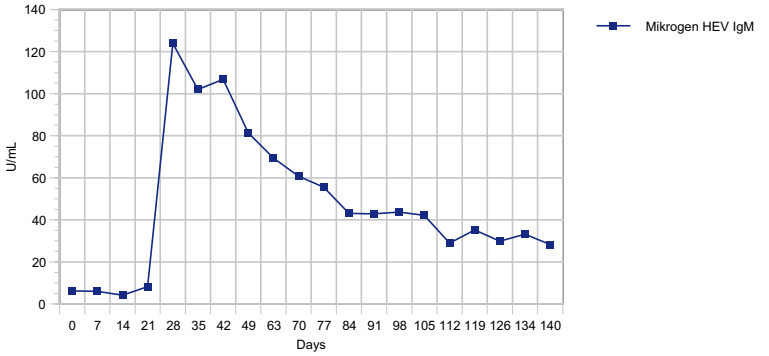
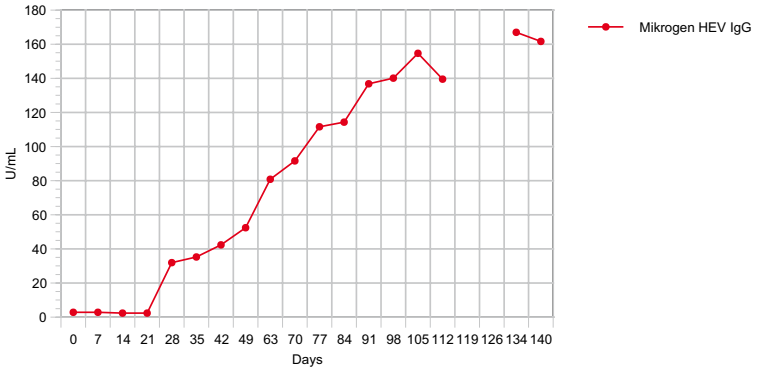
Panel Member	Day	Bleed Date	RealStar HEV RT PCR IU/mL	Mikrogen recom-Well HEV IgM U/mL	Mikrogen recomWell HEV IgM Valuation	Mikrogen recomWell HEV IgG U/mL	Mikrogen recomWell HEV IgG Valuation	GLDH U/L	ALT U/L	AST U/L	BiliT mg/dL
				cut off 24 U/mL		cut off 24 U/mL					
1	0	21.07.2011	2.77E+01	6.19	negative	2.82	negative	<2.0	10	26	0.73
2	7	28.07.2011	2.45E+02	6.03	negative	2.76	negative	2.3	14	36	0.82
3	14	04.08.2011	6.32E+03	4.14	negative	2.39	negative	3.0	14	37	0.82
4	21	11.08.2011	1.63E+04	8.20	negative	2.28	negative	3.3	24	39	0.80
5	28	18.08.2011	2.99E+02	123.91	positive	31.88	positive	2.4	20	34	0.39
6	35	25.08.2011	1.20E+01	102.04	positive	35.23	positive	<2.0	17	30	0.60
7	42	01.09.2011	negative	106.77	positive	42.32	positive	<2.0	15	29	0.52
8	49	08.09.2011	negative	81.28	positive	52.40	positive	<2.0	17	30	0.66
9	63	22.09.2011	negative	69.41	positive	80.80	positive	<2.0	10	23	0.36
10	70	29.09.2011	negative	60.66	positive	91.55	positive	2.4	11	30	0.59
11	77	06.10.2011	negative	55.55	positive	111.60	positive	2.2	12	33	0.54
12	84	13.10.2011	negative	43.02	positive	114.33	positive	2.1	18	31	1.00
13	91	20.10.2011	negative	42.87	positive	136.83	positive	2.0	14	30	0.83
14	98	27.10.2011	negative	43.66	positive	140.12	positive	2.4	14	33	0.42
15	105	03.11.2011	negative	42.12	positive	154.70	positive	2.1	13	26	0.48
16	112	10.11.2011	negative	28.96	positive	139.54	positive	2.5	13	28	0.24
17	119	17.11.2011	negative	35.20	positive	NT	NT	<2.0	14	27	0.35
18	126	24.11.2011	negative	29.88	positive	NT	NT	<2.0	12	25	0.45
19	134	02.12.2011	negative	33.13	positive	167.04	positive	<2.0	17	30	0.56
20	140	08.12.2011	negative	28.23	positive	161.71	positive	2.1	13	27	0.57

NT= not tested

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