HEV Seroconversion Panel

REF **Catalogue No: SCP-HEV-009a**

The Biomex GmbH HEV Seroconversion Panel consists of 9 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 133 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			8°C 2°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: 20
- 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 Biomex 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	09.08.2011	37.8	7.23	negative	7.72	negative	2.3	26	29	0.13
2	21	30.08.2011	2480	13.05	negative	9.59	negative	2.2	42	46	<0.10
3	59	07.10.2011	negative	8.73	negative	65.03	positive	5.2	41	50	0.18
4	63	11.10.2011	negative	7.39	negative	54.14	positive	3.8	35	47	0.18
5	80	28.10.2011	NT	8.43	negative	56.13	positive	2.6	38	44	<0.10
6	84	01.11.2011	NT	6.90	negative	51.73	positive	3.8	48	47	0.14
7	105	22.11.2011	NT	NT	NT	NT	NT	2.6	29	40	<0.10
8	111	28.11.2011	NT	8.83	negative	51.47	positive	3.8	37	42	0.21
9	133	20.12.2011	NT	7.08	negative	47.67	positive	2.4	31	36	0.21

NT= not tested