HIV Seroconversion Panel

REF Catalogue No: SCP-HIV-008

The Biomex GmbH HIV Seroconversion Panel consists of 8 members with each member containing 1.0 mL of human plasma. This panel illustrates the onset of immune system response to HIV from one individual over a period of 46 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 antigene and 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.

Disposal:

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

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.

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 HBsAg and anti-HCV with CE approved tests.

5. Detection methods

Each panel member is assayed for HIV with Abbott ARCHITECT®, HIV Ag/Ab combo assay. Viral load determination is performed with the Abbott m2000 RealTime System. Testing is carried out with CE marked tests.

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 panel 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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08/2023

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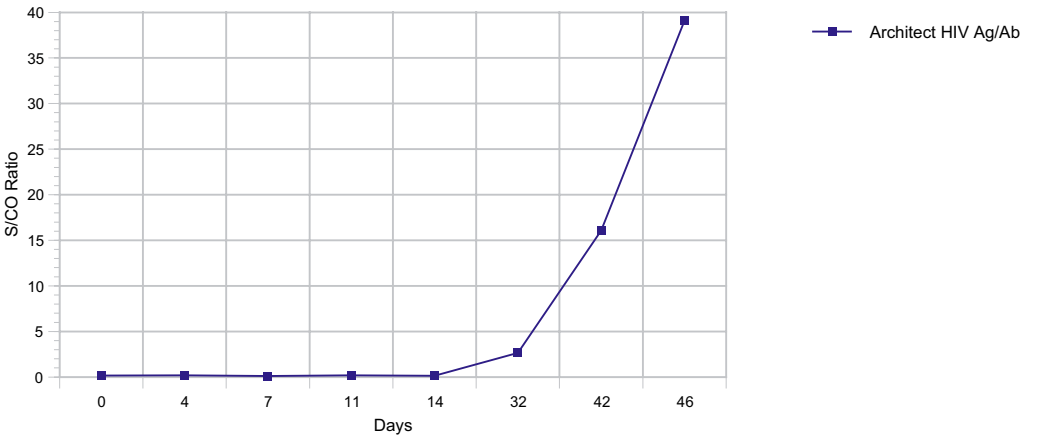
Panel member	Day	Bleed Date	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	Abbott m2000 RealTime System IU/ml	Abbott m2000 RealTime System cp/ml
			cut off 1.0 S/CO		
1	0	26.08.2011	0,16	<70	<40
2	4	30.08.2011	0,19	<70	<40
3	7	02.09.2011	0,12	<70	<40
4	11	06.09.2011	0,18	26	15
5	14	09.09.2011	0,13	<70	<40
6	32	27.09.2011	2,64	414271	238087
7	42	07.10.2011	16,07	1491383	857117
8	46	11.10.2011	39,06	2574559	1479631



Subtype: C

The Subtype has been determined with Applied Biosystems 3130 Genetic Analyzer and a Lab developed test that is similar to the Abbott ViroSeq HIV-1 Genotyping System.

Assay information:

Assay	Lot#	Exp. Date	Test Date
Abbott Architect HIV Ag/Ab combo assay	72171LI00	09.10.2017	13.03.2017
Abbott Architect Anti-HCV assay	70584LI00	10.08.2017	13.03.2017
Abbott Architect HBsAg qualitative II assay	68337FN00	08.09.2017	13.03.2017
Abbott RealTime HIV Amplification Kit	11264191	January 2018	08.03.2017

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