CMV IgM Seroconversion Panel

REF Catalogue No: SCP-CMV-007

The Biomex GmbH CMV IgM Seroconversion Panel consists of 19 members with each member containing 0.5 mL of human plasma. This panel illustrates the onset and decline of IgM and IgG Cytomegalovirus antibodies from one individual over a period of 98 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

				
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.

Donor profile

- Sex: Male
- Age: 22
- Ethnicity: Caucasian
- Residence: Europe

5. Detection Methods

Each panel member is assayed for IgM and IgG antibodies with Abbott ARCHITECT®, Roche COBAS® and Diasorin LIAISON® test devices. 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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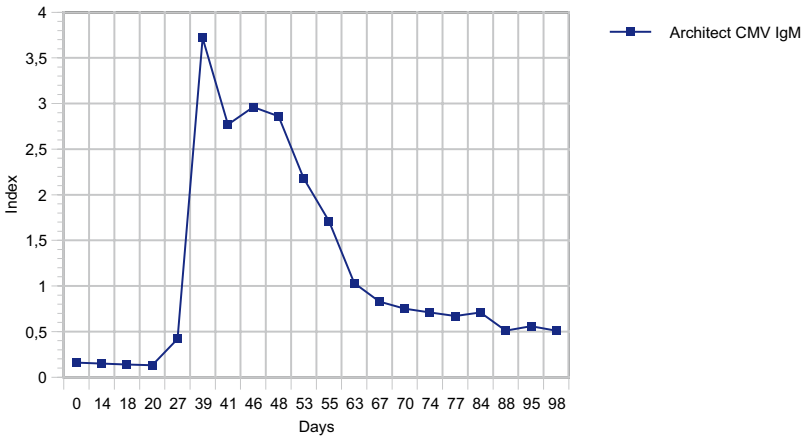
Panel Member	Day	Bleed date	Abbott Architect CMV IgM Index	Abbott Architect CMV IgG AU/mL	Roche Cobas e411 CMV IgM COI	Roche Cobas e411 CMV IgG U/mL	Diasorin Liaison CMV IgM II U/mL	Diasorin Liaison CMV IgG II U/mL
			cut off 1.0 Index	cut off 6.0 AU/mL	cut off 1.0 COI	cut off 1.0 U/mL	cut off 22 U/mL	cut off 14 U/mL
1	0	26.04.2012	0.16	1.0	0.28	0.15	5.5	5.6
2	14	10.05.2012	0.15	1.2	0.28	0.15	5.7	5.9
3	18	14.05.2012	0.14	1.3	0.27	0.15	5.5	5.6
4	20	16.05.2012	0.13	1.1	0.28	0.15	<5.0	5.4
5	27	23.05.2012	0.42	2.0	3.79	0.51	20.3	9.6
~~6~~	~~39~~	~~04.06.2012~~	~~3.72~~	~~44.0~~	~~23.05~~	~~8.76~~	~~84.5~~	~~39.4~~
7	41	06.06.2012	2.77	46.2	22.00	6.19	80.5	39.0
8	46	11.06.2012	2.96	55.1	17.20	4.99	73.9	41.6
9	48	13.06.2012	2.86	59.9	16.05	4.34	72.0	45.8
10	53	18.06.2012	2.18	66.3	13.15	3.02	50.7	47.5
11	55	20.06.2012	1.71	67.3	11.43	2.39	46.2	50.6
12	63	28.06.2012	1.03	71.2	7.89	1.52	29.9	55.8
13	67	02.07.2012	0.83	70.5	6.54	1.20	24.3	56.5
14	70	05.07.2012	0.75	70.1	5.76	1.01	22.9	56.6
15	74	09.07.2012	0.71	73.7	5.01	0.95	20.9	58.3
16	77	12.07.2012	0.67	77.8	4.37	0.86	20.6	58.1
17	84	19.07.2012	0.71	82.4	3.93	0.78	18.3	58.9
18	88	23.07.2012	0.51	75.4	3.52	0.67	16.6	57.4
19	95	30.07.2012	0.56	81.7	3.30	0.69	16.6	61.0
20	98	02.08.2012	0.51	79.1	3.18	0.61	16.0	60.9

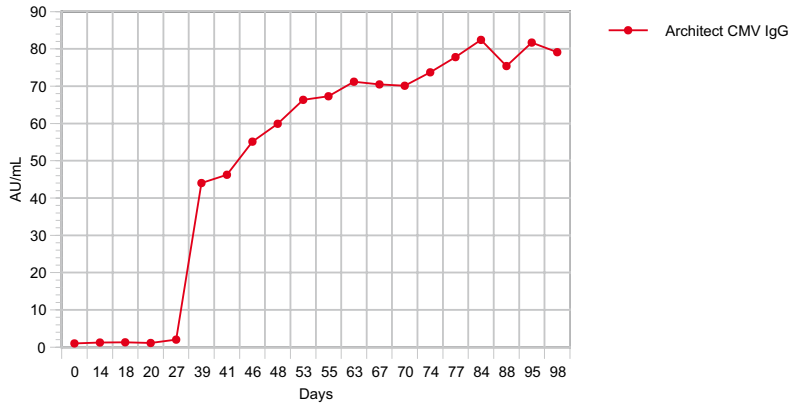
Assay information:

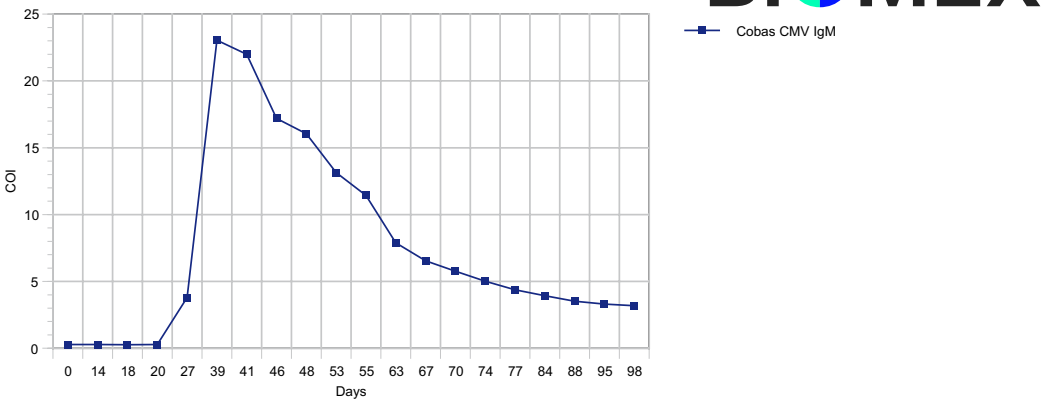
Abbott Architect CMV IgM assay; Lot: 55792LF00; Exp. Date: 09.07.2016; Test Date: 13.11.2015
Abbott Architect CMV IgG assay; Lot: 55683LF00; Exp. Date: 02.07.2016; Test Date: 13.11.2015

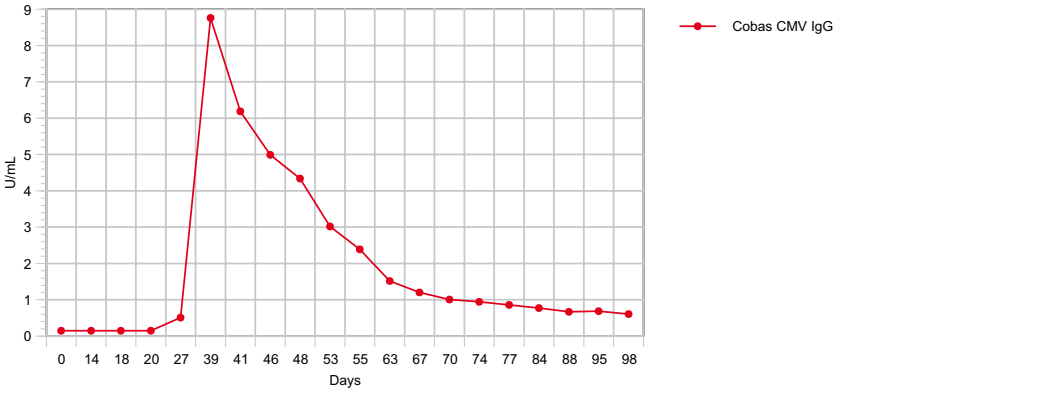
Roche Cobas e411 CMV IgM assay; Lot: 18701702
Roche Cobas e411 CMV IgG assay; Lot: 18551802
Diasorin Liaison CMV IgM II assay; Lot: 167019X/1
Diasorin Liaison CMV IgG II assay; Lot: 161023X

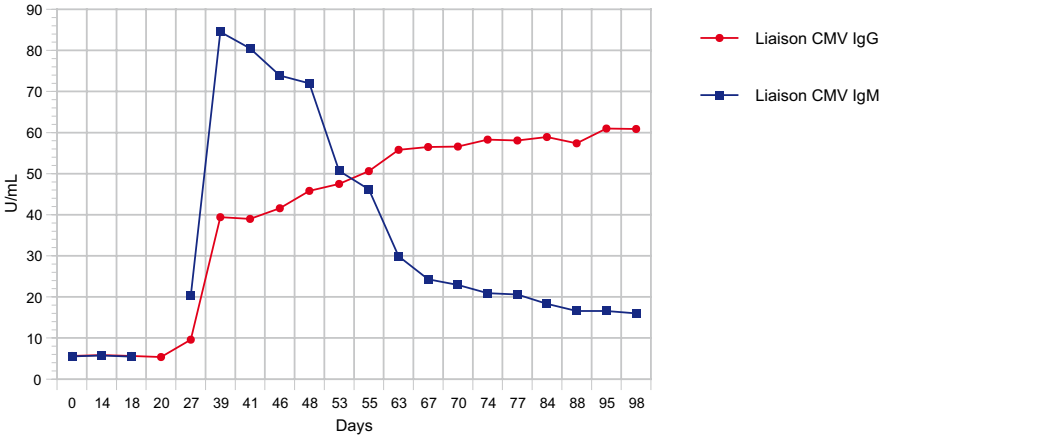
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