

Rubella IgM Seroconversion Panel

REF Catalogue No: SCP-RUB-002

Old Catalogue No: RP-014

The Biomex GmbH Rubella Seroconversion Panel consists of 13 members with each member containing 1.0 mL of human plasma. This panel illustrates the onset and decline of IgM and IgG Rubella virus antibodies from one individual over a period of 42 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, HBsAg and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 45
- Ethnicity: Caucasian
- Residence: U.S. South West

Medical background

- Received Meruvax II Vaccine 3/23/93
- Obese 280+lbs
- No history of Hepatitis or liver disease
- No history of high blood pressure or heart disease
- No history of alcoholism, drug addiction or venereal disease
- No prescription medication

5. Detection Methods

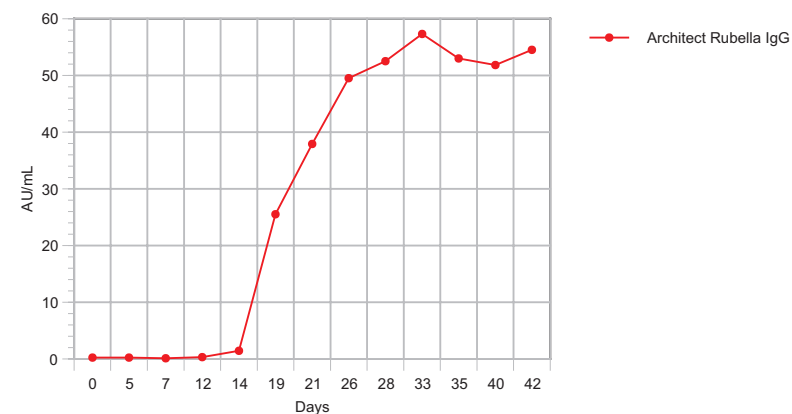
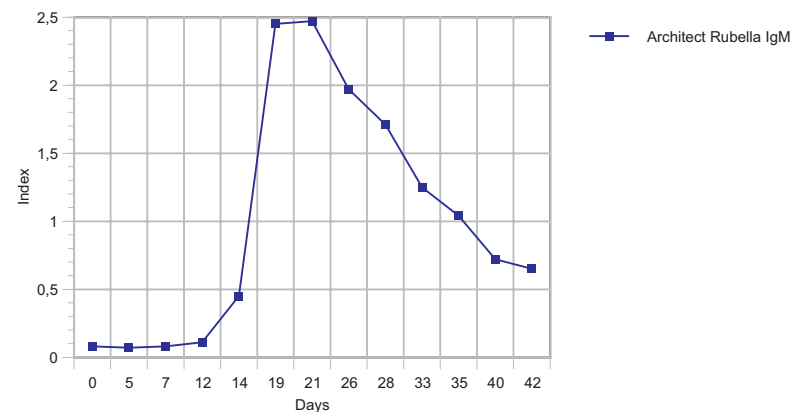
Each panel member is assayed for IgG and IgM antibodies with Abbott ARCHITECT®. Testing is performed with CE marked test.

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	Abbott Architect Rubella IgM Index	Abbott Architect Rubella IgG AU/mL
		cut off 1.6 Index	cut off 10 IU/mL
1	0	0.08	0.2
2	5	0.07	0.2
3	7	0.08	0.1
4	12	0.11	0.3
5	14	0.45	1.4
6	19	2.45	25.5
7	21	2.47	37.9
8	26	1.97	49.5
9	28	1.71	52.5
10	33	1.25	57.3
11	35	1.04	53.0
12	40	0.72	51.8
13	42	0.65	54.5



Assay information:

Abbott Architect Rubella IgM assay; Lot: 52288LF00; Exp. Date: 08.05.2016; Test Date: 21.08.2015
 Abbott Architect Rubella IgG assay; Lot: 56147UN15; Exp. Date: 31.10.2016; Test Date: 21.08.2015