

Rubella IgG Negative Panel

REF Catalogue No: NP-RUB-001

The Biomex GmbH Rubella IgG Negative Panel consists of 100 members with each member containing 0.5 mL of human plasma from four different continents. Test results indicate that each member demonstrates to be less than or equal to 3 IU/mL for anti-rubella IgG on three commercially available immunoassays and negative on an immunoblot assay. This panel was developed in cooperation with NRL, Australia.

1. Intended Use

This IgG Negative Panel (NP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of IgG antibody test systems and methods. Moreover, it serves as validation tool for diagnostic specificity, determination of analytical sensitivity or for the identification of cut-off values.

2. Storage and Stability

Store the NP 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.

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV, anti-HCV and HBsAg.

Donor profile

- Member 001 – 003 (USA)
- Member 004 – 013 (Australia)
- Member 014 – 026 (Asia)
- Member 027 – 100 (EU)

5. Detection Methods

Each panel member is assayed for Rubella IgG antibodies with Abbott ARCHITECT®, DiaSorin LIAISON® and Roche ELECSYS®. The Mikrogen recomBlot also confirmed negative results for Rubella IgG. 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 NP 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.

Declaration of used symbols

Catalog Number	Lot Number	Warning	Consult Instructions for Use	Manufactured by	Temperature Limitation

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Panel Member	Origin	Results Rubella IgG testing (cut off: 10 IU/mL)			Microgen recomBlot Rubella IgG				
		Abbott Architect (IU/mL)	Roche Elecsys (IU/mL)	Diasorin Liaison (IU/mL)	E1-E2 band	c-band	E1- band	E2- band	Interpretation
001	USA	0.9	0.1460	<3.00	-	-	+/-	-	negative
002	USA	0.8	0.1380	<3.00	-	-	+/-	-	negative
003	USA	0.8	0.1520	<3.00	-	-	-	-	negative
004	Australia	0.1	0.0000	<3.00	-	-	-	-	negative
005	Australia	0.4	0.0000	<3.00	-	-	-	-	negative
006	Australia	0.3	0.0000	<3.00	-	-	-	-	negative
007	Australia	0.4	0.0000	<3.00	-	-	-	-	negative
008	Australia	0.1	0.0000	<3.00	-	-	-	-	negative
009	Australia	0.5	0.0000	<3.00	-	-	-	-	negative
010	Australia	0.1	0.0000	<3.00	-	-	-	-	negative
011	Australia	0.2	0.0180	<3.00	-	-	-	-	negative
012	Australia	0.3	0.0000	<3.00	-	-	-	-	negative
013	Australia	0.2	0.0000	<3.00	-	-	-	-	negative
014	Turkey	0.1	0.0000	<3.00	-	-	-	-	negative
015	Turkey	0.1	0.0000	<3.00	-	-	-	-	negative
016	Turkey	0.2	0.0000	<3.00	-	-	-	-	negative
017	Hong Kong	0.1	0.0000	<3.00	-	-	-	-	negative
018	Hong Kong	0.1	0.0000	<3.00	-	-	-	-	negative
019	Hong Kong	1.2	1.8900	<3.00	-	-	+/-	+/-	negative
020	Hong Kong	0.4	0.0000	<3.00	-	-	-	-	negative
021	Hong Kong	0.1	0.0000	<3.00	-	-	-	-	negative
022	Hong Kong	0.2	0.0000	<3.00	-	-	-	-	negative
023	Hong Kong	0.1	0.0000	<3.00	-	-	-	-	negative
024	Hong Kong	0.1	0.0000	<3.00	-	-	-	-	negative
025	Hong Kong	0.8	0.0000	<3.00	-	-	-	-	negative
026	Myanmar	0.1	0.0000	<3.00	-	-	-	-	negative

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		Abbott Architect (IU/mL)	Roche Elecsys (IU/mL)	Diasorin Liaison (IU/mL)	E1-E2 band	c-band	E1- band	E2- band	Interpretation
027	Netherlands	0.0	0.0000	<3.00	-	-	-	-	negative
028	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
029	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
030	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
031	Netherlands	1.8	2.9100	<3.00	-	-	+/-	-	negative
032	Netherlands	0.2	0.0000	<3.00	-	-	-	-	negative
033	Netherlands	0.2	0.0205	<3.00	-	-	-	-	negative
034	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
035	Netherlands	0.5	0.0110	<3.00	-	-	-	+/-	negative
036	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
037	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
038	Netherlands	0.1	0.0000	<3.00	-	-	-	-	negative
039	France	0.1	0.0000	<3.00	-	-	-	-	negative
040	France	0.2	0.0000	<3.00	-	-	-	-	negative
041	France	0.0	0.0000	<3.00	-	-	-	-	negative
042	France	0.0	0.0000	<3.00	-	-	-	-	negative
043	France	0.0	0.0000	<3.00	-	-	-	-	negative
044	France	0.1	0.0000	<3.00	-	-	-	-	negative
045	France	0.1	0.0000	<3.00	-	-	-	-	negative
046	France	0.1	0.0000	<3.00	-	-	-	-	negative
047	France	0.0	0.0000	<3.00	-	-	-	-	negative
048	France	0.1	0.0000	<3.00	-	-	-	-	negative
049	France	0.0	0.0000	<3.00	-	-	-	-	negative
050	France	0.0	0.0000	<3.00	-	-	-	-	negative
051	France	0.0	0.0000	<3.00	-	-	-	-	negative
052	France	0.0	0.0000	<3.00	-	-	-	-	negative

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		Abbott Architect (IU/mL)	Roche Elecsys (IU/mL)	Diasorin Liaison (IU/mL)	E1-E2 band	c-band	E1- band	E2- band	Interpretation
053	France	0.1	0.0025	<3.00	-	-	-	-	negative
054	France	0.1	0.0000	<3.00	-	-	-	-	negative
055	France	0.1	0.0000	<3.00	-	-	-	-	negative
056	France	0.0	0.0000	<3.00	-	-	-	-	negative
057	France	0.2	0.0000	<3.00	-	-	-	-	negative
058	France	0.1	0.0000	<3.00	-	-	-	-	negative
059	France	0.1	0.0000	<3.00	-	+/-	-	-	negative
060	France	0.1	0.0000	<3.00	-	-	-	-	negative
061	France	0.6	0.0000	<3.00	-	-	-	-	negative
062	France	0.2	0.0000	<3.00	-	-	-	-	negative
063	France	0.1	0.0000	<3.00	-	-	-	-	negative
064	France	0.1	0.0000	<3.00	-	-	-	-	negative
065	France	0.1	0.0000	<3.00	-	-	-	-	negative
066	France	0.1	0.0000	<3.00	-	-	-	-	negative
067	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
068	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
069	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
070	Germany	0.4	0.0000	<3.00	-	-	-	-	negative
071	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
072	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
073	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
074	Germany	0.3	0.0000	<3.00	-	-	-	-	negative
075	Germany	0.3	0.0000	<3.00	-	-	-	-	negative
076	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
077	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
078	Germany	0.2	0.0000	<3.00	-	-	-	-	negative

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079	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
080	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
081	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
082	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
083	Germany	0.1	0.7710	<3.00	-	-	-	-	negative
084	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
085	Germany	0.2	0.0000	<3.00	-	-	-	-	negative
086	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
087	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
088	Germany	0.1	0.0130	<3.00	-	-	-	-	negative
089	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
090	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
091	Germany	0.1	0.0050	<3.00	-	-	-	-	negative
092	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
093	Germany	0.1	0.0025	<3.00	-	-	-	-	negative
094	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
095	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
096	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
097	Germany	0.1	0.0000	<3.00	-	-	-	-	negative
098	Germany	0.1	0.0060	<3.00	-	-	-	-	negative
099	Germany	0.0	0.0000	<3.00	-	-	-	-	negative
100	Germany	0.1	0.0150	<3.00	-	-	-	-	negative

Assay information:

Roche: Elecsys Rubella IgG assay, Lot: 185927, Testdate: 08/09 2015

Diasorin: Liaison Rubella IgG assay, Lot: 036078X and Lot: 036079X, Testdate: 08/09 2015

Abbott: Architect Rubella IgG assay, Lot: 56147UN15, Testdate: 08/09 2015

Blot: Microgen recomBlot Rubella IgG Lot: RU061501 and Lot: RU081501, Testdate: 08/09 2015

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