



GanglioCombi/-Light/anti-GM1

Procedure

A Commitment to Diagnostics

Kit components*

	EK-GCL-GM EK-GM1-GM	EK-GCO-GM	EK-GCO EK-GCL
Microtiter plate (wells)	1 x 96	2 x 96	1 x 96
Calibrator	1 vial	1 vial	1 vial
Ratio [%]	100	100	200
Controls - negative, low, medium	3 vials	3 vials	3 vials
Enzyme Label IgG	x	x	-
Enzyme Label IgM	x	x	-
Enzyme Label Mix IgG/IgM	-	-	x

*Substrate, stop solution, incubation and wash buffer included but not mentioned in the table.

Standardization

1 Calibrator (B-GCO-CA) set to 100% (Enzyme Label IgG & IgM) and 200% (Enzyme Label Mix IgG/IgM).

Controls

3 Controls: Control negative, Control low, Control medium.

Quantification

The measured absorbance is proportional to the amount of anti-ganglioside antibodies present in the respective sample. **Samples are quantified as percentage of the calibrator (% Ratio). The results are classified according to % ratio categories.**

BÜHLMANN GanglioCombi® ELISA product family - more than just a profile

Enzyme Label	Mix IgG/IgM						IgG						IgM						No. of patients/kit
	GAL	GM1	GM2	GD1a	GD1b	GQ1b	GAL	GM1	GM2	GD1a	GD1b	GQ1b	GAL	GM1	GM2	GD1a	GD1b	GQ1b	
EK-GCO	x	x	x	x	x	x													12 profiles IgG/IgM-Mix; 1 profile/ patient
EK-GCO-GM							x	x	x	x	x	x	x	x	x	x	x	x	12 profiles IgG 12 profiles IgM 2 profiles / patient
EK-GCL		x			x	x													24 profiles IgG/IgM-Mix; 1 profile/ patient
EK-GCL-GM								x			x	x		x			x	x	12/24 profiles IgG and 12/24 profiles IgM 2/1 profiles / patient
EK-GM1-GM								x						x					20 patients IgG & IgM 44 patients IgG or IgM

ELISA

Reagents except of TMB and stop solution must be used at 2-8°C

Precoated Microtiter Plate



add 100 µl of Calibrator, Controls and diluted Samples (1:50)

2 hrs incubate 2 hrs +/- 5 min. at 2-8°C



add 100 µl of Enzyme Label(s)

2 hrs incubate 2 hrs +/- 5 min. at 2-8°C



add 100 µl of TMB Substrate

30' incubate 30 ± 2 min at 18-28°C on a plate rotator

add 100 µl of Stop Solution

4.5 hrs Read at 450 nm (within 30 min)

Time to Result: ~5.0 hrs





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Characteristics

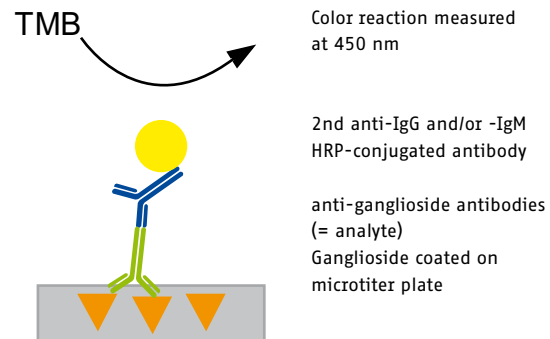
Intended Use

The BÜHLMANN GanglioCombi® ELISA product family, EK-GCO and (-GM), EK-GCL and (-GM), and EK-GM1-GM has been designed for the quantitative determination of anti-ganglioside IgG and/or IgM autoantibodies directed against 6, 3 or just 1 of the following auto-antigens in human serum:

asialo-GM1 (GA1), GM1, GM2, GD1a, GD1b and GQ1b

Principle of the Assay

EK-GCO and EK-GCO-GM: Plates are stripwise coated with each of the 6 gangliosides (1 ganglioside/well); EK-GCL and EK-GCL-GM: Plates are stripwise coated with three of the most important gangliosides: GM1, GD1b and GQ1b (2 profiles/strip), and EK-GM1-GM plates are coated with GM1.



Assay Performance Data

Intra-assay precision 4.3 %

CV range: 1.4 - 14.2 %

GanglioCombi and GanglioCombi-Light: Calculated from 12 results of 2 positive samples using the Enzyme Labels IgG, IgM and Mix. The mean was calculated over all Gangliosides.

Anti-GM1: Calculated from 20 results of 2 positive samples for IgG and IgM using the Enzyme Label IgG, IgM.

Inter-assay precision 12.1 %

CV range: 7.3 - 24.1 %

2 positive samples determined in 20 runs using the Enzyme Labels IgG, IgM and Mix. Value denotes mean of all Gangliosides.

Clinical Data

Blood donors

Frequency distribution of IgM and IgG autoantibodies directed against gangliosides determined from n = 100 healthy blood donors using GanglioCombi products with IgG, IgM and Mix conjugate.

Frequency distribution of anti-Ganglioside autoantibodies [%] in healthy blood donors*

Classification	GanglioCombi product family				
	GCO-GM	GCO	GCL-GM	GCL	GM1-GM
Negative	90-99	95-100	92-98	95-100	96
Greyzone	0-9	0-5	1-6	0-4	2
Positive	0-4	0-1	1-2	0-1	2
Fortement positive	0-1	0	0	0	0

*Calculated over all gangliosides and isotypes

Cut-off and clinical classification

Values have been determined from n = 100 blood donors and n = 277 patients with peripheral Neuropathies. % Ratio ranges have been assigned to titer categories in order to classify patients into negative, grey zone, positive, strongly positive. We recommend using titer categories as follows:

Ratio of the calibrator [%]	Classification
≤30	Negative
>30 - 50	Grey zone
50	Cut-off
>50 - 100	Positive
>100	Strongly positive

Product codes:

EK-GCO	1 x 12 profiles (Mix IgG/IgM)
EK-GCO-GM	2 x 12 profiles (IgG & IgM)
EK-GCL	1 x 24 profiles (Mix IgG/IgM)
EK-GCL-GM	2 x 12 profiles (IgG & IgM)
EK-GM1-GM	96 wells (IgG & IgM)



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