

# BÜHLMANN GanglioCombi® MAG ELISA

## Pre-Analytics

<b>Specimen</b>	Serum
<b>Specimen collection</b>	Use conventional plain tubes to collect blood. Process to serum according to manufacturer's instruction
<b>Storage of Serum</b>	<ul style="list-style-type: none"> <li>• Prepare aliquots</li> <li>• Freeze/thaw cycles</li> <li>• 2-8°C (up to 16 days)</li> <li>• - 20°C (up to 12 months)</li> </ul>

## Number of Analysis

- GanglioCombi MAG ELISA allows for full flexibility regarding:
  - number of samples to be pipetted
  - use and arrangement of enzyme conjugates on microtiter plates
- A sample is investigated for 6 different antibodies with IgG and IgM and/or with IgG/IgM mix conjugate.
- Each kit contains 2 microtitre plates.

Enzyme Conjugate	Number of Analysis per Kit	Number of Analysis per individual Sample
IgG & IgM	12 + 12	2 x 6 (2 conjugates / 6 antigens)
IgG/IgM Mix	24	1 x 6 (1 mix conjugate / 6 antigens)

## Literature References

Kuijff M et al., Journal of the Neurological Sciences, 2005  
 Spatola M et al., Neurology, 2016  
 Franciotta D et al., Clin Chem Lab Med, 2018  
 Delmont E et al., Journal of Neurology, 2019

## Microtiter Plate Layout

	1	2	3	4	5	6	7	8	9	10	11	12	
	Cal	Ctrl Med											A
	Ctrl low	Ctrl Neg											B
HNK-1													C
GM1													D
GT1a													E
GD1a													F
GD1b													G
GQ1b													H

- Microtiter plate uniformly coated with purified human MAG
- Break-away strip convenience

## Reagent Preparation

Reagent	Temperature °C
Wash buffer	2-8
Incubation Buffer	2-8
Enzyme conjugate	2-8
TMB substrate	18-28
Stop solution	18-28

## Sample Preparation

1. Dilute samples 1:50 with incubation buffer and vortex gently.
2. Leave diluted samples, reconstituted calibrators and controls at 2-8°C for 30 minutes prior pipetting (for targeted investigation).

## ELISA Procedure

### Precoated Microtiter Plate

↓ ↻ wash 2x (≥ 300 µL wash buffer)

### Calibrators, Controls, Sera (100 µL; dilution of sera 1:50)

↓ ↻ incubate (2 hr ± 5 min)

↓ ↻ wash 3x (≥ 300 µL wash buffer)

### Enzyme Label (100 µL)

↓ ↻ incubate (2 hr ± 5 min)

↓ ↻ wash 3x (≥ 300 µL wash buffer)

### TMB Substrate (100 µL)

↓ ↻ incubate (30 min ± 2 min)  
plate shaker: (400-600 rpm)

### Stop Solution (100 µL) ≤ 30 min

### Absorbance (450 nm)

cold  
(2 - 8°C)

ambient  
(18 - 28°C)

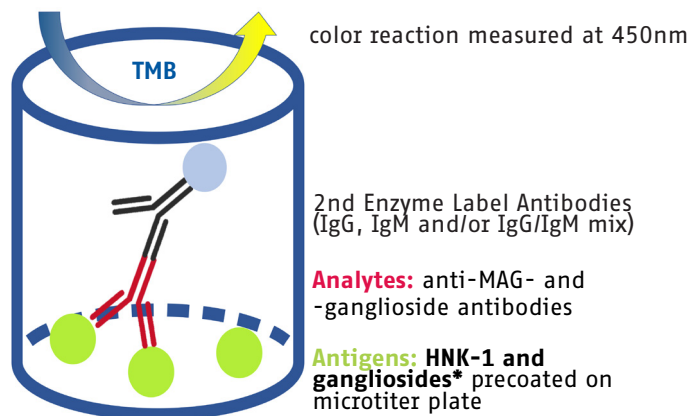
This document is for information purpose only, before performing the assay please carefully refer/read the respective IFU available (<https://www.buhlmannlabs.ch/support/downloads/eifus/>).

# BÜHLMANN GanglioCombi® MAG ELISA

## Methodology

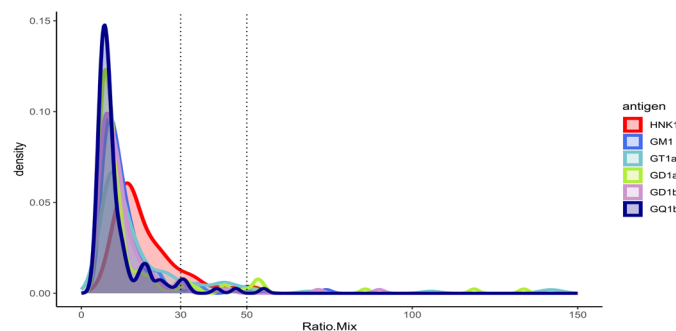
<b>Method</b>	ELISA For laboratory use only
<b>Analyte</b>	anti-MAG* and -ganglioside** antibodies *Antigen: HNK-1 chemically synthesized sulphated disaccharide **Gangliosides: GM1, GD1a, GD1b, GT1a, GQ1b
<b>Test</b>	multi-parametric, semi-quantitative
<b>Suggested Use</b>	Targeted investigation of most relevant anti-MAG and/or -ganglioside antibodies of IgG, IgM and/or IgG/IgM Mix. anti-HNK-1 antibodies >50% Ratio may be confirmed with anti-MAG Antibodies ELISA (ordering code: EM-MAG)

## Principle of the Assay



\*We use double-quality control-checked gangliosides for the coating of the microtitre plates

## Reference Interval



Healthy Individuals: N = 120 (m = 60; f = 60)

Negative: 90.8%; Grey zone: 6.3%; Positive: 2.9%

<sup>1</sup> Autoimmune diseases (N = 50): Vasculitis and ANCA positive denoted: 3 and 10; SLE: 5; RA: 9 Sjögren Syndrome: 6; Others (ANA positive denoted): 3; Autoimmune Thyroiditis: 5; MCTD: 1; Autoimmune peripheral neuropathies (GM1 and GQ1b pos): 1; MG: 7

<sup>2</sup> Other neurological diseases (N = 34): Alcoholic: 1; diabetic: 5; ALS: 15; Sarcoidosis: 4; WM: 4; Chagas Disease: 5

## Performance Data

**Crossreactivity:** No (incl. AIDs<sup>1</sup> and ONDs<sup>2</sup>)

**Reproducibility (%CV):** 7.7–19.1% (anti-ganglioside antibodies)  
23.5–33.2% (anti-MAG antibodies)

**Specificity (95 %CI):** 88.0% (72.3–95.3%)

**Sensitivity (95 %CI):** 68.1% (39.6–87.5%)

## Results

- The measurement of absorbance is proportional to the titer of (MAG- and/or -gangliosides) antibodies in a given sample.
- Calibrators and Controls are anti-GM1 antibodies
  - Tites are expressed as %Ratio of anti-GM1 antibodies
  - Calculation:  
IgG and IgM: OD Sample/OD Calibrator x 100%;  
Mix: OD Sample/OD Calibrator x 200%

## Handling of Titer levels

Titer levels [%Ratio]	Interpretation [titer]
< 30	negative
30 - 50	grey zone (equivocal)
> 50	positive

## Ordering information

•BÜHLMANN GanglioCombi® MAG ELISA 3 gangliosides EK-GCL-S

## Variants:

•BÜHLMANN GanglioCombi® Light ELISA 5 gangliosides, 1xMAG EK-GCM

•anti-GM1 Antibodies ELISA 1 ganglioside EK-GM1-GM

CE 0123

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