

anti-Ganglioside M1 (-GM1) Antibodies ELISA

Pre-Analytics

- Specimen** Serum
- Specimen collection** Use conventional plain tubes to collect blood. Process to serum according to manufacturer's instruction.
- Storage of Serum**
- Prepare aliquots
 - 2-8°C (up to 16 days)
 - -20°C (up to 12 months)
 - Freeze/thaw cycles not recommended

Number of Analyses

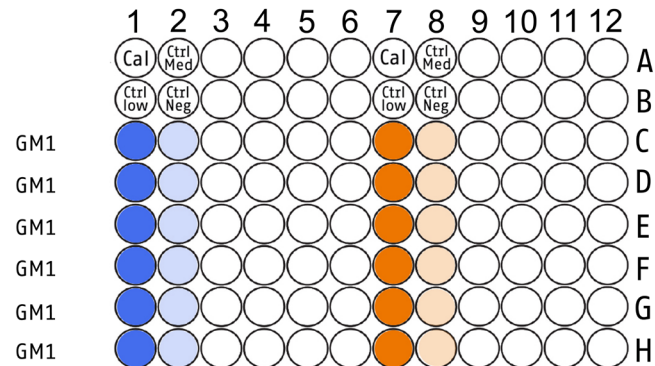
- Kit allows for full flexibility regarding:
 - number of samples to be pipetted
 - use and arrangement of enzyme conjugates on microtiter plate
- Generally, a sample can be investigated for IgG and IgM.
- Each kit contains 1 microtiter plate.

Enzyme Conjugate	Number of Analyses per Kit	Number of Analyses per individual Sample
IgG & IgM	21 -42	2 x 1 (2 conjugates / GM1)

Literature References

Kuijf M et al., Journal of the Neurological Sciences, 2005
 Franciotta D et al., Clin Chem Lab Med, 2018

Microtiter Plate Layout



- Rows coated with GM1
- Break-away strip convenience

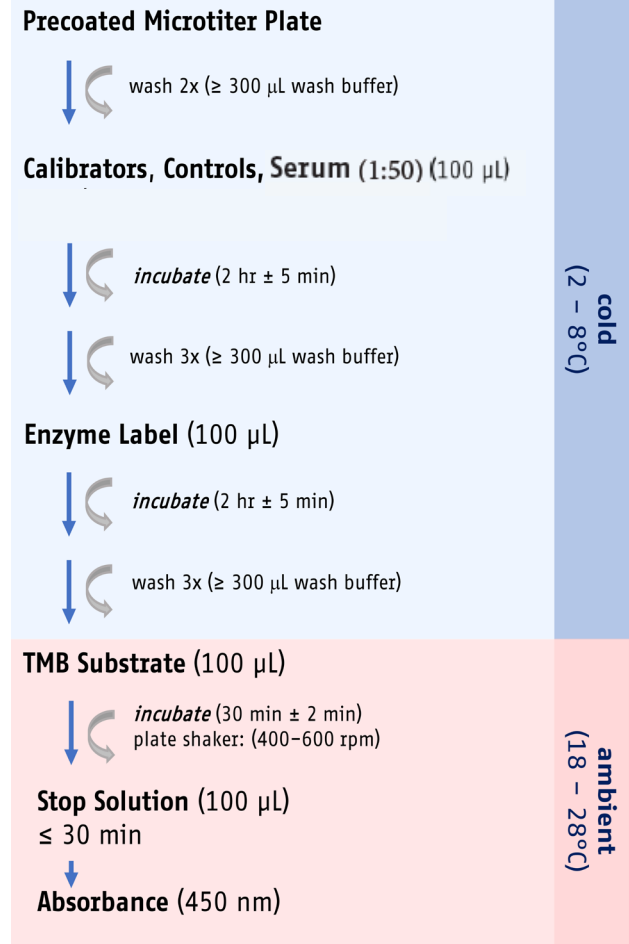
Reagent Preparation

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 serum 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



*Please see the full instructions for use (IFU) on buhlmannlabs.com for more detailed information prior to use.

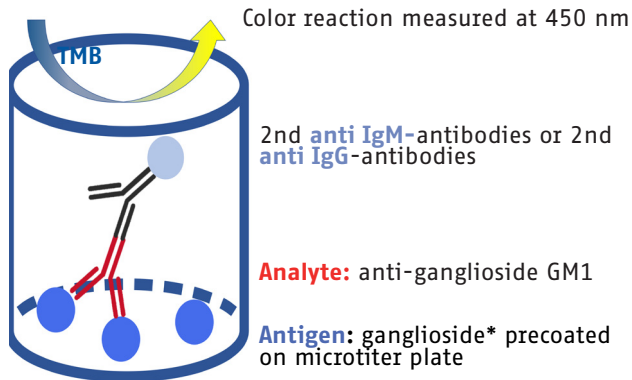
BÜHLMANN GanglioCombi® MAG ELISA. Not for use in diagnostic procedures. For product availability outside the US, please contact BÜHLMANN Laboratories for further information.

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Methodology

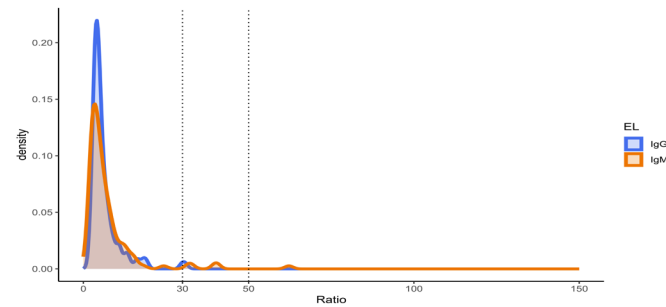
Method	ELISA For laboratory use only
Analyte	anti-ganglioside M1 (-GM1) antibodies.
Test	Semi-quantitative ELISA
Suggested Use	Targeted investigation of anti-GM1 antibodies with IgG and IgM.

Principle of the Assay



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

Reference Interval



Healthy Individuals: N = 120 (m = 60; f = 60)
 IgG: Negative: 99.2%; Grey zone: 0.8%; Positive: 0%
 IgM: Negative: 95.8%; Grey zone: 3.3%; Positive: 0.8%

Performance Data

Crossreactivity:	No (incl. AIDS ¹ and ONDs ²)
Reproducibility (%CV):	7.7-16.1%
Specificity (95 %CI):	77.8% (60.9-97.4%)
Sensitivity (95 %CI):	48.7% (27.9-69.5%)

¹ 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

² Other neurological diseases (N = 34): Alcoholism 1; diabetes: 5; ALS: 15; Sarcoidosis: 4; WM: 4; Chagas Disease: 5

Results

- The measurement of absorbance is proportional to the titer of anti-GM1 antibodies present in a given sample.
- Calibrators (GM1)
- Titers are expressed as %Ratio of anti-GM1 Antibodies

Handling of Titer levels

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

Ordering information

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

Variants:

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

• BÜHLMANN GanglioCombi® Light ELISA 3 gangliosides EK-GCL-S-U

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