

BÜHLMANN GanglioCombi® Light ELISA

Pre-Analytcs

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

Number of Analysis

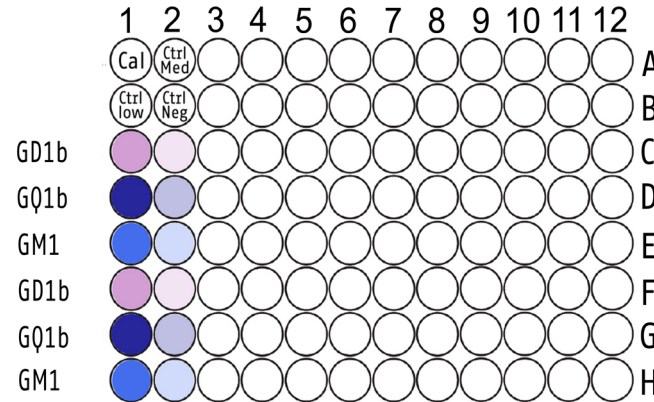
- Kit allows for full flexibility regarding:
 - number of samples to be pipetted
 - use and arrangement of enzyme conjugates on microtiter plates
- Generally, a sample can be investigated for 3 different antibodies with IgG and IgM and/or with IgG/IgM mix conjugate.
- Each kit contains 1 microtiter plate.

Enzyme Conjugate	Number of Analysis per Kit	Number of Analysis per individual Sample
IgG & IgM	12 + 12	2 x 3 (2 conjugates/3 gangliosides)
IgG/IgM Mix	24	1 x 3 (1 mix conjugate/3 gangliosides)

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

Microtiter Plate Layout



- Rows coated with 3 different gangliosides
- Break-away strip convenience

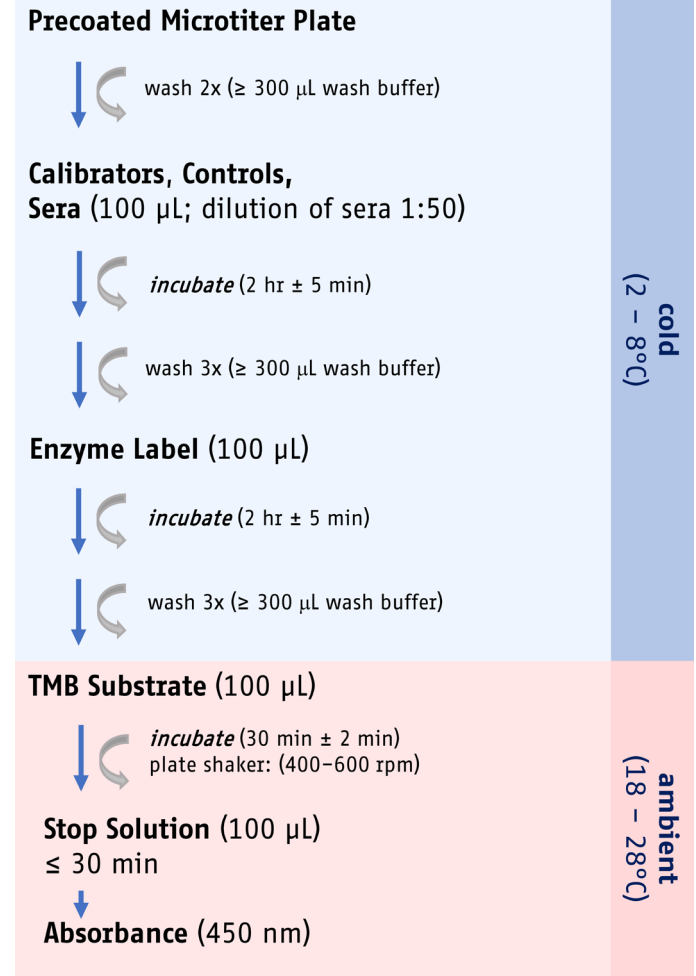
Reagent Preparation

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



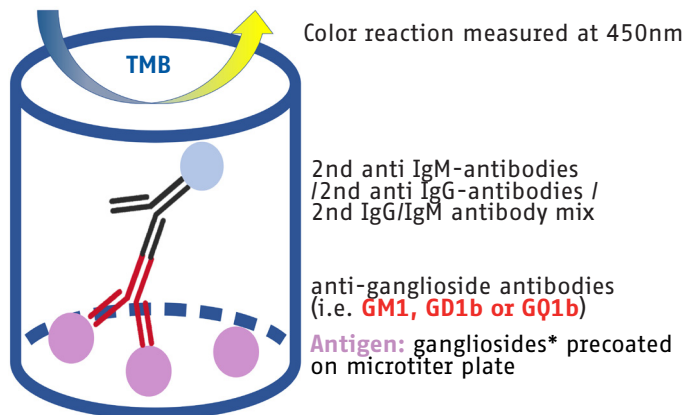
This document is for information purpose only, before performing the assay please carefully refer/read the respective IFU available (<https://www.buhlmannlabs.ch/support/downloads/eifus/>).

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Methodology

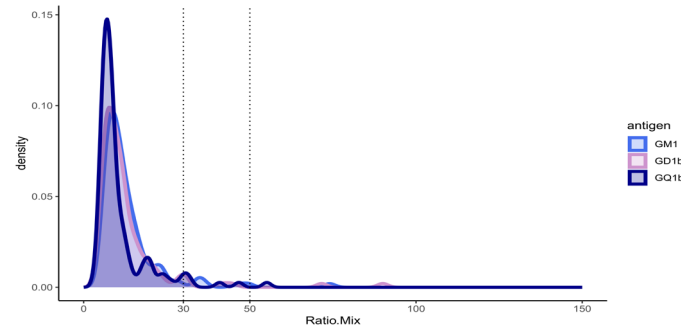
Method	ELISA For laboratory use only
Analyte	anti-ganglioside antibodies: GM1, GD1b, GQ1b
Test	IVD, multi-parametric, semi-quantitative
Suggested Use	Targeted investigation of anti-ganglioside antibodies with IgG and IgM and/or IgG/IgM Mix.

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)
Negative: 95.0%; Grey zone: 3.9%; Positive: 1.1%

Performance Date

Crossreactivity:	No (incl. AIDS ¹ and ONDs ²)
Reproducibility (%CV):	7.7-19.1%
Specificity (95 %CI):	79.8% (66.8-93.2%)
Sensitivity (95 %CI):	57.0% (38.6-75.4%)

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): Alcoholic: 1; diabetic: 5; ALS: 15; Sarcoidosis: 4; WM: 4; Chagas Disease: 5

Results

- The measurement of absorbance is proportional to the titer of ganglioside antibodies 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

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

Variants:

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

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

CE 0123

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