

CE marked under **IVDR**

- MAG* and Gangliosides combined
- High Specificity
- Flexibility in sero-diagnostic Protocols
- Comprehensive and targeted

NEUROimmunology (Autoimmune Neurology)

BÜHLMANN GanglioCombi® MAG* ELISA

Multiparametric IVD ELISA test to investigate autoimmune Neuropathies, including HNK-1

* Myelin-Associated Glycoprotein (featured by HNK-1 mimic)

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Diagnostic Focus: Autoimmune Peripheral Neuropathy

Peripheral neuropathies are a complex condition caused by damage to the peripheral nerves, leading to symptoms such as numbness, tingling, and muscle weakness in the extremities. Rather than being a single disease, Peripheral Neuropathies represent a spectrum of disorders with diverse known and unknown causes *(Figure 1)*. Among these, autoimmune-related peripheral neuropathies are rare but amenable to treatment, offering the potential for significant patient improvement.

GanglioCombi is a cutting-edge diagnostic solution designed to detect specific anti-nerve antibodies, enabling precise diagnosis in critical situations. When early and accurate results are essential – **"time is nerve"** – this innovative tool empowers clinicians to make timely and informed decisions for optimal patient care.

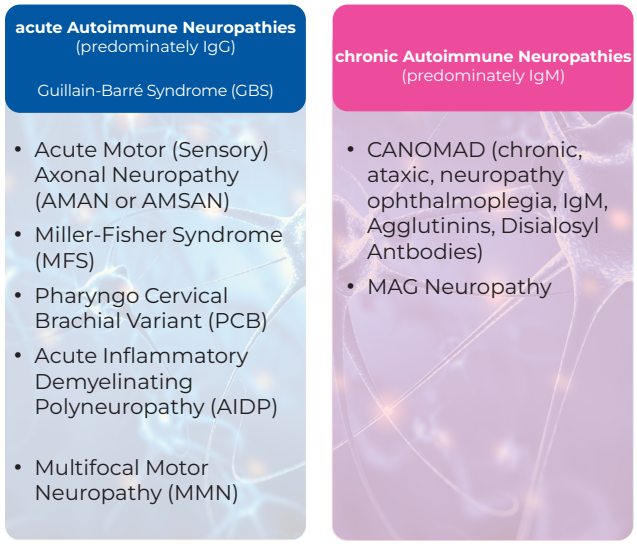


Figure 1 Autoimmune Peripheral Neuropathies

Defining Autoimmune Neuropathies with Ganglioside and MAG Antibodies

Gangliosides, sialic acid-containing glycosphingolipids, are abundant on peripheral nerves and serve as key targets for ganglioside antibodies. Of the many gangliosides, only a select few – GM1, GD1a, GD1b, GT1a, GQ1b, and MAG *(Myelin-Associated Glycoprotein; Figure 2)* – are clinically relevant binding targets for anti-nerve Antibodies. Antibodies against the select targets are strongly associated with distinct demyelinating or axonal peripheral neuropathies, as supported by clinical literature.

HNK-1, a sulfated trisaccharide present on MAG, further highlights MAG's significance in autoimmune neuropathies. Anti-MAG and Ganglioside antibodies are the most reliable biomarkers for anti-nerve antibody testing, a conclusion reinforced by a comprehensive meta-analysis.

GanglioCombi MAG ELISA

features a unique blend of HNK-1 and five key gangliosides, calibrated with monoclonal GM1-antibodies – the most prevalent in neuropathy cases. Its specificity has been rigorously validated across diverse patient samples, including other autoimmune and mimicking diseases, various neuropathies, and common peripheral neuropathy mimics seen in clinical practice.

Anti-ganglioside and -MAG antibody testing is crucial in suspected autoimmune neuropathies, helping pinpoint both, the autoimmune cause (etiology), and the clinical phenotype.

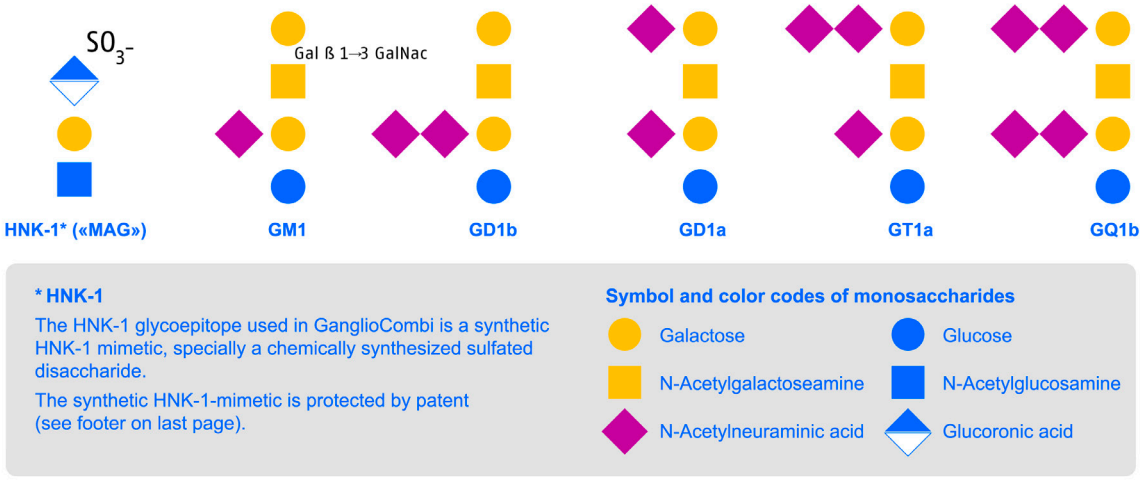


Figure 2 Clinically relevant nerve antigens such as Gangliosides (GM1, GD1a, GD1b, GT1a and GQ1b) and HNK-1

Synthetic HNK-1 is equivalent to the natural HNK-1 (MAG epitope)

HNK-1 antibodies, found on the MAG glycoprotein, show diagnostic equivalence to antibodies against wildtype MAG (Delmont et al., 2019[2]; *Figure 3)*. Testing for HNK-1 alongside ganglioside antibodies enhances diagnostic accuracy by uncovering their role in neuro-immunological processes. This dual approach provides valuable insights into neuro-autoimmune mechanisms, supporting more targeted and effective therapies.

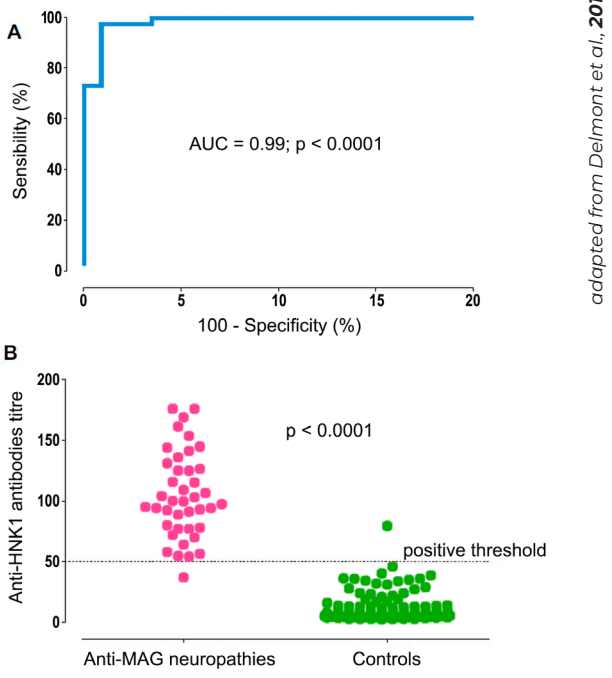


Figure 3 **A:** ROC curve for diagnostic accuracy of anti-HNK-1 Antibodies in anti-MAG neuropathies. **B:** Comparison of anti-HNK-1 antibodies in anti-MAG Neuropathies and Controls.

Specifying Nerve Antibodies of Clinical Importance

GanglioCombi MAG ELISA is an essential tool for routine lab work, offering comprehensive testing with outstanding specificity. It accurately detects antibodies targeting gangliosides and HNK-1, critical for diagnosing autoimmune neuropathies *(Figure 5)*. Even with diverse patient samples and disease mimics, GanglioCombi shows high reliability in differentiating neuropathy causes *(Figure 4)*. Its exceptional specificity makes GanglioCombi a valuable asset for precise anti-ganglioside- and -HNK-1-antibody detection and effective neuropathy management.

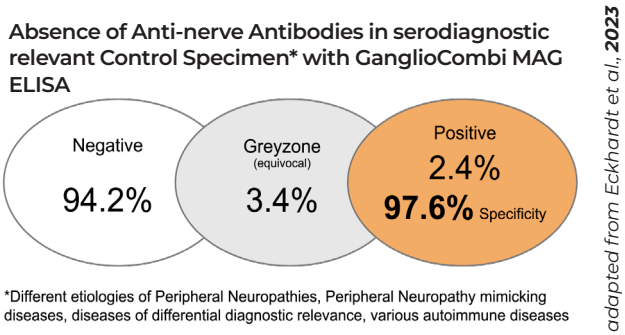


Figure 4 Anti-nerve antibodies are not detected in serodiagnostic relevant specimens, thus underlining the specificity of GanglioCombi MAG ELISA..

	IgG related Neuropathies				IgM related Neuropathies		
	AIDP	AMAN / AMSAN	PCB	MFS	MMN	MAG	CANOMAD
MAG						high	
GM1	Low	Med			Med to High		Low
GD1a		Med			Med		Low
GD1b		Med			Med to High		Med to High
GT1a			High	High			Med
GQ1b				High			Med to High

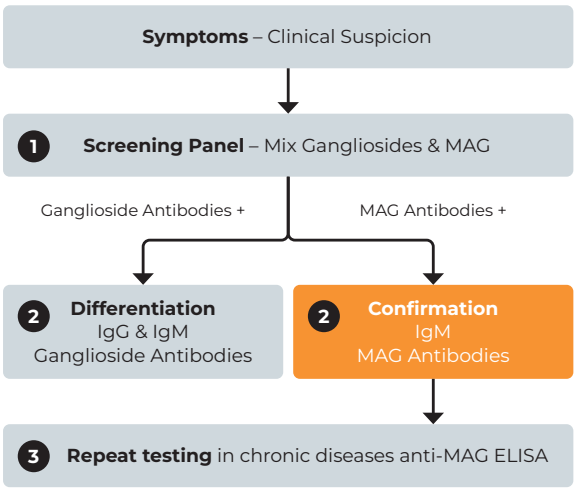
Figure 5 Relevant set of anti-nerve (*i e* MAG and Ganglioside Antibodies) and associated autoimmune neuropathies of the peripheral nervous system. For acronyms and abbreviations see Figure 1. Low, Med (medium) and High designate typical levels of antibodies.

Diagnostic Workflow

The anti-MAG Antibodies ELISA is designed to support clinical decision-making with a structured, stepwise and economic approach *(Figure 6)*.

1. Clinical suspicion in neurology initiates a comprehensive screening panel for ganglioside and MAG antibodies.
2. Positive screening results guide reflex testing for differentiation (IgG/IgM ganglioside antibodies) or confirmation of IgM anti-MAG antibodies, as clinically indicated.
3. Follow-up testing may support monitoring in chronic conditions.

For in vitro diagnostic use. Results should be interpreted in conjunction with clinical findings and other laboratory data.



Portfolio of NEUROimmunology CE-Marked IVD ELISA Tests under IVDR

Antigens	Product Designation	Ordering code
HNK-1 (“MAG”), GM1, GD1a, GD1b, GT1a, GQ1b (multiparametric IgG/IgM mix, IgG, IgM)	BÜHLMANN GanglioCombi® MAG ELISA	EK-GCM
GM1, GD1b, GQ1b (multiparametric IgG/IgM mix, IgG, IgM)	BÜHLMANN GanglioCombi® *Light* ELISA	EK-GCL-S
GM1 Antibodies (single test IgG, IgM)	anti-GM1 Antibodies ELISA	EK-GM1-GM
MAG Antibodies (single test IgM)	anti-MAG Antibodies ELISA	EK-MAG
SGPG Antibodies (single test IgM)	anti-SGPG Antibodies ELISA (RUO)	EK-SGPG-U

Key Benefits of GanglioCombi MAG ELISA

1. **Precision Diagnosis:** Definite selection of nerve antigens
2. **Comprehensive Evaluation:** Unique combination of HNK-1 and 5 essential Gangliosides
3. **Reliable Support of Diagnosis:** Calibration against prevalent monoclonal GM1-antibodies
4. **HNK-1 Antibodies** equaling diagnostic accuracy of wildtype MAG Antibodies
5. **Three Titer Categories** incl. Greyzone representing “real life immunology”

Key Literature

1. Collet, R., Caballero-Ávila, M. and Querol, L.; Revue Neurologique, 179(8), pp. 831–843 (2023).
2. Delmont, E. and Willison, H.; Journal of Neuromuscular Diseases, 2(2), pp. 107–112 (2015).
3. Goodfellow, J.A. and Willison, H.J.; Nature Reviews Neurology, 12(12), pp. 723–731 (2016).
4. Gwathmey, K.G. and Smith, A.G.; Neurologic Clinics, 38(3), pp. 711–735 (2020).
5. Nutma, E. et al.; ‘Neuroimmunology – the past, present and future’, Clinical and Experimental Immunology, 197(3), pp. 278–293 (2019).

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