

# Measuring A Case Series With A Unique Commercially Available Anti-Ganglioside Antibodies ELISA

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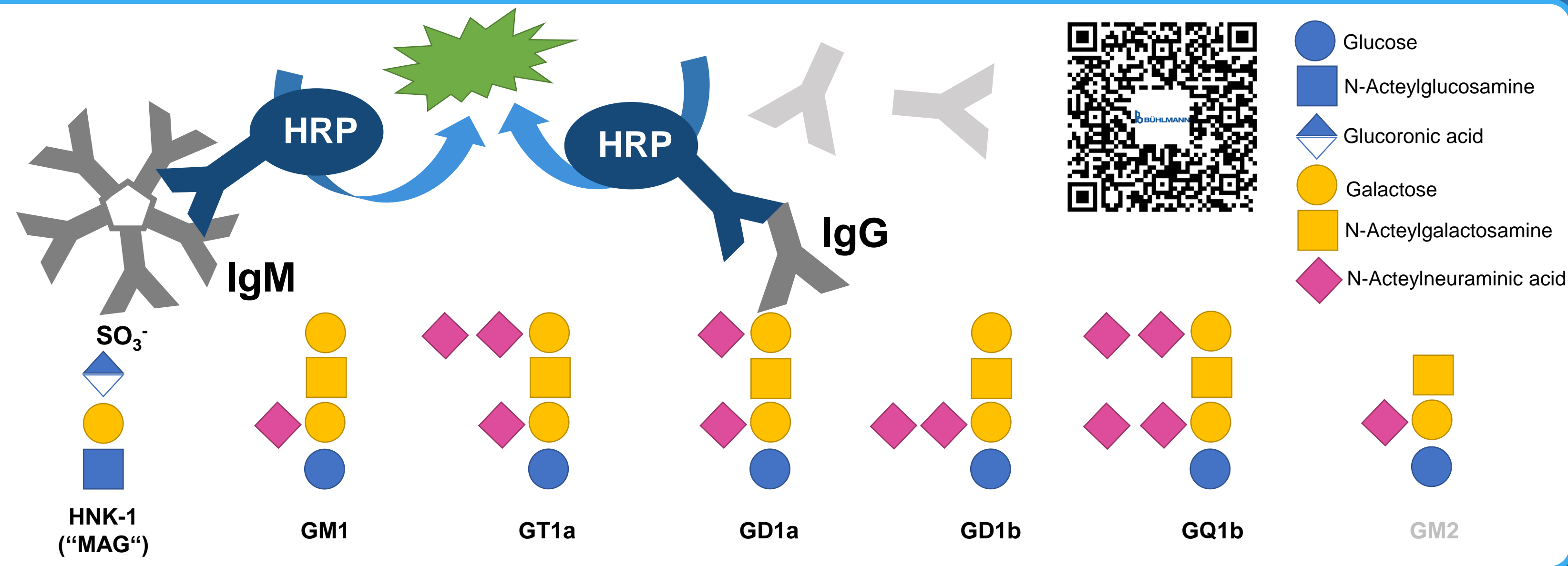
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## INTRODUCTION

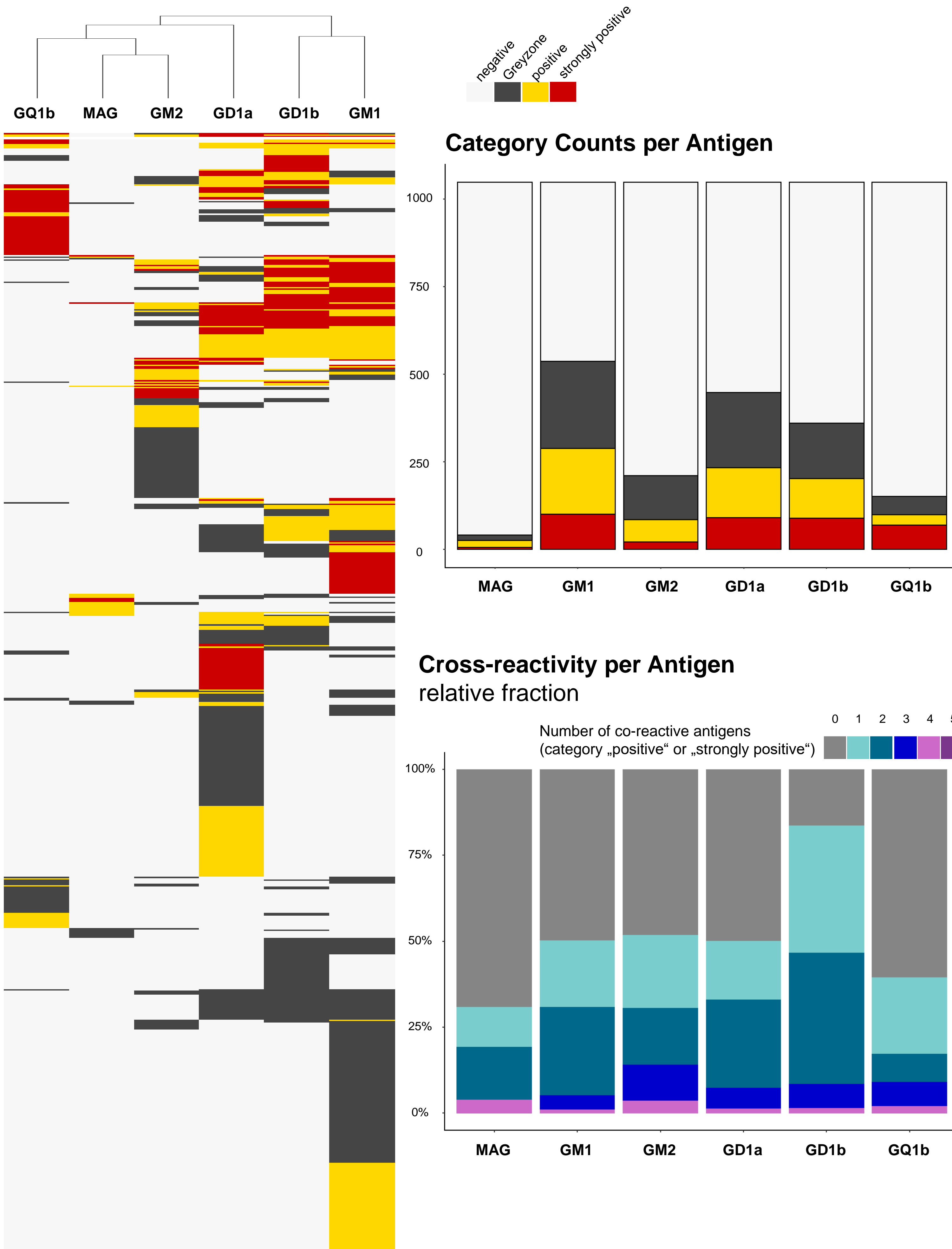
There are >500 causes for a peripheral neuropathy and >200 mimicking disorders, e.g. other neurological or autoimmune diseases. ELISA is most frequently used as a reliable and sensitive method to determine anti-ganglioside antibodies to support diagnosis of a distinct type of neuro-autoimmune disease (i.e. confirming an autoimmune etiology) and suggesting appropriate treatment. The only commercially available multiparametric anti-Ganglioside antibodies ELISA (BÜHLMANN GanglioCombi® MAG ELISA, aka GanglioCombi) allows for specific detection of neural antibodies and has been recently renovated to meet In Vitro Diagnostic Device Regulation (IVDR) standards.



## Real Life Data

We have analyzed the reaction profile of > 1000 patient samples. Data were generated over the course of several years by a diagnostics laboratory in the EU during routine testing using the IgG/IgM-Mix enzymelabel of the IVDD kit version.

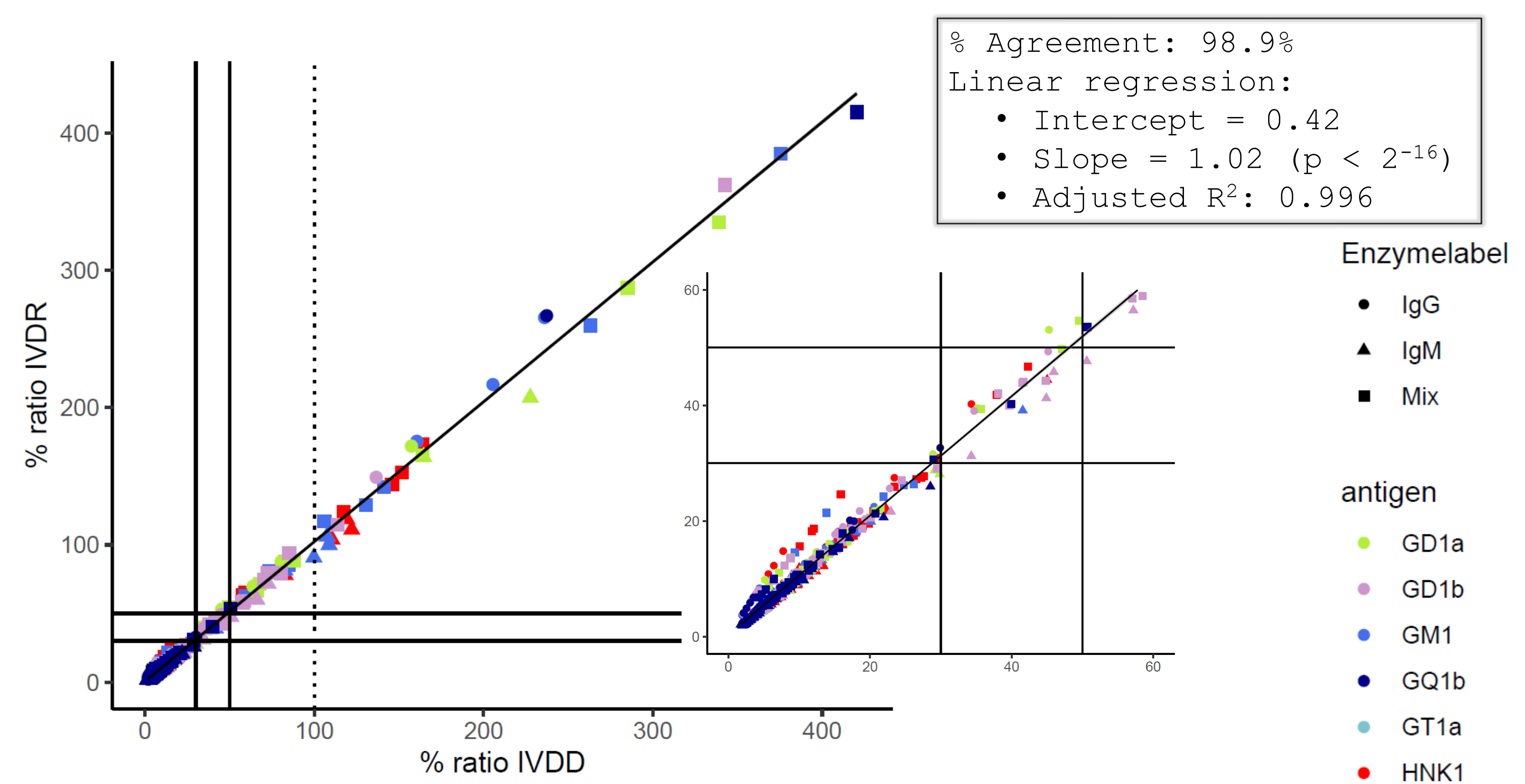
### Heatmap: Data Overview



- Anti-GM1 antibodies are the most frequently occurring antibodies, followed by GD1a and GD1b
- With the exception of GD1b, there is a unique reaction to a single antigen in about 50% of cases
- About 25% of sera react to > 3 antigens simultaneously

## Case Series for Comparing Assay Versions

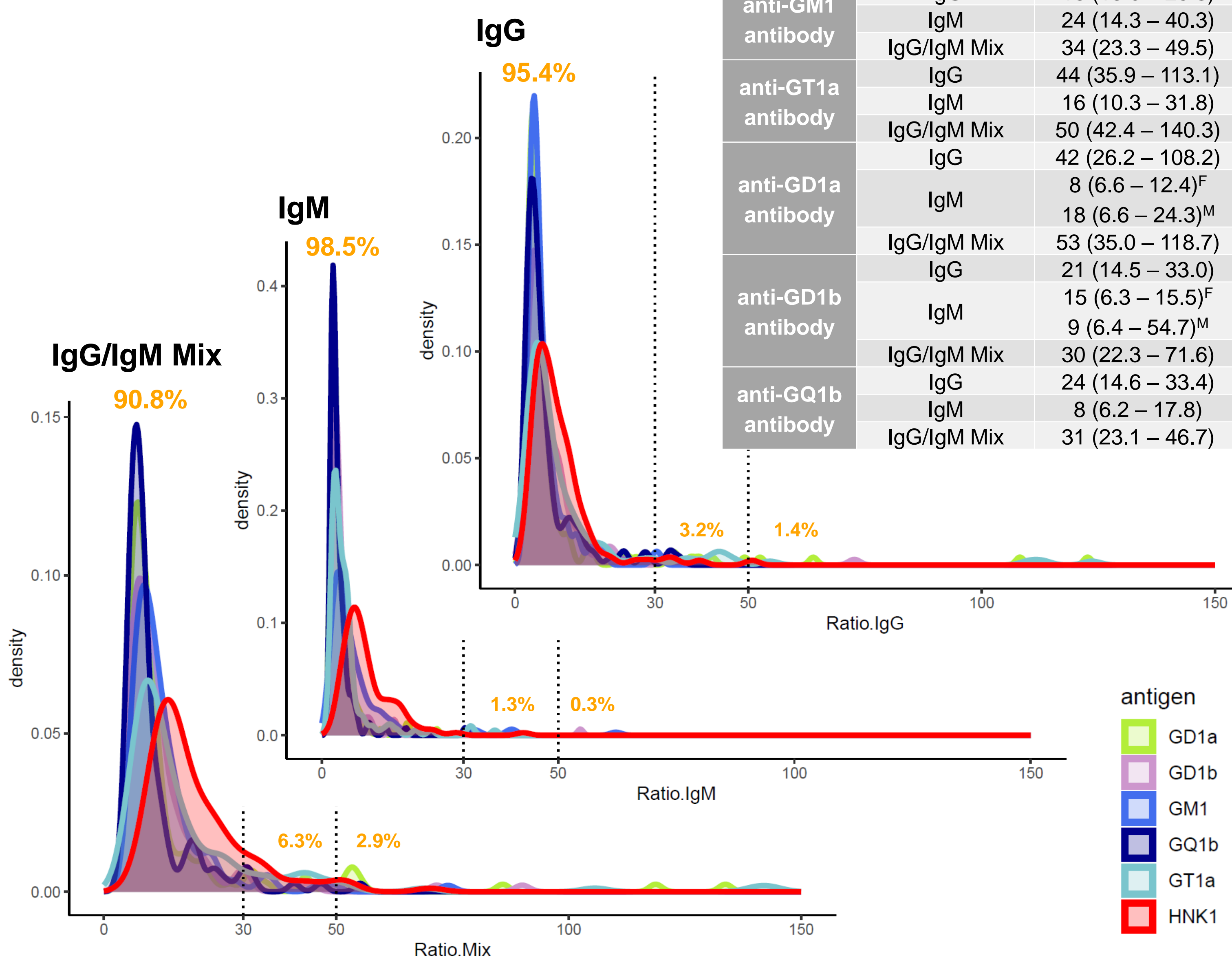
To test the comparability between the current (IVDD) and the renovated IVDR-compatible version of the GanglioCombi, we have measured a case series of 16 normal blood donors, 15 disease controls (other neurological or autoimmune disorders), and 20 patient sera. Data are presented as %Ratio relative to the current (IVDD) and newly standardized (IVDR) calibrator.



## Reference Interval Study

The reference interval study was performed using 120 apparently healthy normal blood donors, 60 male and 60 female, in two consecutive kit lots. The reference interval is based on the observed 95% confidence intervals.

Analyte	Enzyme Label (Isotype)	Reference limit (90% CI)
anti-HNK-1 antibody	IgG	25 (15.7 – 39.5)
	IgM	20 (18.6 – 28.4)
anti-GM1 antibody	IgG/IgM Mix	44 (34.8 – 52.9)
	IgG	16 (13.0 – 29.8)
anti-GT1a antibody	IgG/IgM Mix	34 (23.3 – 49.5)
	IgG	44 (35.9 – 113.1)
anti-GD1a antibody	IgG/IgM Mix	50 (42.4 – 140.3)
	IgG	42 (26.2 – 108.2)
anti-GD1b antibody	IgM	18 (6.6 – 24.3) <sup>M</sup>
	IgG/IgM Mix	53 (35.0 – 118.7)
anti-GQ1b antibody	IgG	21 (14.5 – 33.0)
	IgM	15 (6.3 – 15.5) <sup>F</sup>
anti-GM1 antibody	IgG/IgM Mix	9 (6.4 – 54.7) <sup>M</sup>
	IgG/IgM Mix	30 (22.3 – 71.6)
anti-GQ1b antibody	IgG	24 (14.6 – 33.4)
	IgM	8 (6.2 – 17.8)
anti-GM1 antibody	IgG/IgM Mix	31 (23.1 – 46.7)
	IgG/IgM Mix	



## CONCLUSION

Antibodies against GM1 are most frequently observed in "real life" diagnostic routine. Therefore, the BÜHLMANN GanglioCombi® MAG ELISA uses anti-GM1 antibodies as standardized and traceable calibrator material. The reference interval study with 120 healthy individuals justifies a distinct grey-zone in addition to seronegative and -positive samples. The two compared regulatory versions (current IVDD and renovated IVDR-compatible) are in perfect agreement. The new version is a suitable tool for laboratories that need to comply with new and more stringent IVDR standards. IVDR-clearance of GanglioCombi by regulatory bodies is expected soon.

BÜHLMANN GanglioCombi® is a registered trademark in many countries.

