Clinical Performance Report: Microblot-Array Autoimmune gastroenteritis panel IgA, IgG

(Abbreviated Version)

The Microblot-Array Autoimmune Gastroenteritis panel IgA and IgG assays were evaluated in an external clinical performance study at the independent specialized laboratory Laboratoře Agel a.s. (Nový Jičín, Czech Republic), in compliance with IVDR requirements.

The study aimed to generate objective, reliable performance data under real clinical conditions.

Monitored performance characteristics

- Diagnostic sensitivity and specificity
- Positive and negative predictive value
- Likelihood ratios of the kit for positive and negative test
- Comparison with reference method

Samples

- Anonymous archived residual samples of IgA and IgG antibodies for the diagnosis of autoimmune gastrointestinal disorders (*ASCA, p-ANCA, celiac disease, pernicious anaemia*) from Laboratoře Agel a.s, Nový Jičín
- Commercially available samples

Table 1: Tested samples

	Panel of positive samples		**Panel of negative samples**	
	IgA	**IgG**	**IgA**	**IgG**
Number of samples tested (n=501)	159	211	61	70
Population	General			
Sample source	Residual from routine commercial[1]			
Date of sample collection	2024–2025			

Reference method for clinical performance comparison

Reference methods like the Microblot-Array Autoimmune gastroenteritis panel IgA and IgG are immunoenzymatic tests for quantitative determination of IgA antibodies (gliadin, ASCA, tTG, parietal cells, intrinsic factor).

Name of Method	Catalog No.	Manufacturer
Autoimmune Gastrointestinal Diseases IgA	DL 1360-6401 A	Euroimmun
Autoimmune Gastrointestinal Diseases IgA	DL 1360-6401 G	
AESKUBLOTS Gastro Pro	4005	AESKU.GROUP
AESKULISA MPO ELISA	3303OEM	

Results

Table 1: Results for Microblot-Array Autoimmune gastroenteritis panel IgA and IgG: reference samples'results. The values correspond to the results obtained by measuring the tested and reference methods.

	IBD		Celiac diseas		Pernicious anemia	
	IgA	IgG	IgA	IgG	IgA	IgG
Number of tested samples	220	281	220	242	220	242
Positive	77	85	85	70	45	91
Borderline (not evaluated)	0	1	0	0	0	0
Negative	143	195	135	172	175	151

Table 2: Clinical performance results for MBA Autoimmune gastroenteritis panel IgA

	IgA			
	IBD	Celiac Disease	Pernicious Anemia	Overall
Diagnostic sensitivity	88.31%	91.76%	91.76%	99.99%
Diagnostic specificity	97.89%	97.04%	97.78%	99.99%
Positive predictive value	95.77%	95.12%	99.99%	95.21%
Negative predictive value	93.92%	94.93%	99.43%	99.99%
Positive likelihood ratio	41.801	30.971	>100	23.623
Negative likelihood ratio	0.119	0.085	0.022	0.001
Agreement with reference method (n=220)	94.52%	95.39%	99.08%	99.99%

Table 3: Clinical performance results for MBA Autoimmune gastroenteritis panel IgG

	IgG			
	IBD	**Celiac Disease**	**Pernicious Anemia**	**Overall**
Diagnostic sensitivity	92.59%	96.97%	95.60%	98.10%
Diagnostic specificity	91.49%	95.35%	96.03%	85.71%
Positive predictive value	82.42%	88.89%	93.55%	95.39%
Negative predictive value	96.63%	98.80%	97.32%	93.75%
Positive likelihood ratio	10.880	20.848	24.060	6.867
Negative likelihood ratio	0.081	0.032	0.046	0.222
Agreement with reference method (n=281)	91.82%	96.20%	95.83%	95.02

Clinical benefit

- Diagnostic procedures based on antibody detection use immunoblotting technologies for autoimmune diseases of the gastrointestinal tract
- Helps experts detect the presence of disease in suspected cases
- The results support differentiation between different types of autoimmune gastrointestinal diseases
- Antibody profiles may also assist in assessing the stage of the disease.
- The information is interpreted in the context of the overall clinical picture to support appropriate medical decision-making

Conclusion

- Clinical performance was comparable to the reference method, with no significant differences
- Reliable performance was demonstrated under routine clinical conditions using clinical samples
- Diagnostic sensitivity and specificity met the predefined acceptance criterion (≥60%)
- The assay fulfilled the manufacturer's intended purpose intended for professional laboratory use in the diagnosis of gastrointestinal autoimmune diseases using IgA and IgG antibodies in human serum or plasma

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