POSTER NUMBER **P1564**

Clinical performance of a novel, fully automated multiplexed microarray immunoassay for the detection of celiac disease autoantibodies

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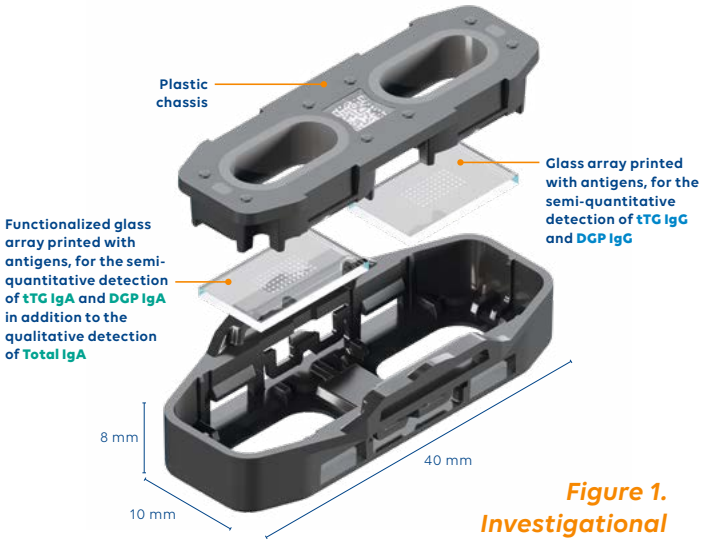

Figure 1. Investigational multiplexed microarray

1. Clinical Affairs, AliveDx, Switzerland. **2.** Georges Pompidou European Hospital, APHP, Université Paris Cité, France. **3.** Laboratory of Immunology, Georges Pompidou European Hospital, APHP, France. **4.** Laboratory of Immunology, Necker-Enfants maladies Hospital, APHP, France. **5.** North East Innovation Lab, The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK. **6.** Research & Development, AliveDx, UK. 7. Scientific & Medical Affairs, AliveDx, Switzerland

Background-aim

We assessed the clinical performance for the identification of celiac disease (CD) of a novel, single-use, multiplexed microarray immunoassay (MosaiQ AiPlex® CD microarray. AliveDx, Switzerland) (***Figure 1***), used with its fully automated high-throughput proprietary system (***Figure 2***), for the qualitative detection of total IgA and semi-quantitative detection of autoantibodies (IgA and IgG isotypes) against tissue transglutaminase (tTG) and deamidated gliadin peptide (DGP).

Methods

Included human serum samples (n=167) were banked, de-identified and clinically characterized from unselected patients diagnosed with CD (under and without gluten-free diet) as per current guidelines (ESPGHAN 2020, ACG 2023) or with other conditions, used as disease controls (n=858). Samples were tested with the investigational microarray. Clinical sensitivity and specificity were calculated. Double-sided 95% Confidence Intervals (CI) were calculated using Clopper-Pearson Exact Method.

Figure 2. MosaiQ® instrument

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Results

The clinical performance of individual measurands in the identification of CD are shown in ***Table 1***.

Table 1. Clinical sensitivity and specificity in the identification of CD of measurands on the investigational multiplexed microarray

		tTg IgA		DGP IgA		tTG IgG		DGP IgG	
Summary		% value n/N	95% CI	% value n/N	95% CI	% value n/N	95% CI	% value n/N	95% CI
Equivocal as **Positive Result**	**Sensitivity**	**75.4%** 126/167	68.2, 81.8	**67.7%** 113/167	60, 74.7	**38.3%** 64/167	30.9, 46.2	**74.9%** 125/167	67.6, 81.2
	Specificity	**96.7%** 849/878	95.3, 97.8	**94.2%** 827/878	92.4, 95.6	**99.3%** 872/878	98.5, 99.7	**93.2%** 818/878	91.3, 94.7
Equivocal as **Negative Result**	**Sensitivity**	**71.9%** 120/167	64.4, 78.5	**65.9%** 110/167	58.1, 73	**24.0%** 40/167	17.7, 31.2	**70.7%** 118/167	63.1, 77.4
	Specificity	**97.5%** 856/878	96.2, 97.9	**95.4%** 838/878	93.8, 95.9	**99.8%** 876/878	99.2, 99.9	**94.3%** 828/878	92.6, 94.9

n/N: number of concordant results, N: number of total results after including equivocal results. Two-sided 95% CI using Clopper-Pearson Exact Method.

Conclusions

The clinical performance of the investigational microarray using clinically characterized frozen human serum samples for the identification of CD was successfully demonstrated. This platform has the potential to assist in the simplification of CD evaluation by simultaneously and automatically analyzing key serological markers associated with this condition.

Presented at the 26th European Congress of Clinical Chemistry and Laboratory Medicine (EuroMedLab 2025). May 18 - 22, 2025 - Brussels, Belgium.

Suggestie klant

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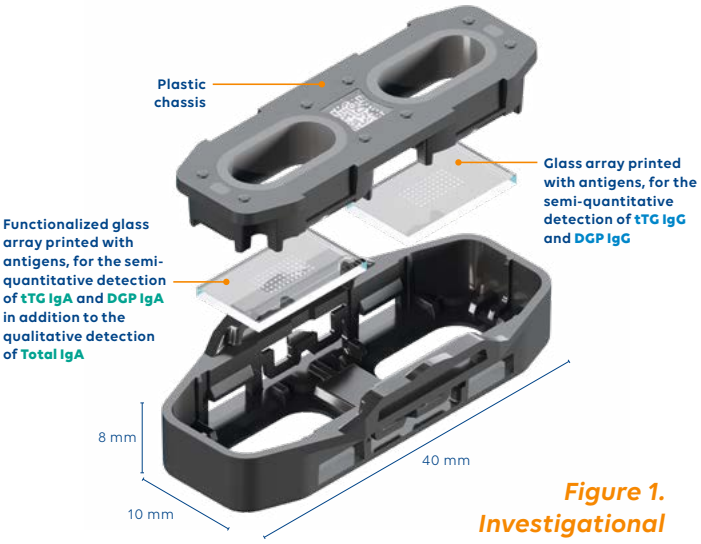

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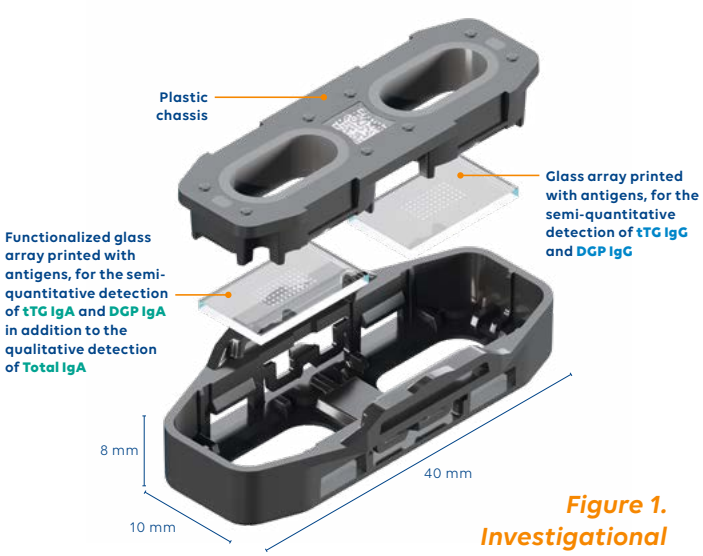

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