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

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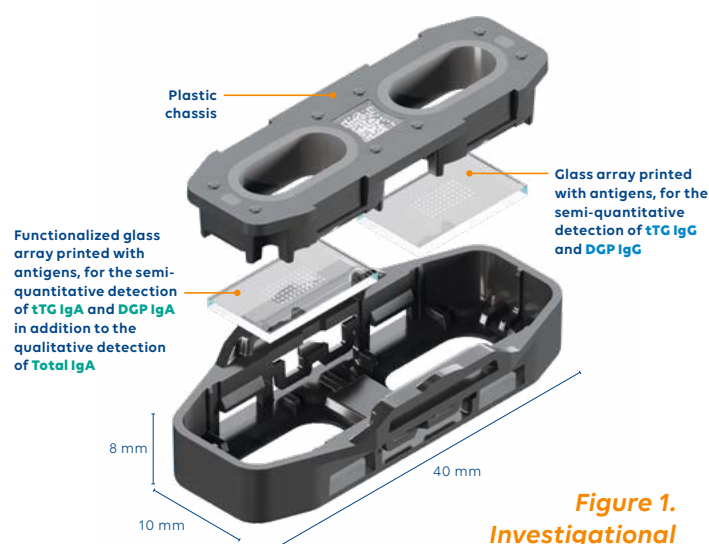
Figure 1. Investigational multiplexed microarray

Background-aim

Autoantibody detection is a cornerstone in the evaluation of Celiac Disease (CD); however, there is a limited offer of multiplexed testing devices. We assessed the analytical performance 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 semiquantitative detection of autoantibodies (IgA and IgG isotypes) against tissue transglutaminase (tTG) and deamidated gliadin peptide (DGP), compared with selected devices.

Methods

The study was conducted at two sites. Site 1: North East Innovation Lab (The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK), Site 2: AliveDx (Eysins, Switzerland). Included human serum samples were banked, de-identified and tested using the investigational device after characterization as reactive or non-reactive to the respective measurand by Phadia AB assays: tTG IgA (EliA Celikey tTG IgA), tTG IgG (EliA Celikey tTG IgG), DGP IgA (EliA Gliadin[DP] IgA) and DGP IgG (EliA Gliadin[DP] IgG). Comparator for total IgA was Tina-quant IgA Gen.2 (Roche Diagnostics GmbH). Positive percent agreement (PPA) and negative percent agreement (NPA) were calculated. Double-sided 95% Confidence Intervals (CI) were calculated using Clopper-Pearson Exact Method.

Summary results

The studied device showed high concordance with the comparator devices. PPA and NPA ranges can be seen to the right.

PPA | **96% - 100%**   NPA | **88% - 99%**

Detailed results

PPA ranged from 96% for DGP IgA and DGP IgG to 100% in the case of tTG IgA, tTG IgG and Total IgA. NPA ranged from 88% for Total IgA to 99% for tTG IgA. Details on the performance of individual measurands are shown in *Table 1*.

Table 1. Agreement of the investigational microarray immunoassay with comparators

	tTG IgA	DGP IgA	tTG IgG	DGP IgG	Total IgA
Reactive results (n)	61	72	25	47	158
PPA	100%	96%	100%	96%	100%
95% CI	94.1 to 100	88.3 to 99.1	86.3 to 100	85.5 to 99.5	97.7 to 100
Non-reactive results (n)	462	455	485	470	40
NPA	99%	97%	97%	95%	88%
95% CI	97.2 to 99.5	94.4 to 98	95.2 to 98.4	93 to 97	73.2 to 95.8

PPA: positive percent agreement; NPA: negative percent agreement. Two-sided 95% CI using Clopper-Pearson Exact Method.

Conclusions

The MosaiQ AiPlex® CD microarray used with the MosaiQ System showed high level of agreement with the compared singleplex devices, providing laboratorians and clinicians with unified results coming from one multiplexed device. This platform has the potential to assist in the simplification of CD evaluation by simultaneously and automatically analyzing key serological markers.

Figure 2. MosaiQ® instrument