Analytical Evaluation of a Novel, Fully Automated Multiplexed Microarray Immunoassay for the Simultaneous Detection of Eleven Autoantibodies Associated with Connective Tissue Diseases in a Spanish Reference Laboratory

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Scan for the abstract

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Background

Detection of autoantibodies is key in the identification of autoimmune diseases; however, most available devices are either individual tests and/or manual/semi-automated. Development of fully-automated multiplexed devices for autoantibody testing is needed.

We evaluated the analytical performance of the novel MosaiQ® AiPlex CTD (AiPlex-CTD) microarray (**Figure 1**), used with the fully-automated MosaiQ® system, for simultaneous qualitative detection of eleven autoantibodies associated with connective tissue diseases (CTD), compared with selected CE-marked devices.

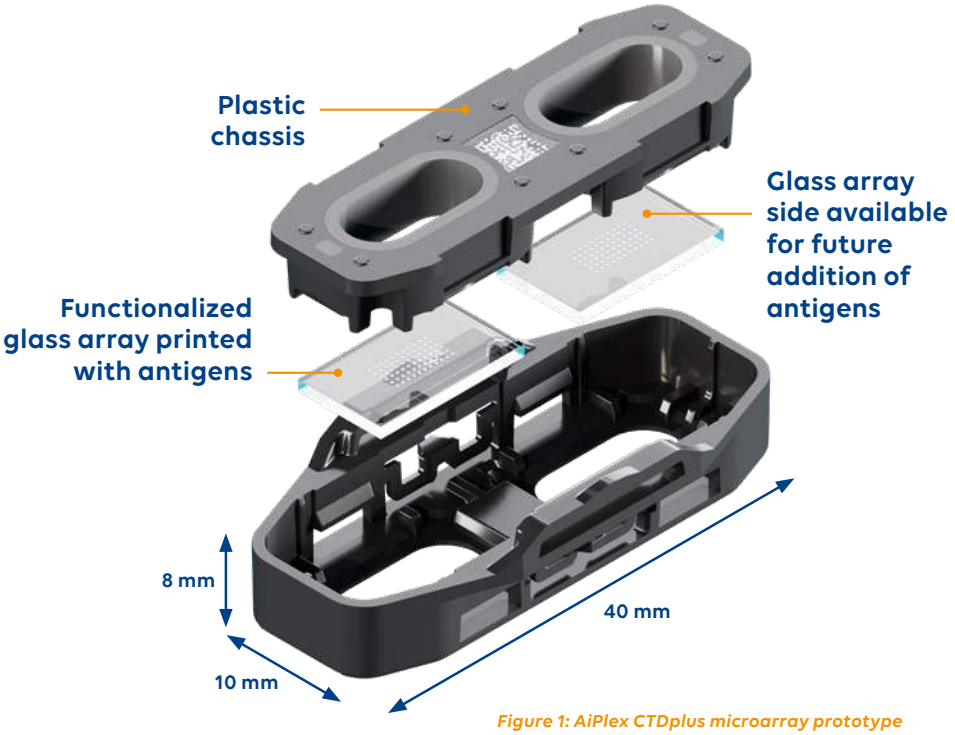

Figure 1: AiPlex CTDplus microarray prototype

Methods

AiPlex-CTD microarrays (AliveDx, Switzerland) were prepared by printing antigens onto functionalized glass chips. Microarrays consisting of 2 separate sides (1 side was printed, leaving the other side available for future addition of antigens) were assembled into magazines (containing 250 microarrays) for processing on the MosaiQ® instrument (**Figure 2**).

Serum samples from a Spanish refence laboratory, characterized as reactive to ≥1 autoantibodies using QUANTA Flash® (Werfen, Spain) or as non-reactive by FIDIS™ Connective Profile (Theradiag, France).

All samples were tested with AiPlex-CTD. Positive percentage agreement (PPA) and negative percentage agreement (NPA), overall and for individual analytes were calculated.

Results

No adverse device events were reported during the conduction of this study. Compared with QUANTA Flash®, AiPlex-CTD showed PPA ranging from 80% for Sm to 100% for SS-A 60, TRIM21, U1RNP, Jo-1 and Scl-70. No reactive samples were available for Sm/RNP and Ribosomal P. Compared with FIDIS, NPA ranged from 95% for dsDNA, Scl-70 and CENP-B and 100% for SS-A 60, TRIM21, SS-B, Sm, Sm/RNP, U1RNP, Jo-1 and Ribosomal P. Performance details for individual analytes are shown in the **Table**.

Performance of AiPlex CTD versus selected CE-Marked devices*

	dsDNA	Ribosomal P	Sm	Sm/RNP	U1RNP	SS-B	SS-A 60	TRIM21	Scl-70	CENP B	Jo-1
Main clinical association(s)	SLE	SLE	SLE	SLE, MCTD	MCTD, SLE	SjS, SLE	SjS, SLE	SjS, SLE, SSc, IIM	SSc	SSc	IIM
PPA (%) n/N / [95% CI]	**91.4** 32/35 [76.94, 98.2]	**NA** 0/0 [NA]	**80.0** 4/5 [28.36, 99.49]	**NA** 0/0 [NA]	**100** 5/5 [47.82, 100]	**85.7** 6/7 [42.13, 99.64]	**100** 19/19 [82.35, 100]	**100** 21/21 [83.89, 100]	**100** 9/9 [66.37, 100]	**95.2** 20/21 [76.18, 99.88]	**100** 4/4 [39.76, 100]
NPA (%) n/N / [95% CI]	**95** 19/20 [75.13, 99.87]	**100** 20/20 [83.16, 100]	**100** 20/20 [83.16, 100]	**100** 20/20 [83.16, 100]	**100** 20/20 [83.16, 100]	**100** 18/18 [81.47, 100]	**100** 20/20 [83.16, 100]	**100** 19/19 [82.35, 100]	**95.5** 19/20 [75.13, 99.87]	**95** 19/20 [75.13, 99.87]	**100** 20/20 [83.16, 100]

*QUANTA Flash® (Werfen) for reactive samples and FIDIS Connective Profile (Theradiag) for non-reactive samples. Two-sides 95% CI using Clopper-Pearson Exact Method. n/N: number of results in agreement/number of results, CI: Confidence Interval, NA: Not applicable; NPA: Negative percentage agreement; PPA: Positive percentage agreement

Systemic lupus erythematosus (SLE) | Sjögrens syndrome (SjS) | Systemic sclerosis (SSc) | Mixed connective tissue disease (MCTD) | Idiopathic inflammatory myopathy (IIM)

Conclusions

- **In this sample cohort, AiPlex-CTD demonstrated high concordance with the compared CE-marked devices for the automated qualitative detection of the autoantibodies included in the assay, which is line with previous observations in a larger cohort using FIDIS and other CE-marked devices.**

- **This solution has the potential to advance the diagnosis of several systemic autoimmune rheumatic diseases by accelerating laboratory workflow and time to results, empowering clinicians to make better-informed, early and personalized clinical decisions.**

Figure 2: MosaiQ® instrument

AliveDx