Analytical Performance of a Novel, Fully Automated Multiplexed Microarray Immunoassay Prototype for the Simultaneous Detection of Fifteen Autoantibodies Associated with Connective Tissue Diseases

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Background

There is currently a limited offer of automated multi-analyte tests for autoantibody testing in autoimmune connective tissue diseases (CTD). We assessed the analytical performance, in comparison with CE-marked devices, of MosaiQ® AiPlex CTDplus, a novel, single-use, multiplexed microarray immunoassay prototype (**Figure 1**), used with the fully automated MosaiQ® system (MosaiQ® instrument shown in **Figure 2**), for the simultaneous detection of fifteen autoantibodies associated with autoimmune CTD.

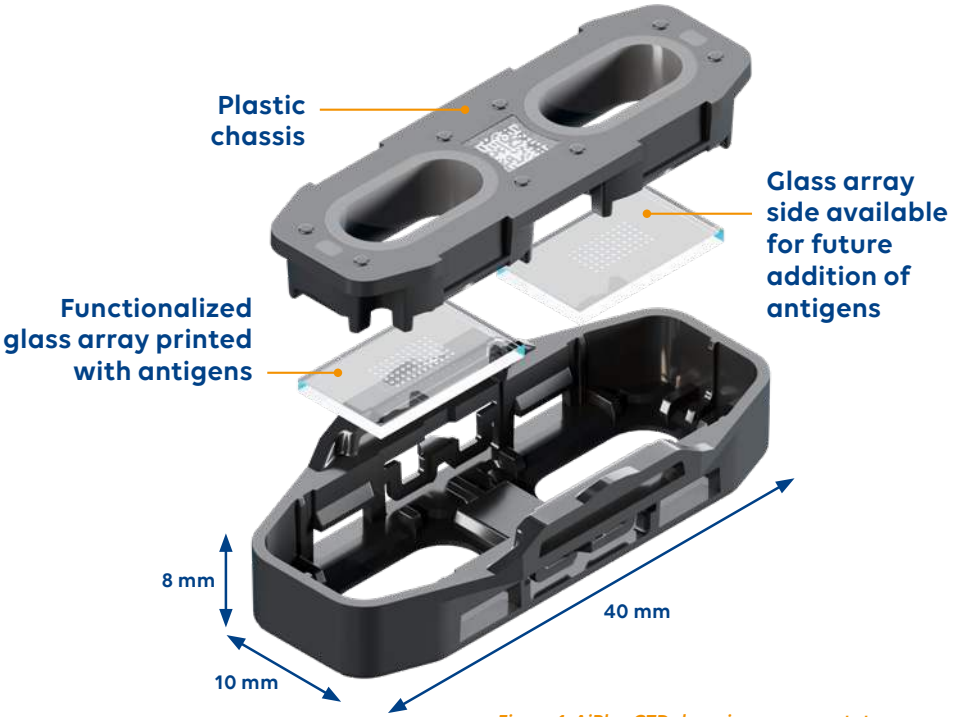

Figure 1: AiPlex CTDplus microarray prototype

Methods

- Method comparison study conducted at Hôpital Pitié-Salpêtrière (Paris, France)
- Samples: banked, serum, anonymized, characterized as per site's routine testing
- Non-reactive samples were characterized using both immunofluorescence (ANA-Ro IgG FLUORESCENT HEp-2000®; Immuno Concepts, Germany) and ANAscreen ELISA (ORGENTEC-Diagnostika-GmbH, Germany)
- Reactive samples were characterized as follows:
  - FIDIS™ Connective Profile (Theradiag, France) for CENP B, Jo-1, Ribosomal P, Scl-70, Sm, Sm/RNP, SS-A 60, TRIM21 (SS-A 52), SS-B and U1RNP
  - EliA CCP (Phadia, Germany) for CCP2
  - QUANTA Lite® Chromatin (Werfen, Spain) for Chromatin
  - QUANTA Flash® DFS70 (Werfen, Spain) for DFS70
  - Anti-dsDNA-IgG-ELISA (DRG, Germany) for dsDNA
  - Immunodot (Euroimmun, Germany) for RNA polymerase III (RNAP III)
- For CCP2, only reactive samples were included
- Each individual non-reactive sample was tested with the investigational device once and reactive samples were tested in duplicates
- The study was conducted under Good Clinical Practices and in compliance with the Declaration of Helsinki.

Results

Compared with relevant CE-marked devices, the investigational prototype device showed positive percentage agreement (PPA) ranging from 75% for Chromatin to 99% for SS-A 60 and TRIM21. Negative percentage agreement (NPA) ranged from 95% for Chromatin, RNAP III, Scl-70 and Sm to 100% for DFS70, SS-A 60 and TRIM21.
The **Table** shows the performance of individual analytes. No device adverse events were reported during the course of this study.

Performance of the Investigational Microarray Prototype versus Comparator Results

	dsDNA	Chromatin	Ribosomal P	Sm	Sm/RNP	U1RNP	SS-B	SS-A 60	TRIM21	RNAP III	Scl-70	CENP B	Jo-1	CCP2	DFS70
Main clinical association(s)	SLE	SLE	SLE	SLE	SLE, MCTD	MCTD, SLE	SjS, SLE	SjS, SLE	SjS, SLE, SSc, IIM	SSc	SSc	SSc	IIM	RA	
Reactive results (n)	202	75	93	104	135	161	112	199	184	46	70	92	70	70	48
PPA	**95%**	**75%**	**98%**	**88%**	**98%**	**97%**	**93%**	**99%**	**99%**	**76%**	**81%**	**98%**	**93%**	**86%**	**94%**
95% CI	91-97	64-83	93-99	81-93	94-99	93-9	87-96	96-100	96-100	62-86	71-89	92-99	84-97	76-92	83-98
Non-reactive results (n)	100	100	100	99	99	99	99	99	99	100	100	100	100	-	100
NPA	**97%**	**95%**	**96%**	**95%**	**98%**	**98%**	**97%**	**100%**	**100%**	**95%**	**95%**	**97%**	**96%**	**NA**	**100%**
95% CI	90-98	89-98	90-98	89-98	93-99	93-99	92-99	96-100	96-100	89-98	89-98	92-99	90-98	NA	96-100

Rheumatoid arthritis (RA) | Systemic Lupus Erythematosus (SLE) | Sjögren's syndrome (SjS) | Systemic sclerosis (SSc) | Mixed connective tissue disease (MCTD) | Idiopathic inflammatory myopathy (IIM)
PPA: Positive percentage agreement | NPA: negative percentage agreement | 95% CI: 95% confidence interval | NA: not applicable

Conclusions

- **MosaiQ AiPlex CTDplus prototype demonstrated substantial agreement with CE-marked devices for the detection of the fifteen evaluated autoantibodies.**
- **Formal clinical and analytical performance evaluation studies will demonstrate the performance characteristics of the final product design that will provide semi-quantitative / quantitative results.**
- **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

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