Preliminary results support **MosaiQ AiPlex CTD prototype** for the **simultaneous detection of 11 autoantibodies** found in Connective Tissue Diseases

Performance Characteristics of a Novel, Fully Automated Multiplexed Immunoassay Microarray Prototype for the Serological Detection of Eleven Autoantibodies Commonly Found in Connective Tissue Diseases

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BACKGROUND/PURPOSE Detection of autoantibodies is key for the identification and prognosis of patients with connective tissue diseases (CTD); however, some current testing methods are manual, time-consuming, and fragmented, highlighting the need for the development of new fully automated diagnostic tools. We report the performance characteristics of MosaiQ® AiPlex CTD prototype, AliveDx, Eysins, Switzerland), a new planar microarray (MA) immunoassay designed for use with the fully automated, continuous random access, high-throughput MosaiQ system for qualitative serological detection of eleven autoantibodies found in CTD (dsDNA, SS-A 60, TRIM21, SS-B, Sm, Sm/RNP, U1RNP, Jo-1, Scl-70, Centromere-B, Ribosomal-P).

METHODS Each MA has two wells, each enclosing an epoxy-silane functionalized glass chip, framed in a plastic chassis ***(Figure 1)***. Antigen probes were printed in duplicate on one side of the MA, except in triplicate for dsDNA. MA were assembled into magazines, loaded in the MosaiQ 125 instrument and read by the on-board Radio Frequency Identification (RFID) antenna. Key information (i.e., number of MA, lot number, expiry date) is transmitted to the instrument which evaluates the adequacy of resources to execute the selected test order and alerts user when replacement of reagents is required. MAs are released from the magazine and automatically processed in the system where they undergo sample/buffer/reagent addition and removal to generate a final spot signal for interpretation by the instrument ***(Figure 2)***.

RESULTS 123 individual serum samples, 20 obtained from blood donations and the rest from a CTD sample bank, were tested in 6-8 replicates with the investigational device, across 3 instruments and 3 MA lots (except for U1RNP, tested on two lots) and compared with the results obtained with a CE-marked device. The table shows that across analytes the total positive, negative, and overall percent agreement (PPA, NPA and OPA) respectively, were 82.5% (95% CI 80.7-84.2), 94.6% (95% CI 93.9-95.1), and 91.6% (95% CI 91.1-92.4). Rates of indeterminate and invalid results were 0.3% and 2.1%, respectively.

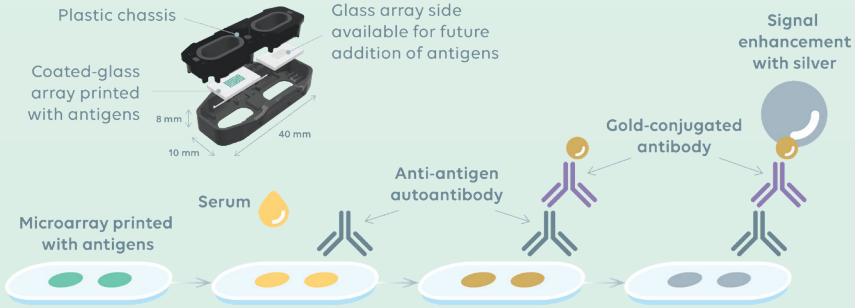
CONCLUSION These preliminary results support the performance of the MosaiQ MA technology platform and AiPlex CTD prototype device for the serological qualitative detection of autoantibodies commonly found in CTD. Larger studies to further evaluate the performance of the investigational device are ongoing. Future versions of the MA are planned to expand the number of analytes included. The MosaiQ System has the potential to advance CTD testing by increasing laboratory efficiency and productivity by automatically analyzing multiple autoantibodies simultaneously and processing large number of samples per day.

Disclosures: Authors are employees of the study sponsor or were so by the time the study was conducted.

Figure 1. MosaiQ System

(Objects not to scale)

Figure 2. MosaiQ AiPlex CTD Microarray and Reactions



Performance of MosaiQ AiPlex CTD Microarray Prototype

Concordant results n	Discordant results n	True positive n	True negative n	False positive n	False negative n	Indeterminate n (%)	Invalid n (%)	PPA % (95%CI)	NPA % (95% CI)	OPA % (95% CI)
6,608	592	1,506	5,208	304	320	36 (0.3)	158 (2.1)	82.5 (80.7–84.2)	94.6 (93.9–95.1)	91.6 (91.1–92.4)

PPA: positive percent agreement | NPA: negative percent agreement | OPA: overall percent agreement | CI: confidence interval