

# MosaiQ® Scientific Communications Autoimmunity



The MosaiQ® solution is designed to empower laboratories to deliver diagnostic confidence to clinicians. This material is intended to provide an overview of the scientific communications of the MosaiQ® Autoimmune Program.

MosaiQ® offers comprehensive panels with the potential to advance the diagnosis of autoimmune diseases by accelerating laboratory workflows and time to result. Designed to aid clinicians to make better informed, early and personalized clinical decisions.

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### MosaiQ AiPlex® CTDplus



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### MosaiQ AiPlex® CTDplus 15-plex autoantibody profile showed clinical value in the identification of autoimmune CTD.<sup>1</sup>

A Random Forest classifier with all 15 autoantibodies featured in the MosaiQ AiPlex® CTDplus microarray outperformed individual markers and groups associated with disease in predicting autoimmune CTD. Multiplex autoantibody testing combined with machine learning algorithms has the potential to improve the diagnosis of autoimmune CTD.

### MosaiQ AiPlex® CD



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### MosaiQ AiPlex® CD showed substantial agreement with the compared devices for the detection of celiac disease autoantibodies.<sup>2</sup>

The MosaiQ AiPlex® CD used with the MosaiQ® System showed high level of agreement with the compared single-plex 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.

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### MosaiQ AiPlex® CD



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#### **Clinical performance of MosaiQ AiPlex® CD in the identification of celiac disease was demonstrated.<sup>3</sup>**

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.

### MosaiQ AiPlex® CD



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#### **MosaiQ AiPlex® CD prototype's preliminary results showed substantial agreement with the compared CE-marked devices for the detection of celiac disease autoantibodies.<sup>4</sup>**

The investigational microarray prototype showed solid concordance with the compared CE-marked singleplex devices. Additional completed steps include semi-quantification and addition of probe to control for total IgA deficiency. This platform has the potential to assist in the simplification of the evaluation of celiac disease and other autoimmune diseases by automatically analyzing key serological markers in one step.

### MosaiQ AiPlex® CTDplus



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#### **MosaiQ AiPlex® CTDplus prototype showed substantial agreement with the standard of care in a French major reference center.<sup>5</sup>**

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. 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.

### MosaiQ AiPlex® CTD



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#### **MosaiQ AiPlex® CTD showed substantial agreement with the compared CE-marked devices.<sup>6</sup>**

In this sample cohort from a Spanish reference center, MosaiQ AiPlex® CTD showed high concordance with CE-marked devices for the detection of the eleven studied autoantibodies, which is in line with previous observations in a larger cohort using FIDIS and other CE-marked devices.

### MosaiQ AiPlex® CTDplus



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#### **MosaiQ AiPlex® CTDplus prototype's preliminary results showed substantial agreement with the compared CE-marked devices.<sup>7</sup>**

MosaiQ AiPlex® CTDplus prototype's preliminary results showed substantial agreement with the compared CE-marked devices. Further studies with the final product design will allow for expanded performance assessment of the device. This fully automated multiplexed platform could help optimize CTD evaluation by simplifying complex testing pathways and analyzing larger number of samples per day.

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AiPlex® CTD**



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**MosaiQ AiPlex® CTD showed significant agreement with the compared CE-marked devices.<sup>8</sup>**

MosaiQ AiPlex® CTD showed high concordance with compared CE-marked devices, for the automated simultaneous qualitative detection of the eleven autoantibodies included in the assay. Future product developments will include the addition of other autoantibodies to the microarray and semi-quantification.

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AiPlex® CTD**



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**MosaiQ AiPlex® CTD preliminary results showed substantial agreement with the compared CE-marked devices.<sup>9</sup>**

Solid preliminary performance results support the MosaiQ AiPlex® CTD microarray. Larger studies to further evaluate the performance of the investigational device are ongoing. The MosaiQ® System has the potential to advance CTD testing by increasing laboratory efficiency and productivity by automatically analyzing multiple autoantibodies simultaneously and processing larger number of samples per day.

**MosaiQ  
AiPlex® CENP-B**



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**MosaiQ AiPlex® CENP-B showed notable agreement with the compared CE-marked devices.<sup>10</sup>**

MosaiQ® CENP-B microarray shows high concordance with other CE-marked assays for detecting autoantibodies against CENP-B, with demonstrated reproducibility and repeatability. MosaiQ® System has the potential to improve laboratory efficiency and productivity, with the ability to multiplex the detection of various autoantibodies on a single microarray and a capacity to automatically process samples, delivering a large number of results per day.

**MosaiQ  
AiPlex® CENP-B**



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**MosaiQ AiPlex® CENP-B prototype's preliminary results showed substantial agreement with the compared CE-marked devices.<sup>11</sup>**

MosaiQ® CENP-B microarray provides a high level of clinical concordance with other CE-marked assays for detecting anti-CENP-B autoantibodies (ACA-B). The MosaiQ® System has the potential to advance autoimmune disease testing by increasing laboratory efficiency and productivity, with the ability to multiplex the detection of various autoantibodies on a single microarray, and a capacity to automatically process large number of samples per day.

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GFD#:0.0122.v2