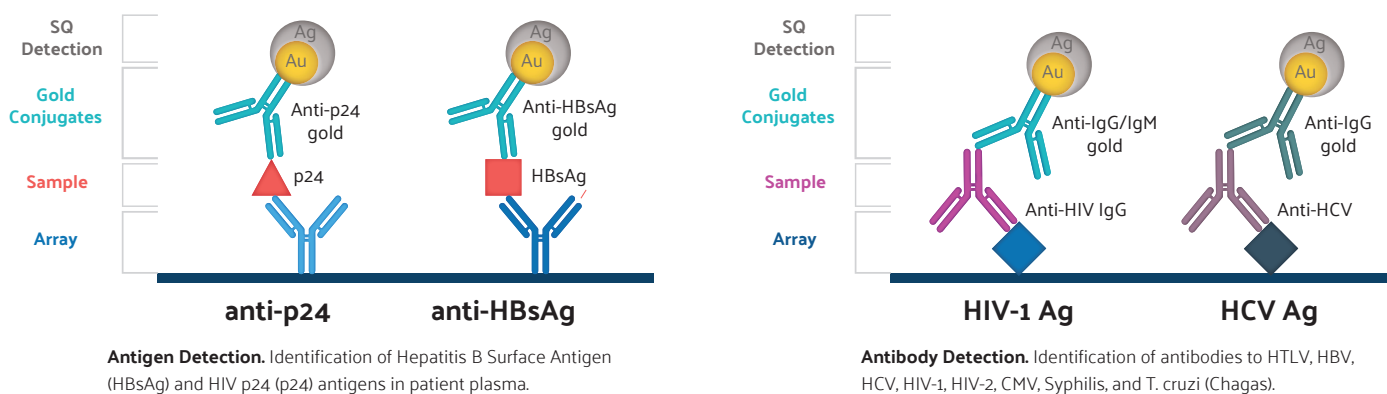


Case Study: AIM for Diagnostics Development

Developing a Novel Antibody and Antigen Detection Assay

Intuitive Biosciences utilized the Arrayed Intuitive Multiplexing (AIM) platform to develop assays to be incorporated onto a custom immunoassay platform. To identify the best antigens and antibodies for the Quotient MosaiQ™ Disease Screening methodology, Intuitive Biosciences sourced materials from commercial vendors and characterized performance on a manual benchtop platform. Assay development was performed in compliance with the required Quality Management System, and resulted in two rapid and accurate multiplex assays for transfer to the Quotient MosaiQ™ Disease Screening platform. The goal of this custom assay development project was to design two assays; an infectious disease test for antigen detection, and a test to identify antibodies to infectious diseases.



Design Requirements

Assay must be compatible with current MosaiQ™ methodology including minimum pipetting volumes, assay buffers, custom modified surface, incubation times, and temperature. All aspects of assay must be compatible with Quotient imaging system and automation configuration.

Development Outputs

Identification of best sample concentration, sample dilution buffer, arraying conditions, and post-arraying treatment procedures. Characterized and selected best performing antigens and antibodies. Completed prototype validation with over 5,000 clinical samples with a prototype assay accuracy of over 98%.

Conclusion

Using the AIM platform to develop the assay, Intuitive Biosciences met the Milestone requirements on time and within budget. By 2018, Quotient Biodiagnostics will have taken the MosaiQ™ Disease Screening assay through clinical trials. MosaiQ™ will offer improved clinical decision-making and considerable efficiencies through a complete automation solution.