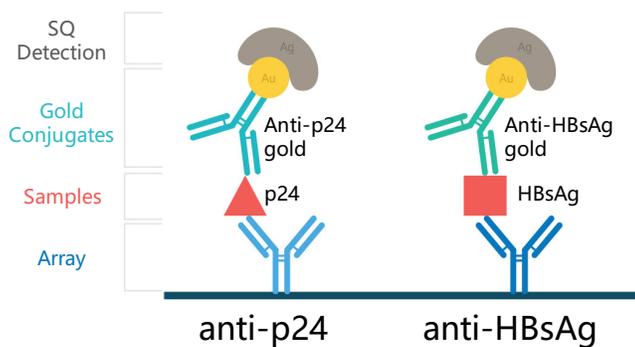


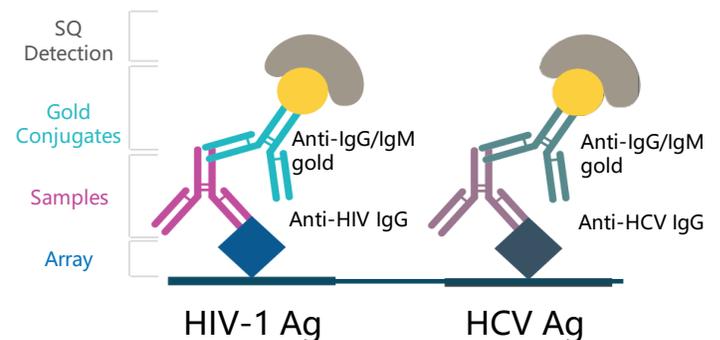
Case Study: AIM for Diagnostics Development

Developing a Novel Antibody and Antigen Detection Assay

Intuitive Biosciences utilized the Array 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 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.



Antigen Detection. Identification of Hepatitis B Surface Antigen (HBsAg) and HIV p24 (p24) antigens in patient plasma.



Antibody Detection. Identification of antibodies to HTLV, HBV, HCV, HIV-1, HIV-2, CMV, Syphilis, and T. cruzi (Chagas).

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.