Transitioning to an ‘Automation-First’ Culture in Bioanalysis: Our Learnings From the Last 3 Years

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Bioanalysis, Immunogenicity & Biomarkers BIB)

STRONG ROI FROM INTERNAL SUPPORT

BIB (TODAY)

- Cellular Biomarkers
- Bioanalysis & Biomarkers
- Immunogenicity
- Systems
- Scientific Quality

REGULATED SUPPORT (GLP TK, CLINICAL)

RESEARCH (NonGLP TK, Biopharm PK, TE)

APPROX. 100 LAB-BASED SCIENTIFIC STAFF

PEOPLE

- *MAKE BEST USE OF SCIENTFIC KNOWLEDGE (ASSAY DESIGN, VALIDATION, TROUBLE SHOOTING)*

AUTOMATE

- MECHANISE WHAT WE CAN (ROUTINE WORKFLOWS)
- ENABLE STAFF TO FLEX AS EASILY AS POSSIBLE ACROSS ASSAY PLATFORMS

ROI FOR INTERNAL CAPABILITIES

- *MAKES SIGNIFICANT IMPACT TO PROJECT PROGRESSION (TECHNICIAL DIFFICULTY, AGILITY WITH DYNAMIC PORTFOLIO DECISION-MAKING)*

3-YR INVESTMENT (CAPABILTY BUILD)

75% of BIB workflows benefited (including automation of key bottlenecks up to E2E)

CAPACITY

- ADA Testing

QUALITY

- Meth Dev / Val
- Sample Testing
- Protein MS

TIME SAVING

- FTiH (f/t)
- Histology Inventory
- Compound Inventory
- Reagent Workflows

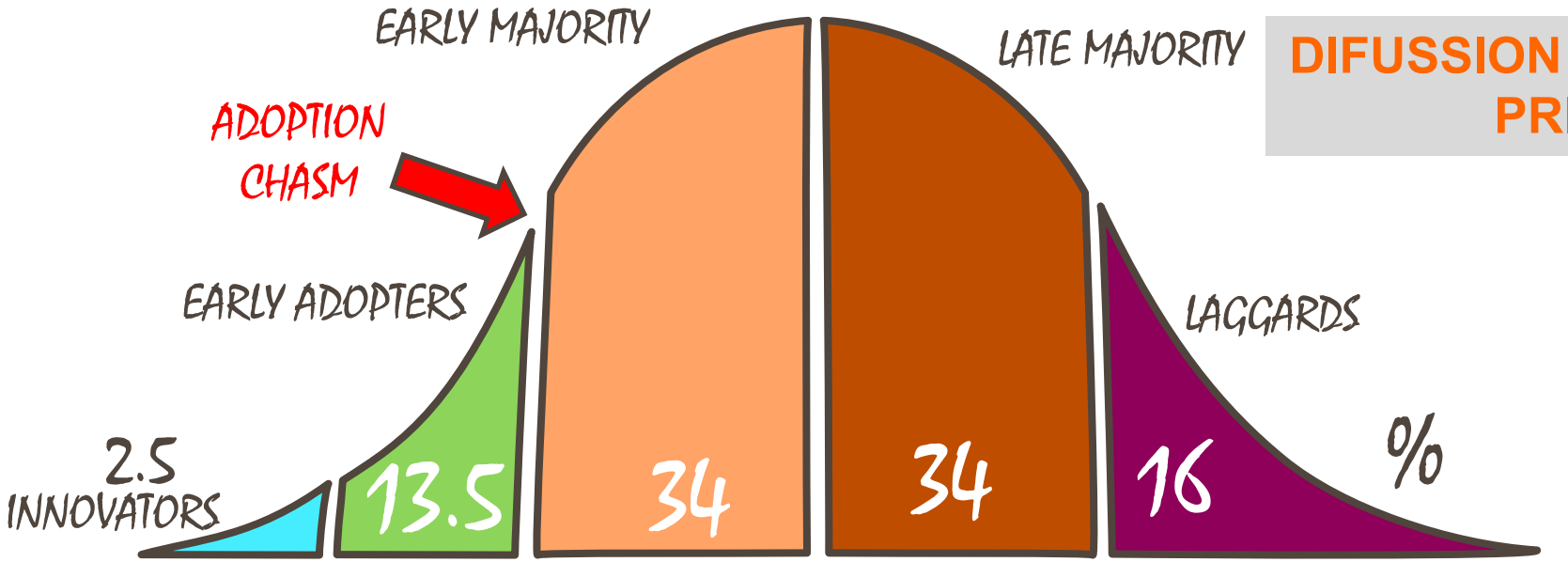
COST

- Ultra-high sensitivity LBA
- T-Cell Response

2 Automation Specialists hired (1UK, 1 US)
Drive strategy, automation literacy, advanced programming

LEARNINGS (1)

CONVINCING THE MAJORITY THAT IT'S WORTH THEIR INVESTMENT



DIFUSSION OF INNOVATION PRINCIPLE

INNOVATORS "I found this and I want one"

EARLY ADOPTERS "Great, I'll give that a go"

EARLY MAJORITY "I need to see some data first"

LATE MAJORITY "It's likely to fizzle out so I'll wait-see"

LAGGARDS "Uh! They took my favourite lab gizmo away and now I'm forced to use this!"

LEARNINGS (2)

ENHANCE THE 'SCIENTIST EXPERIENCE'

- INTUITIVE USER INTERFACES
- INTUITIVE ERROR HANDLING (MORE IMPORTANTLY)

AUTOMATION LEADS

- AUTOMATION ADDRESSES TRUE BOTTLENECKS

HIGHER USER ACCEPTANCE

- GOOD THINGS CAN COME IN SMALL PACKAGES

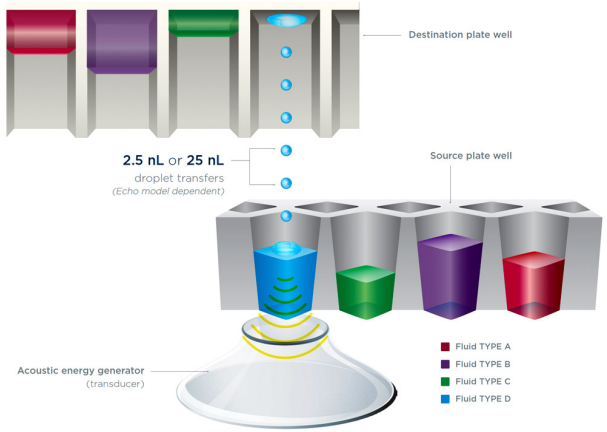
NO NEED TO BUILD LARGE E2E SOLUTIONS TO MAKE A DIFFERENCE

- HORIZON SCANNING

ENCOURAGE INNOVATORS TO INNOVATE

NICHES FOR PIPETTE ALTERNATIVES

LabCyte Echo



Rapid, Non-Contact

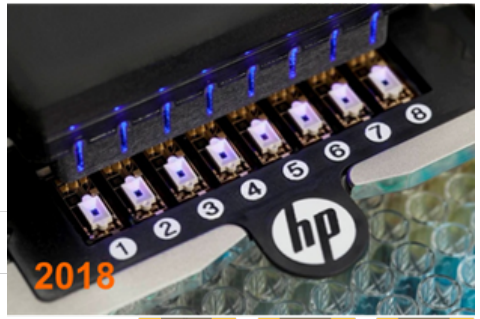
- 200 - 500 droplets per second (any well to any well)
- Consistent drop size 25 nL
- Surveys volume and viscosity (automatically adjusts)
- Low energy transfer (no impact on sample integrity)

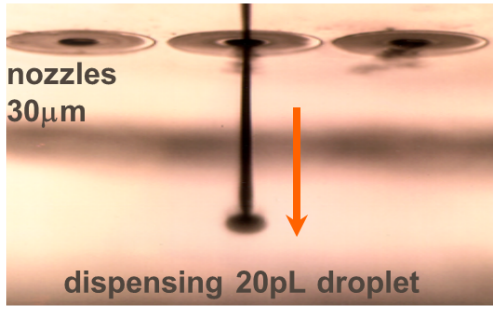
Advantages

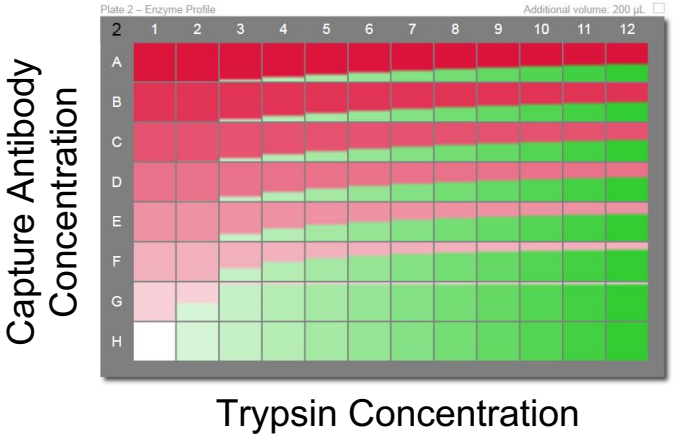
- Improved accuracy and precision
- Reduced volumes (sample, compound, matrix)
- No carryover

LBA PK Assays

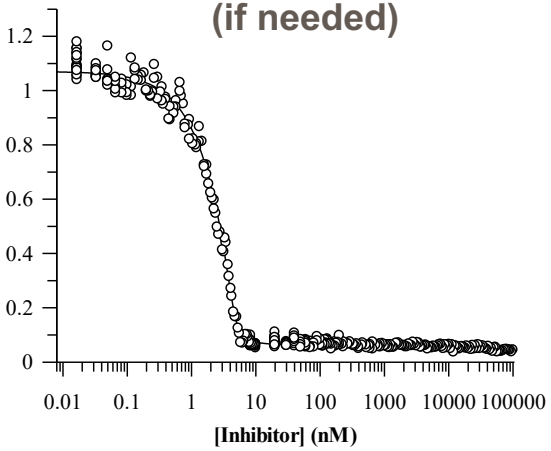
Tecan D300e







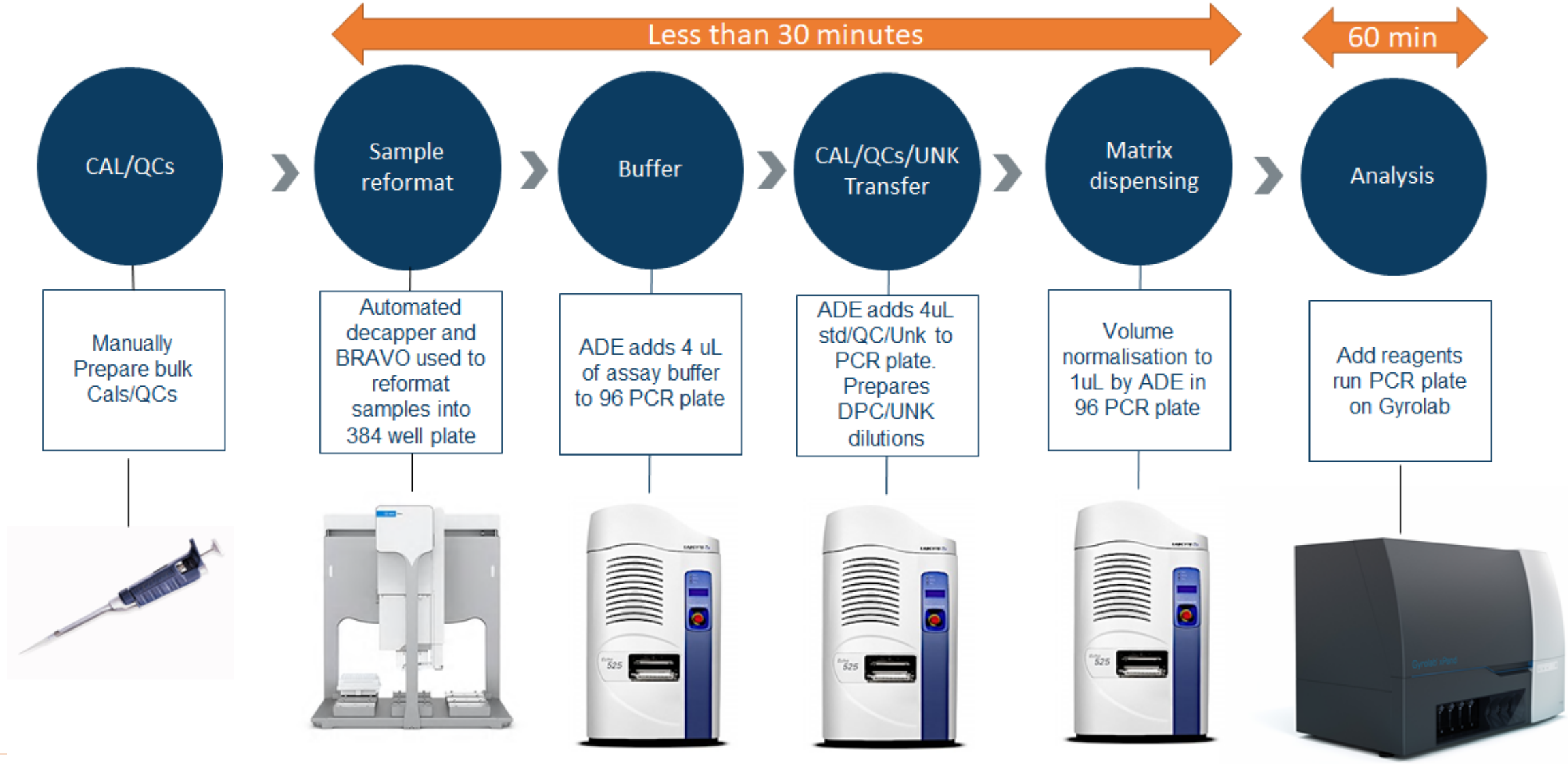
High Density Dispensing (if needed)



Condition Optimisation, High Density Dispensing Low Volumes/Rare Matrices

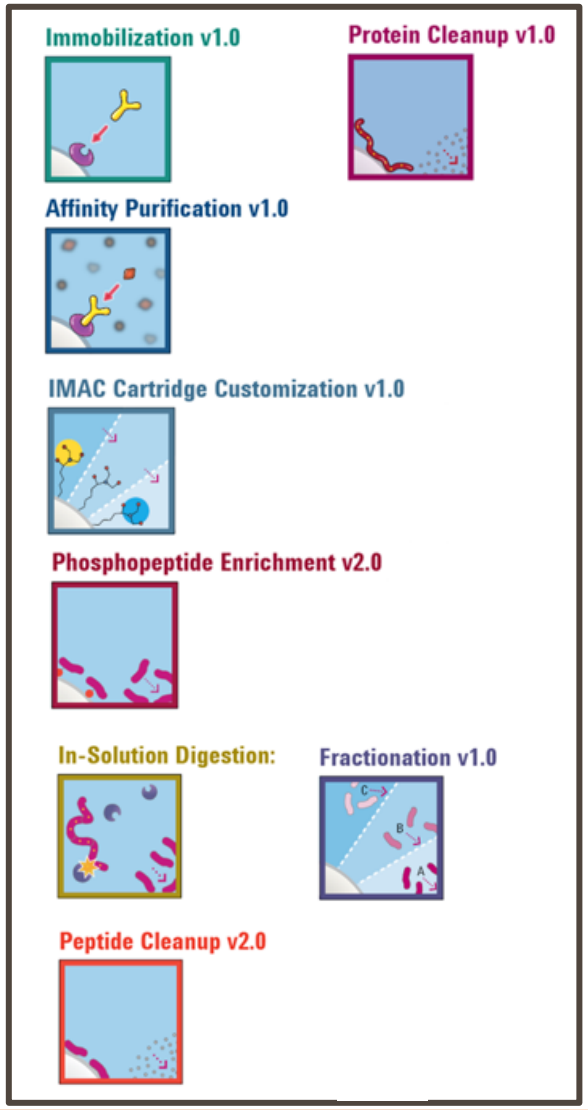
ACOUSTIC DISPENSING

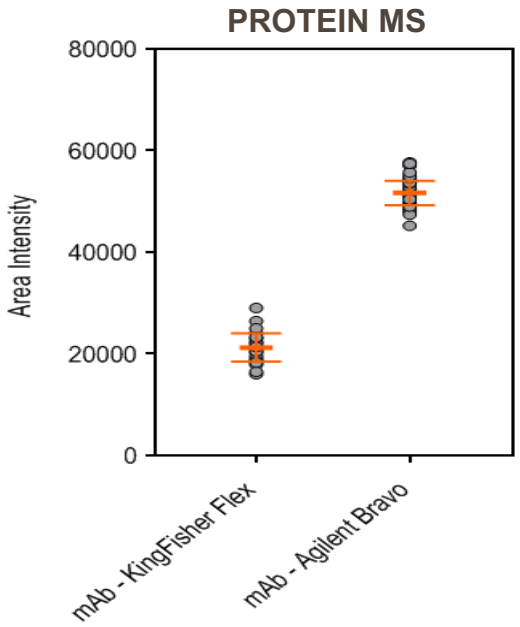
ECHO Validated to Prepare Calibration Standards From Working Solutions

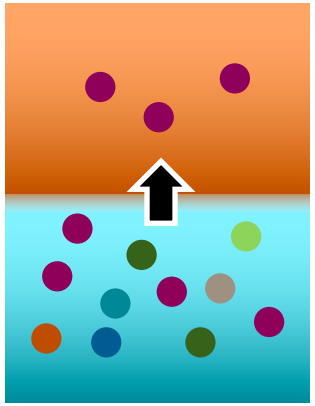


PLATFORM FUNCTIONALITY (1)

CHARACTERIZATION AND QUANTIFICATION (NCE and PROTEIN MS)







Analyte Extraction into Tertiary Methyl Butyl-Ether

Human Plasma

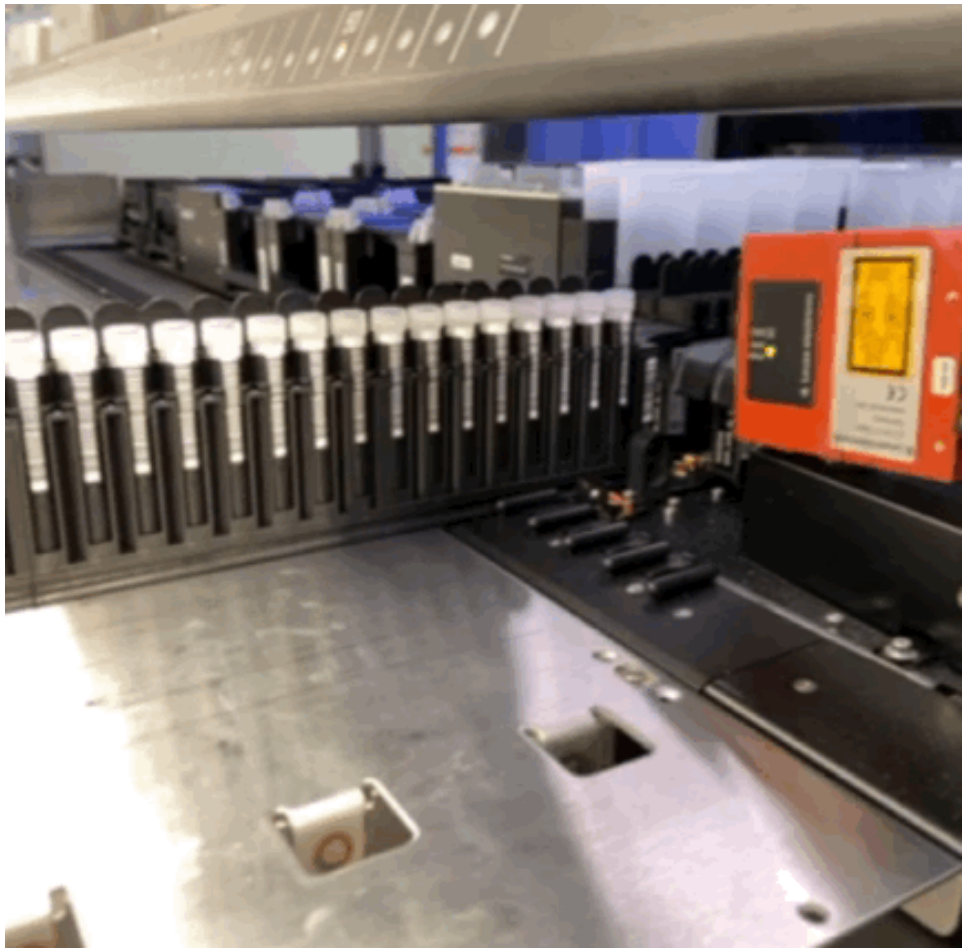
Subunit Heavy Chain / Light Chain
Intact Protein MS (on-going work)

PK, Biomarker Quantification
Signature peptide (enzymatically cleaved)

PLATFORM FUNCTIONALITY (2)

ADA

- Using Hamilton STAR system to scan 1D/2D study tube barcodes and prepare samples without human intervention
  - Sample barcode tracing
  - Limited inter-user variability
  - Setup for screening and confirmation across all project plate maps
  - Ran study with 11,110 samples successfully using this



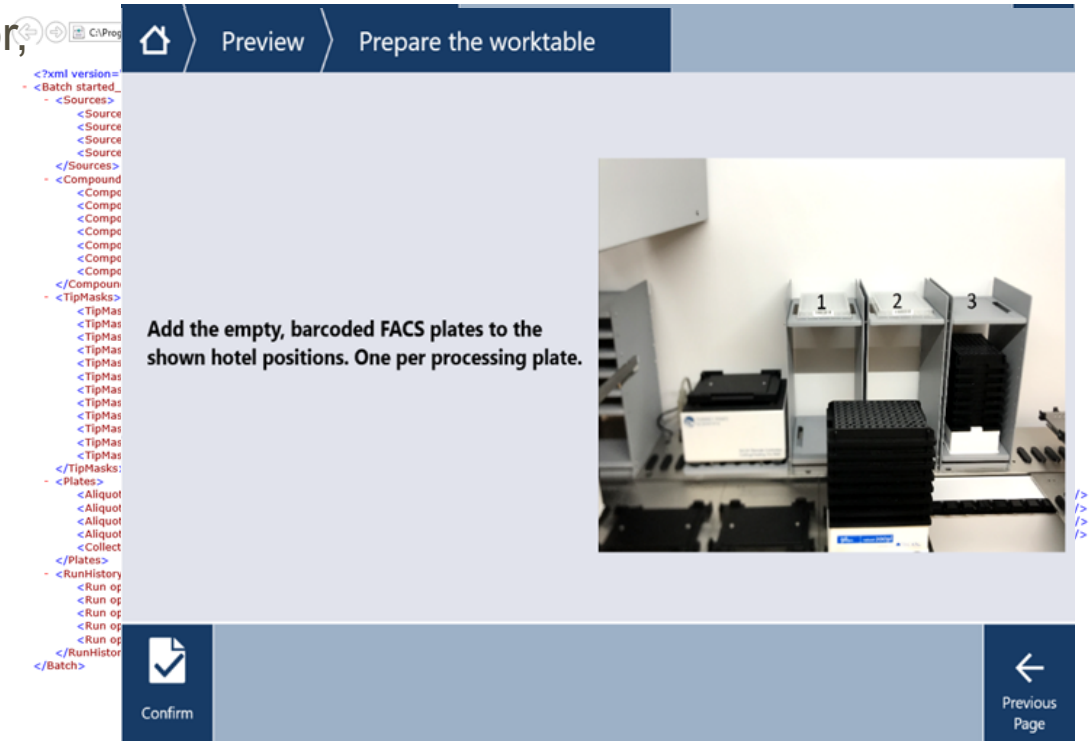
AUTO-ANTIBODY METHOD

- Using the ADA barcode handling work as a template, the same method design can be used in different assays

PBMC T-cell Proliferation Assay

IMMUNOGENICITY RISK ASSESSMENT

- End-to-end automation of 8-day cell-based method
  - Tecan Fluent with integrated plate centrifuge, cell incubator, barcode scanners, heating/chilling units
  - GUI prompts guide end user through process
  - Full barcode implementation (cells, compounds, plates)
    - Tracked through each active day of workflow
- Applied to Lead Optimisation for BioPharm Platforms



ROI

- **Internalizing saves ~150k/study x 5 studies to date**
- **Anticipating higher demand in 2021**

THANKS ALSO TO…

Bob Biddlecombe

Eric Yang

Sarah Childs