APIS
Assay Technologies Ltd.

ISO 13485:2016
Contract Assay Development & Manufacturing

APIS Assay Technologies offers high-quality and efficient assay development services, with end-to-end competency: from Assay Definition & Feasibility to Product Registration. Whether developing a simple manual assay or a complex automated multiplex assay, APIS' contract development services offer extensive diagnostic expertise and dedicated laboratory space to accelerate your assay development and manufacturing, in accordance with ISO 13485:2016. Additionally, APIS' clinical compliance services provide support across the clinical performance pipeline, including CE-IVDR submissions (ISO 20916:2019).

Diagnostic Assay Development

- End-to-end contract development services: Assay Design Input & Planning, Feasibility, Development, Verification & Validation, to Product Realisation
- Expertise in multiplex PCR (RT-qPCR, qPCR, digital PCR), NGS and Immunoassay (e.g. ELISA) technology
- Experience in numerous sample preparation methods (RNA, DNA, Protein & Direct) and sample matrices (including blood, FFPE, swab, stool, sputum, BAL, CSF, urine, saliva)
- Technical documentation generation (e.g. Instructions for Use, Product Master Record)
- Integrating novel synthetic diagnostic and detection ligand-binders (Clickmers) into diagnostic assays
- Diagnostic Software Development solutions to enable automatic results interpretation (ISO 27001)

Clinical Compliance Services

- APIS offers a Clinical and Regulatory Affairs consultancy service to help navigate the IVD regulatory environment across different regions (including CE-IVDR, UKCA, FDA)
  - Clinical Performance Study design and management (ISO 20916:2019 and ICH E6)
  - Clinical site selection, management, and monitoring, including sample procurement
  - Clinical Evidence documentation (e.g. Performance Evaluation Plans/Reports and Scientific Validity)
  - Technical file generation for submission to regulatory bodies (e.g. CE-IVDR)
  - Post-market surveillance and post-market performance follow-up studies
  - Supporting the IVDD to IVDR CE-marking transition

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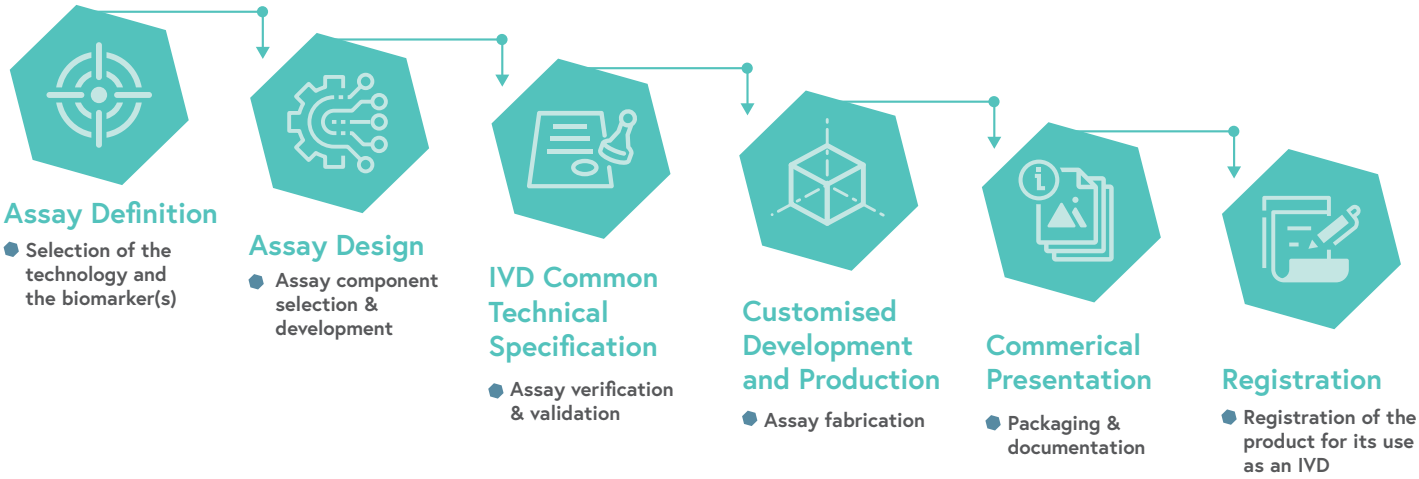
Diagram showing APIS End-To-End MDx Capabilities



Manufacturing Services

- Prototyping – Early phase kit configurations
- Pilot/Commercial manufacturing
- Design Transfer and Process Validation Capabilities
- Designated manufacturing facilities in compliance with ISO 13485:2016
- Raw material sourcing
- Cold-chain logistics, storage and distribution
- Stability studies

Microbiological Capabilities

- Expertise in the development of highly complex, multiplex infectious disease syndromic panels
- Category Level 2 facilities with HSE clearance to work with HG1 and HG2 pathogens, with further clearance for work with SARS-CoV-2, STEC and EIEC
- State-of-the-art microbiological laboratory, for the identification/characterisation of Bacterial and Fungal species, as well as antimicrobial resistance assessment
- Contriving pathogenic samples for performance studies, including clinical workflow simulations (e.g. blood culture systems for clinical validation studies)

Previous Assay Development Work

- The APIS Breast Cancer Subtyping Kit is available as an IVD product (in certain territories) and RUO
  - Successful exemplars of developing and taking APIS products to market
  - Experienced in balancing business risks and have developed trade-off knowledge having gone through the end-to-end development process internally
- Proven track record delivering milestones for a large Global Diagnostic company, providing highly multiplexed assay development services across various phases and projects

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