Companion Diagnostic Development Services

Supporting drug development, improving patient outcomes
Hologic’s Tepnel Pharma Services is uniquely placed to provide a front-to-end CDx development service.

We can support CDx development from early pre-clinical research and biomarker discovery through to the development, manufacture and regulatory approval of a CDx test. We support all stages of the CDx development process, including design control, cGMP kit manufacture, validation studies, production of Investigational Use Only assays for use in clinical trials and regulatory submission.

The Drug Development Pipeline

Concept and Feasibility Services
- Platform and technology choice
- Voice of customer
- IP/Legal

Development and Verification Services
- Technology transfer and platform migration
- Regulatory assessment of clinical trial design

Regulatory Submission Services
- The ability to gain regulatory approvals in multiple countries is instrumental to the success of any treatment and its associated CDx.
- The guidance of our Regulatory Team will occur throughout the entire product development process.
- Our service is designed to meet the requirements of the FDA and other global regulatory bodies by supporting the regulatory approvals/registrations of your CDx in any country.

Validation Services
- Clearly defining the design inputs required for initiation of the design control process
- Developing the technical strategies to be used in the product development process
- Planning all product development activities and timelines.
- Design and Stage Reviews allow gated process with Stop/Go decision points
- Your Project Manager will liaise with all stakeholders including Client, R&D, GC, Operations, Manufacturing, Quality, Regulatory Affairs, Clinical Affairs and Marketing to ensure success

Key highlights to our services:
- Fee-for-service
- Flexible IP strategy
- Proprietary chemistries and Dx hardware
- Proven diagnostic track history
- Front-to-end CDx service

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Wide Platform Range:
- Affymetrix and Illumina microarrays
- qPCR
- Sequencing
- Proprietary Invader® Chemistry
- Panther® System

Applications:
- Gene expression
- Genotyping
- Methylation
- miRNA
- Copy number variation
- Custom assays

Biomarker Discovery and Verification Services
Product Definition and Planning Services
Validation Services
Tepnel as the Partner of Choice

- Hologic is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products.

- Tepnel Pharma Services is the Contract Research Organisation (CRO) arm of Hologic Inc.

- Hologic has developed a full range of best-in-class testing solutions across a range of healthcare scenarios.

- Hologic’s innovative assays and advanced automation platforms work together to give laboratories the power to quickly and accurately screen and detect disease.

- Tepnel Pharma Services’ companion diagnostic development service coupled with Hologic’s expertise in the diagnostic industry, provides a service platform that supports each phase of development initiatives.