



Assay Development Services

From Biomarker to Product



Biotech Startup and University Spin-off Companies

Are you a biotech startup or university spin-off company and you want to transform your biomarker or concept assay into a product that is ready for the CE/IVD market or FDA approval? Have you thought about the steps that are required to get to this point? Do you have the experience and/or the resources to make this conversion?

Concept assays

Great concept assays and newly found biomarkers can come from anywhere, but especially startups come up with new innovative ideas to eventually improve patient health. Although startups staff has a strong scientific background; feedback and advise from experienced biotech companies can be valuable to create an actual product from a great concept assay.

Our services

Future Diagnostics Solutions supports startups to get their concept assay to an IVD product that is ready for the CE-IVD market or even FDA approved. In some cases, a Research Use Only (RUO) product is developed, for commercialization, as intermediate for the CE/FDA approved product.

With more than 20 years of experience and over 50 highly experienced employees, we are dedicated to make your development successful.

www.future-diagnostics.com



The Extension
of Your
Internal R&D

Future Diagnostics Solutions BV offers services for the development and manufacturing of IVD (immuno) assays to IVD multinationals, mid-sized biotech and small start-up companies within the global medical diagnostics and device industry. Since 1997, more than 150 products are developed in accordance with IVD requirements and regulations (ISO13485/ FDA/cGMP). The profound experience makes Future Diagnostics a trusted partner for assay development of any type of assay, with any type of technology on any type of analyzer.



Point of Care

With many years of experience in quantitative POC test developments on whole blood, using dry chemistry and short assay times, we are the obvious choice to bring the lab to the patient.



Immunoassays

Future Diagnostics develops high quality IVD immunoassays on demand and offers flexible support plus advice in feasibility, optimization, verification and validation projects, including technical transfer to manufacturing for third parties.



Pre-Feasibility

Pre-feasibility studies are of great value if the development of a specific assay is under consideration. Preliminary experiments are run with available raw materials to determine whether it is worthwhile to proceed to the feasibility phase.



Validation

We provide documented evidence to show that predetermined assay requirements are consistently met. By performing validation studies according to the CLSI guidelines these specified requirements are confirmed.



(Free) Vitamin D

With a patent on the measurements of FREE 25-OH Vitamin D in blood, Future Diagnostics is leading the market with this new Vitamin D application. Furthermore we have a vast experience in Vitamin-D assay developments, either on automated platforms or manual formats.



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