



# Pre-Feasibility Studies

Kick-start your way into the IVD World



## Thinking about entering the IVD market? Or planning to expand?

Future Diagnostics performs pre-feasibility studies for third parties within the global medical technology and IVD market. These pre-feasibility studies can be performed on different types of raw materials or assays. It can also be done on a variety of technologies and analyzers, both immunologically or molecular based. We give a first indication of the performance of key raw materials or assays / technologies / analyzers.

### Is your idea feasible?

Pre-feasibility studies give a rough estimation of specificity, sensitivity, stability, background, the critical components, or whether it is basically a good-working assay suitable for the IVD market. In short: our pre-feasibility studies give a first indication on whether your assay is feasible. They give insight into the technical risks and timelines before the decision to move forward to the next step is made.

### Are your key raw materials feasible?

An example of pre-feasibility studies on key raw materials is a bead evaluation project. We demonstrate the impact of beads on signal quenching, but this can also be done for antibodies, conjugates or buffers.

### Risks & Costs

Eventually we share our advice on what the (technical) risks are and give an estimation on how much time further development will take, including a reasonable accurate budget estimation.



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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