



Analytical Performance Services

compliant to the new European IVDR



Have you heard? The IVDD is replaced by the IVDR

Future Diagnostics offers analytical performance services to IVD (immuno) assay manufacturers for a seamless transition to the new IVD Regulation (IVDR). Before starting the actual studies, it is important to assess the status of the current technical documentation. We give our customers customized advise by performing an assessment on the current technical documentation before starting with the analytical performance studies.

How we work

Assessment

Review current technical documentation



Advise

Determine needed additional studies



Perform

Perform additional analytical performance studies



Deliver

Deliver data reports IVDR registration

Why outsource to Future Diagnostics?

- Future Diagnostics is EN-ISO 13485 certified
- The studies are designed to be compliant with the needed harmonized standards, such as EN 13612:2002, EN 23640:2015 and applicable CLSI guidelines
- We advise you beforehand what needs to be done
- You know that your products will be compliant to the new IVDR on time
- Your team stays focused on their regular activities
- We give you peace of mind





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.



Assay Development

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.



Analytical Performance

We offer analytical performance services to IVD (immuno) assay manufacturers for a seamless transition to the new IVD Regulation.



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.



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.



(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.



Nieuweweg 279
6603 BN Wijchen,
The Netherlands

Contact us at:

phone: +31 (0)24 64 52 900
info@future-diagnostics.nl

www.future-diagnostics.com

