
future
diagnostics
THE OBVIOUS
CHOICE FOR
IVD ASSAY DEVELOPMENT

ISO 13485 Quality Management System

FDA registered Manufacturing Facility

BSL Laboratory Capabilities

Four-phase Product Development Process

Independent Company, since 1997

Based in Wijchen (Nijmegen), NL

Internationally oriented

3500 m^2 facility

150+ IVD developments

80+ professionals

Company owned instruments
such as CLIA analyzers and dispensing systems for spotting

20+ years of
development experience on Point-of-Care

Effective working methods
to achieve better and faster results

25+ years of experience
of developments on a large variety of instruments and technologies

CORE VALUES

We are not afraid to try something new, and we like to innovate and discover things that lead to progress

- Open & Transparent
  - Real Time SharePoint environment
- Driven
- Flexible
- Integrity

NEW PRODUCT DEVELOPMENT PROCESS

By working with our proven **step-by-step** approach we control every single part of the product development process.

To increase our efficiency in all these steps, we implement the **agile working** method.

Phase 0:
Contract & Definition

Phase 1:
Proof of Concept & Feasibility

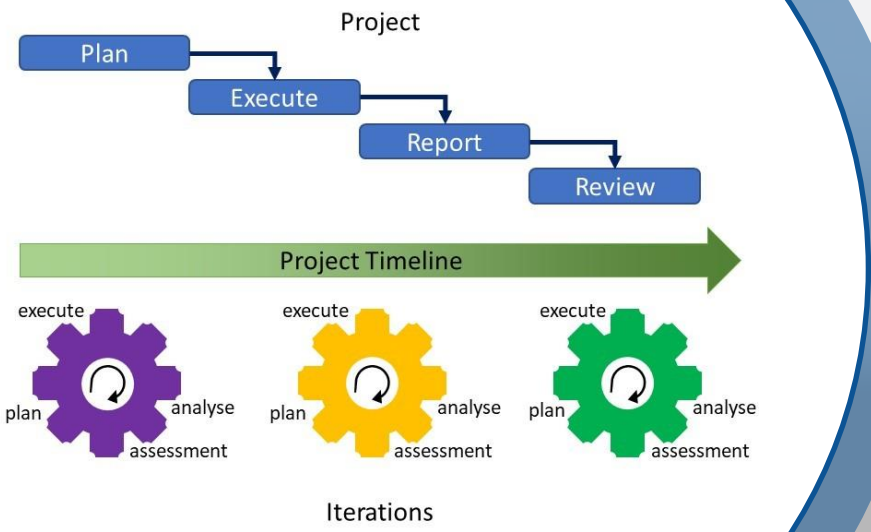
Phase 2:
Design & Verification

Phase 3:
Production & Validation

Phase 4:
Project Closure

AGILE WORKING

- Focus on risks
- Identify potential challenges earlier
- Make changes faster
- Progress is measurable and transparant



PROJECT TRIANGLE

Depending on the parameters that we monitor via the agile working method, we can discuss with clients at an early stage about adjusting Scope, Budget or Timelines as soon as the quality is insufficient.

PROJECT MANAGEMENT

We have equal attention
for Product and Project quality.

TECHNICAL ARCHITECT

Focuses on the quality and technical challenges to ensure the results meet and exceed the agreed specifications.

DELIVERY MANAGER

Focus on deliverables, budget timelines, resources and communication to ensure your project runs smoothly.

MANUFACTURING EXPERT

Focus on implementation of the manufacturing processes within the project.

QUALITY EXPERTS

Focus on compliance with IVD legislation and regulations for quality control.


Certificate of Approval

This is to certify that the Management System of:

Future Diagnostics Solutions B.V.

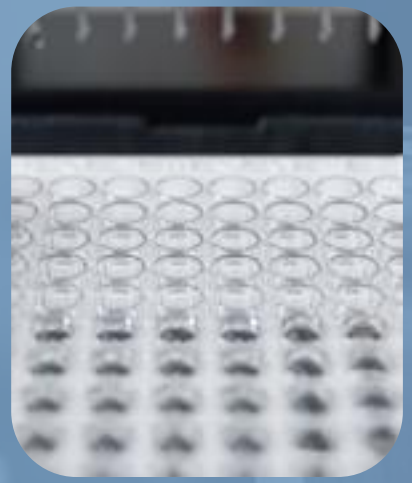
Nieuweweg 279, 6603 BN Wijchen, Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

- **ISO13485:2016** Quality Management System
- **FDA** registered manufacturing facility
- Usage of applicable **CLSI Guidelines**
- **Harmonized standards** such as EN ISO 13612:2002 and EN ISO23640:2015

IVD Product Development for automated use



IVD Product Development for manual use

Multiplex Micro-Array

Point-of-Care Test

Companion Diagnostics

IVDR Analytical Performance studies

Verification, Validation & Stability studies

Conjugation

Accuspheres

Manufacturing

DEVELOPMENT SERVICES

We are a trusted partner for the development of many different types of immunoassays with different technologies, either manually or on automated platforms.

- Colorimetric Assay (ELISA, EIA)
- Fluorescent Assay
- Chemiluminescent Assay (CLIA)
- Multiplex Micro-Array
- Point of Care Test
- Turbidimetric Assay

AREAS OF EXPERIENCE

- Bone Metabolism
- Infectious Disease
- Tumor Markers
- Fertility
- Diabetes
- Thyroid
- Cardiovascular

- Coagulation
- Endocrine
- Autoimmune
- Veterinary
- Anemia
- Growth
- TBI

COMPANION DIAGNOSTICS

- identify patients who most likely benefit from a therapeutic product
- identify patients likely to be at increased risk for serious side effects as a result of treatment with a therapeutic product
- monitor response to treatment with a therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness.

CLINICAL EVIDENCE CONSISTS OUT OF:

SCIENTIFIC VALIDITY

means the association of an analyte to a clinical condition or a physiological state.

ANALYTICAL PERFORMANCE

means the ability of a device to correctly detect and measure a particular analyte.

CLINICAL PERFORMANCE

means the ability of a device to produce results in accordance with a particular clinical condition in the defined population.

The One-Stop-Shop means, that Future Diagnostics organizes the total clinical evidence (scientific validity, analytical and clinical performance) for you.

Therefore we work with **PARTNERS**, who are reliable and use the same high quality standards as we do.

QARAD

is a consulting company, specialized in Regulatory Affairs and Quality Systems offering **scientific validity services**.

FUTURE DIAGNOSTICS

offers **analytical performance** services to ensure a smooth transition from the IVDD to the IVDR.

IN.VENT

is an independent company providing **clinical performance studies** and human biomaterials

SMALL SCALE ON-SITE MANUFACTURING SERVICES

- Assembly of (immuno) assays (50-500 kits per batch)
- Bulk production of e.g. buffers, coated beads, conjugates
- Small scale bead & Microtiter Plate coating
- Lyophilization of kit components (capacity of 1.5 m2, 20 lt. of liquid)
- Accusphere lyophilization & production technology
- Product filling, capping and labeling

BENEFITS

- Documentation and labeling in your format
- Smooth transition from R&D to MFG
- Products readily available for clinical trials

CONJUGATION

We link a specific label (tag) to an antibody, antigen, or any other protein.

Examples of these labels are:

- Iso-Luminol
- Horseradish Peroxidase
- Acridinium Ester
- Alkaline Phosphatase
- Biotin
- Paramagnetic or none paramagnetic particles

STABILIZE YOUR BIOMOLECULE WITH ACCUSPHERES

A combination of a suitable matrix with the component of interest, dripped into liquid nitrogen and freeze dried, forms a stable 50 µl sphere.

ADVANTAGES

- Stabilization of your biomolecule
- Reduction assay turnaround time (e.g. ELISA)
- Ease of handling
- Less incubation steps
- Thermal protective characteristics

Meet us at the following events, we would appreciate to meet you and have the opportunity to answer all your questions.

MEDLAB

AACC
Better health through laboratory medicine.

MEDICA®

OUR CLIENTS


BIOMÉRIEUX
BIOCARTIS
arCell
BANYAN BIOMARKERS
TOSOH
Stago
Volition
bioeq
ids
immunodiagnosticsystems
MyCartis
Collaborate to innovate
sysmex
Janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson
aptec
Diagnostics nv
Ortho
Clinical Diagnostics
PHILIPS
Agilent
Abbott
Canon
CANON MEDICAL SYSTEMS
DSM
BIOVICA
TECAN.
SIEMENS
DIA Source
IDEXX
NOVARTIS
BIO-RAD
BECKMAN COULTER
BGMEDICINE

Claudia Strehle

Working with Future Diagnostics was / is an excellent experience […]successful diagnostic system developments (Assay, disposable, instrument) providing optimal solutions […]

Nicolas Heureux

We have been working with Future Diagnostics Solutions on various projects [...] The collaboration has always gone very smoothly with active and transparent communication. […] I definitely recommend Future Diagnostics as a partner of choice!

Juan Diaz

[…] Agilent has worked with Future Diagnostics Solutions in different projects […] They have a large experience developing these assays and together with their knowledge on multiple automated platforms and the IVD regulation make them the perfect partner to start or speed up any development of an assay […]

In.vent Clinical Services

Future Diagnostics is an excellent provider of development and validation services in the diagnostics sector […] we had the pleasure to discover their modern and efficiently designed main building including an impressive laboratory […]

FOR MORE REVIEWS VISIT GOOGLE

future diagnostics

THANK YOU!

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