FUTURE DIAGNOSTICS

# Enabling optimal healthcare

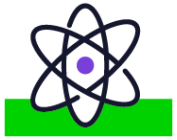
Company Profile

FDx

# About us

- Independent Company, since 1997
- Based in Wijchen (Nijmegen), NL
- Internationally oriented
- ISO 13485 Quality Management System
- FDA registered Manufacturing Facility
- BSL Laboratory Capabilities
- Four-phase Product Development Process
- 3500 m² facility

# Highlights



**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

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

# Distinction

- Multiskilled and passionate professionals
- Fully committed
- Customers are considered as a partner
- Several different company owned analyzers

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

# Quality standards

- **ISO13485:2016** Quality Management System
- **FDA** registered manufacturing facility
- Usage of applicable **CLSI Guidelines**
- **Harmonized standard** such as EN ISO 13612:200 and EN ISO23640:2015


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

# How we work

**New product development process**

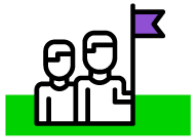
By working with our proven step-by-step approach we control every single part of the product development process. To increase our efficiency in all these steps, we implement the agile working method.

Phase 0
**Contract & Definition**

Phase 1
**Proof of Concept & Feasibility**

Phase 2
**Design & Verification**

Phase 3
**Production & Validation**



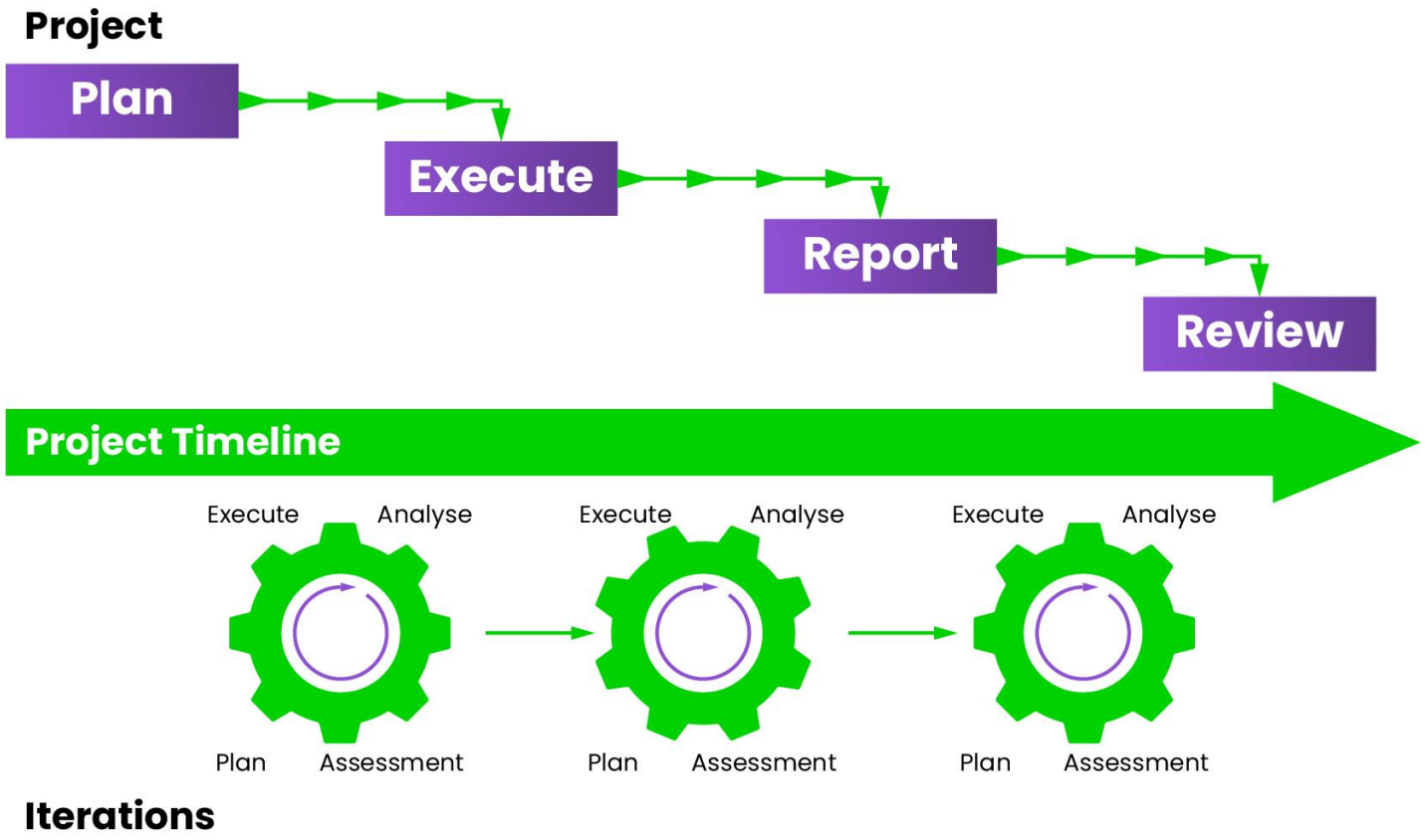
Phase 4
**Project Closure**

# Agile working

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

# Project agile working methode

- Explanation of process



# Project triangle

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

# Projectmanagement

**Technical architect**
Focuses on the quality and technical challenges.

**Manufacturing expert**
Focus on implementation of the manufacturing processes within the project.

**Delivery manager**
Focus on deliverables, budget timelines, resources and communication.

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

# We have equal attention for Product and Project quality

## Our main services

# IVD Product Development for automated use

# Projects

Some examples of development projects:

- Full development of several **Infectious Disease assays (i.e. HIV, HBsAg, HAV, Syphilis, ToRC, etc.)** on different chemiluminescence immuno assay analyzers
- Full development of a 10-multiplex assay for **infectious disease** markers
- Full development of a total **25-OH-Vitamin D** assay on a chemiluminescence immuno assay analyzer
- Full development of a **Cardiac panel (HS-cTnI, BNP and NT-proBNP)** on a Point of Care device
- Full development of an **Intact-PTH assay** on different chemiluminescence immuno assay analyzers
- Full development of several **Immuno assays (i.e. DHEAs, SHBG, D-Dimer, cPeptide, etc.)** on different chemiluminescence immuno assay analyzers

## Our main services

# IVD Product Development for manual use

# Projects

Some examples of development projects:

- Proof of concept study of an ELISA for the measurement of **DHD**
- Proof of concept and feasibility study for the development of an **anti-JCV antibody** ELISA test
- Full development and manufacturing of an ELISA against the **tumor marker TK-210**
- Full development and manufacturing of an ELISA against **Free 25-OH-Vitamin-D**

## Our main services

# Analytical Performance Studies (V&V)

# Clinical Evidence

**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** results in accordance with a particular clinical condition in the defined population.

# Projects

Some examples of analytical performance studies:

- Re-validation of 25 Elisa and 25 automated assays according to the new IVDR
- Interference studies on 10 new developed assays for an automated system
- On-board stability and precision study on 36 different assays on an automated system
- Total analytical performance studies on 17 assays on a newly developed platform
- Analytical Performance studies for IVD-R compliancy on 24 assays on an automated platform
- Analytical Performance studies for several multiplex assays on an automated LC-MS platform

# One-stop-shop

The One-Stop-Shop means, that Future Diagnostics organizes the total clinical evidence (scientific validity, analytical and clinical performance) and the sample sourcing for you. Therefore we work with PARTNERS, who are reliable and use the same high quality standards as we do.

# Technologies

**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)
- Fluorescence Assay
- Chemiluminescence immuno 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

# Company owned Analyzers

**We offer the possibility to perform correlation studies between different platforms with standard reagents, but we can also conduct pilot studies on the automated platforms using reagents under development and study their behavior in these systems.**

- Abbott Architect
- Abbott Alinity
- Beckman Coulter Dxl 600
- Beckman Coulter AU680
- Scienion S12, blocking tool, Sci reader
- Dynex DS2

# Manufacturing services

**Small scale on-site manufacturing services**

- Assembly of (immuno) assays (50-500 kits per batch)
- Bulk production of e.g. buffers, coated beads, conjugates, calibrators
- Small scale bead coating & 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

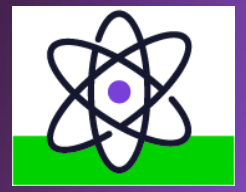
**Benefits**

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

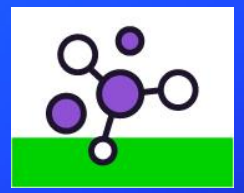
# Additional services

Stability studies

Lyophilisation



Accuspheres



Conjugations

Comparison Studies

# Lyophilization »

Development of optimal lyophilization cycles that are robust and reproducible. We identify the appropriate process parameters for various assay components.

- Buffers
- Enzymes
- Antibodies
- Conjugates
- Calibrators
- Magnetic Beads

# Conjugation ››

Our extensive knowledge of IVD assay development enables us to select the most optimal procedures for conjugation and meet customer expectations.

- Antibody/protein-enzyme conjugations
- Biotinylation of antibodies/proteins
- Antibody/protein-chemiluminescent labeling
- (Covalent) coatings of solid phases
  - Magnetic particles
  - Glass slides
  - Microtiter plates
- Preparation of immunogens


# Bead Coating »

To increase overall performance, we ensure that the antibody or antigen is delivered to the specific type of activated beads in a conformation that provides the best activity for the protein of interest.

# Accuspheres

**Stabilize your biomolecule with accuspheres**

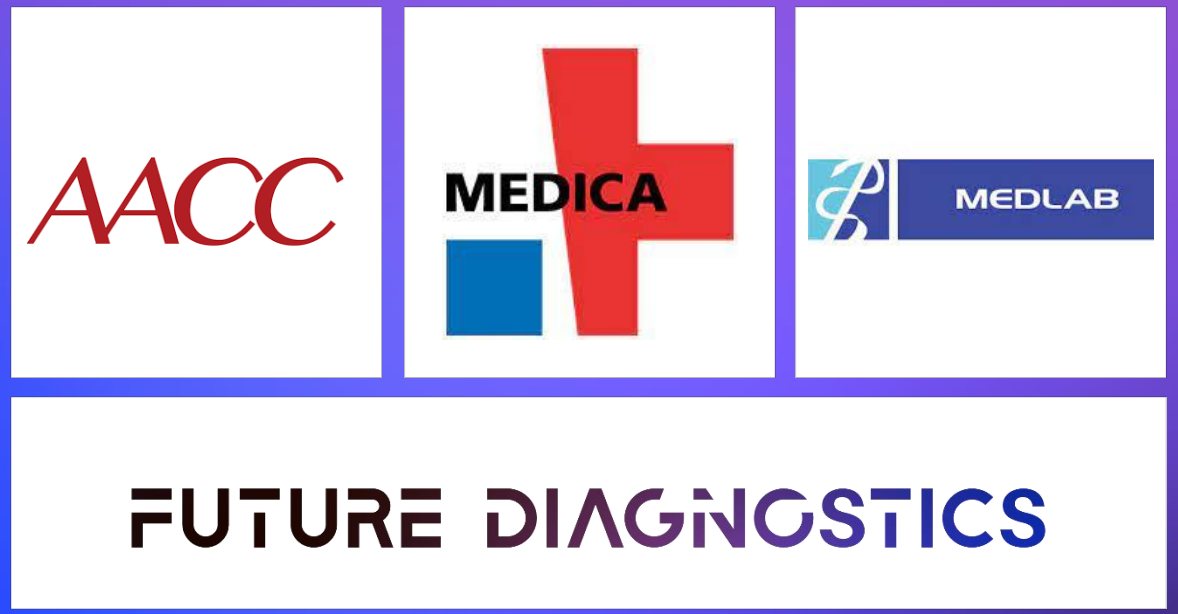
A combination of a suitable matrix with the component of interest, dripped into liquid nitrogen and freeze-dried, forms a stable 50 µl sphere.

**Advantages**

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

# Meet us

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



# Our customers

# This is what our customers say:

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

**– Claudia Strehle**

LRE Medical

[…] 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 […]

**– Juan Diaz**

Agilent



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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!

**- Nicolas Heureux**

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.

**- In.vent Clinical Services**

**FOR MORE REVIEWS VISIT GOOGLE**

www.future-diagnostics.com