

# HumaFIA

## Accurate results on-the-spot

- > Very high sensitivity due to time-resolved fluorescence immunoassay technology
- > Workflow management for multi-throughput
- > One platform for a large range of parameters

FIA



**Human**

Diagnostics Worldwide



# On-the-spot testing

## Why is there an increasing demand for on-the-spot-testing?

The reasons for the increasing demand are the aging of the population and an unhealthy lifestyle. Both aspects result in an increasing demand for cardiac markers, chronic disease management and the control of related inflammations. Appropriate therapies require accurate and timely diagnoses. Methods reducing pre-analytics and avoiding sample transport to a central lab allow for faster patient management.

**On-the-spot testing – fast results on easy-to-use analyzers**



## Where is on-the-spot testing needed?

Solutions require easy-to-use devices, preferably working with whole blood, that provide results within minutes. This is needed in emergency centers in cases of chest pain or cardiac distress, but also in health care posts, physicians' offices and hospital wards.

In more remote areas, this principle is inherent. Here, the prompt initiation of therapy based on a diagnostic result is of even greater importance. Patients who travel long distances to a health post must get the diagnosis on the day of their visit.

**On-the-spot testing - diagnostics carried out where the patient is without the need to transport samples**

## Can on-the-spot testing provide accurate results?

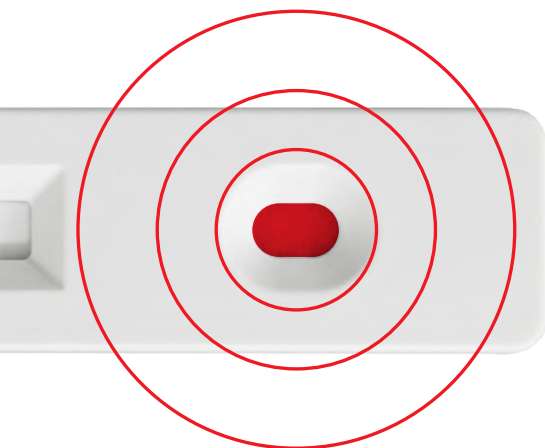
Yes, the new time-resolved immunoassay technology is comparable to a chemiluminescence assay, but available via small, handheld devices.

**On-the-spot results – an attractive alternative**

## Is a single test cartridge cost-efficient?

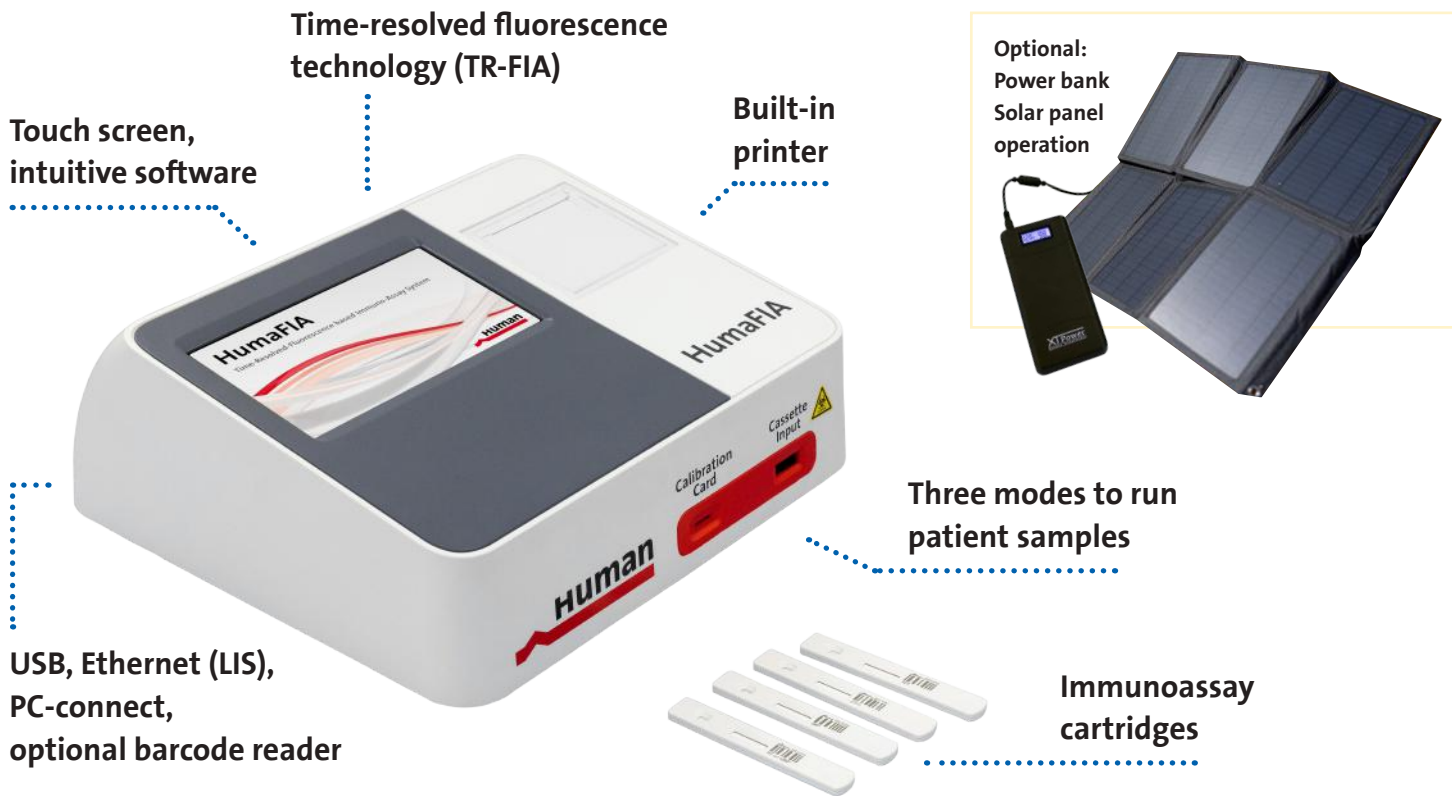
Contrary to the common belief that cartridge-based tests are expensive, there are actually significant cost advantages when taking into account the high initial cost of large analyzers, maintenance and depreciation. But the biggest advantage of cartridge-based assays is efficiency: there are no left-over reagents to be disposed of when the throughput is low and the open-vial stability has expired.

**You pay only for what you need!**



# HumaFIA

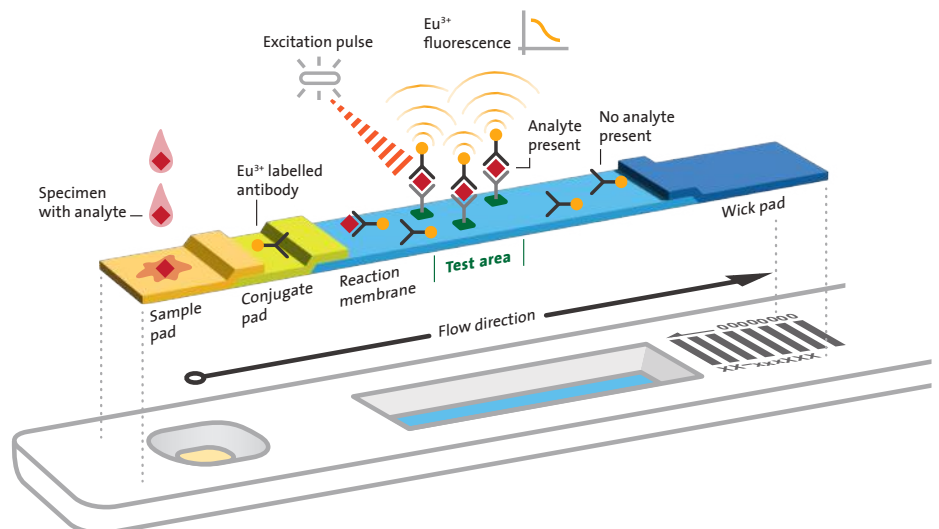
## Semi-automated fluorescence immunoassay system



## Fluorescence immunoassays

Immunoassays are very **specific**, by selection of the analyte with a perfectly matching antibody, and very **sensitive**, as the antibody is labeled by the superior europium fluorochrome, which is **quantitatively** captured in the test area for TR-FIA measurement.

- > **Ready-to-use dry, stable reagents** allow for easy storage and transportation at a wide temperature range (4–30°C).
- > **Whole blood** without sample pre-treatment; alternative use of serum or plasma is possible.
- > **Fewer manual steps**, no buffer needed on most tests.



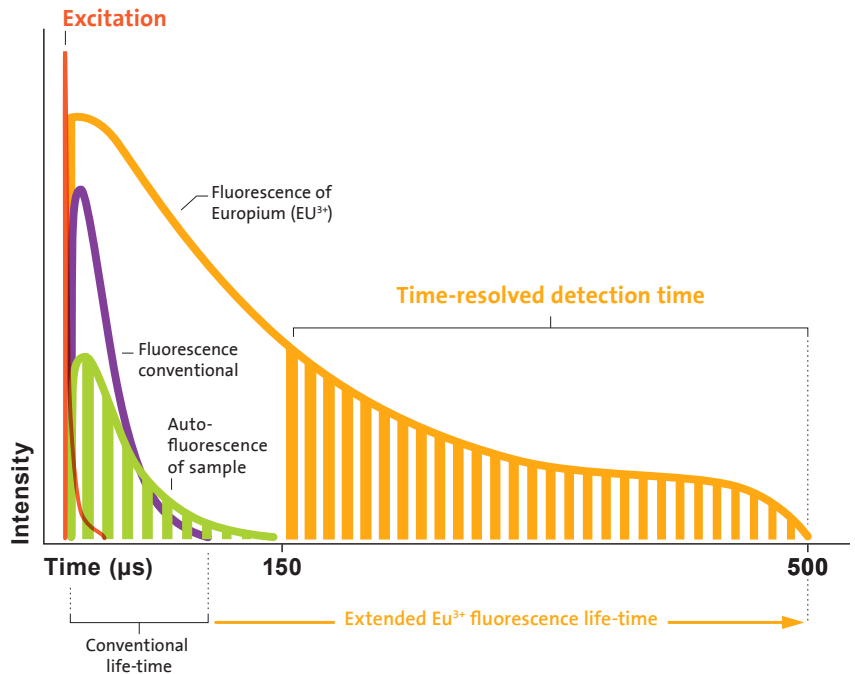
# Time-resolved technology (TR-FIA)

The time-resolved fluorescence immunoassay are comparable to chemiluminescence assays. Fluorescence of europium  $\text{Eu}^{3+}$  chelates supports new strategies to avoid background noise.

Autofluorescence emission occurs immediately after the excitation pulse, which is when conventional fluorescent dyes emit. In conventional methods, autofluorescence always contributes to background noise.

$\text{Eu}^{3+}$  shows an extended fluorescence lifetime. During the prolonged fluorescence, autofluorescence has already completely decayed. This enables very sensitive tests with a low limit of detection (LOD), also in whole blood samples containing auto-fluorescent red blood cells.

Fast reading – one fluorescence cycle requires only 0.5ms.



## Highlights of HumaFIA

### Top features:

- > Excellent usability thanks to automatic sample-type recognition
- > Auto quality check with incubation monitoring and LOT verification
- > Work-flow management allows a test to be run every 20 seconds.
- > Auto pre-dilution factor to extend the measuring range
- > Easy testing by using whole blood, serum or plasma
- > Lab-free calibration by sample-type specific calibration on card

### Three modes to run patient samples



#### Standard sample

Automatic reading after incubation inside analyzer

One Test every 1.5 to 15 min. parameter-dependent



#### Fast sample

Automatic incubation start/stop timing, by work-flow management

One test every 20 seconds.



#### STAT sample

Flexible testing, incubation outside

Reading <3 sec.



Incubation time check Quality Check Incubation temperature monitoring

# One platform – many parameters

Various biomarkers for cardiac, inflammatory or autoimmune diseases are available on the HumaFIA platform.

Highlights: The linearity range of Troponin I starts at 0.02 ng/ml, which underlines its high sensitivity.

The incubation time of only 1.5 minutes for CRP is exceptionally short.

Parameter <sup>(25 tests)</sup>	REF	Linearity	Time to result	Indication
Troponin I	16090/35	0.02–40 ng/ml	15 min.	Cardiac, acute myocardial infarction
Troponin I / Myo / CK-MP	16090/75*	0.02–40 ng/ml 5–800 ng/ml 1–200 ng/ml	15 min.	Cardiac, acute myocardial infarction
NT-proBNP	16090/30**	100–20,000 pg/ml	15 min.	Cardiac, heart failure
D-Dimer	16090/50*	20–4,400 ng/ml	15 min.	Coagulation, Cardiac
CRP	16090/20	0.5–200 mg/l	1.5 min.	Inflammation, Rheumatoid
PCT	16090/25	0.05–50 ng/ml	12 min.	Sepsis, Inflammation
IL-6	16090/70*	3–4,000 pg/ml	15 min.	Sepsis, Inflammation
Vitamin-D	16090/55*	5–100 ng/ml	6+15 min.	Bone Marker

> Reliability, accuracy and precision at clinical thresholds

## Be ready for accreditation, run daily controls

	REF
Troponin I	16090/36**
Myo	16090/91*
CK-MP	16090/96*
NT-proBNP	16090/31**
D-Dimer	16090/51*
CRP	16090/21**
PCT	16090/26**
IL-6	16090/71*
Vitamin-D	16090/56*



\*in development \*\* coming soon

# HumaFIA

## Specifications and ordering information

Product	Description	REF	
HumaFIA	Multi-language Display Dimensions Weight Connectivity Data storage Environment Power	EN, (ES, FR soon), more on demand 7" 450×380×220mm (WxDxH) 4.2kg 4 USB, LAN LIS bi-directional, RS-232 with PC-connect 10,000 results Operating 18–28°C 20–90% rel. hum. non-condensing, air pressure 86–106kPa 100–240V, 50/60Hz, 1.5A max. / 12V, 4A max	16090
Standard Cartridge	Service tool	5-level optical system check	16090/510
Printer paper	5 rolls	57×45mm, 25m each	18144/5
Power Bank	73Wh	20,010mAh	18250/70
Solar Panel	36W	USB connection, 86×62cm (open)	18250/73



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# Human

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HUMAN Gesellschaft für Biochemica und Diagnostica mbH  
Max-Planck-Ring 21 · 65205 Wiesbaden · Germany  
Tel. +49 6122-9988-0 · Fax +49 6122-9988-100 · e-mail: human@human.de · www.human.de