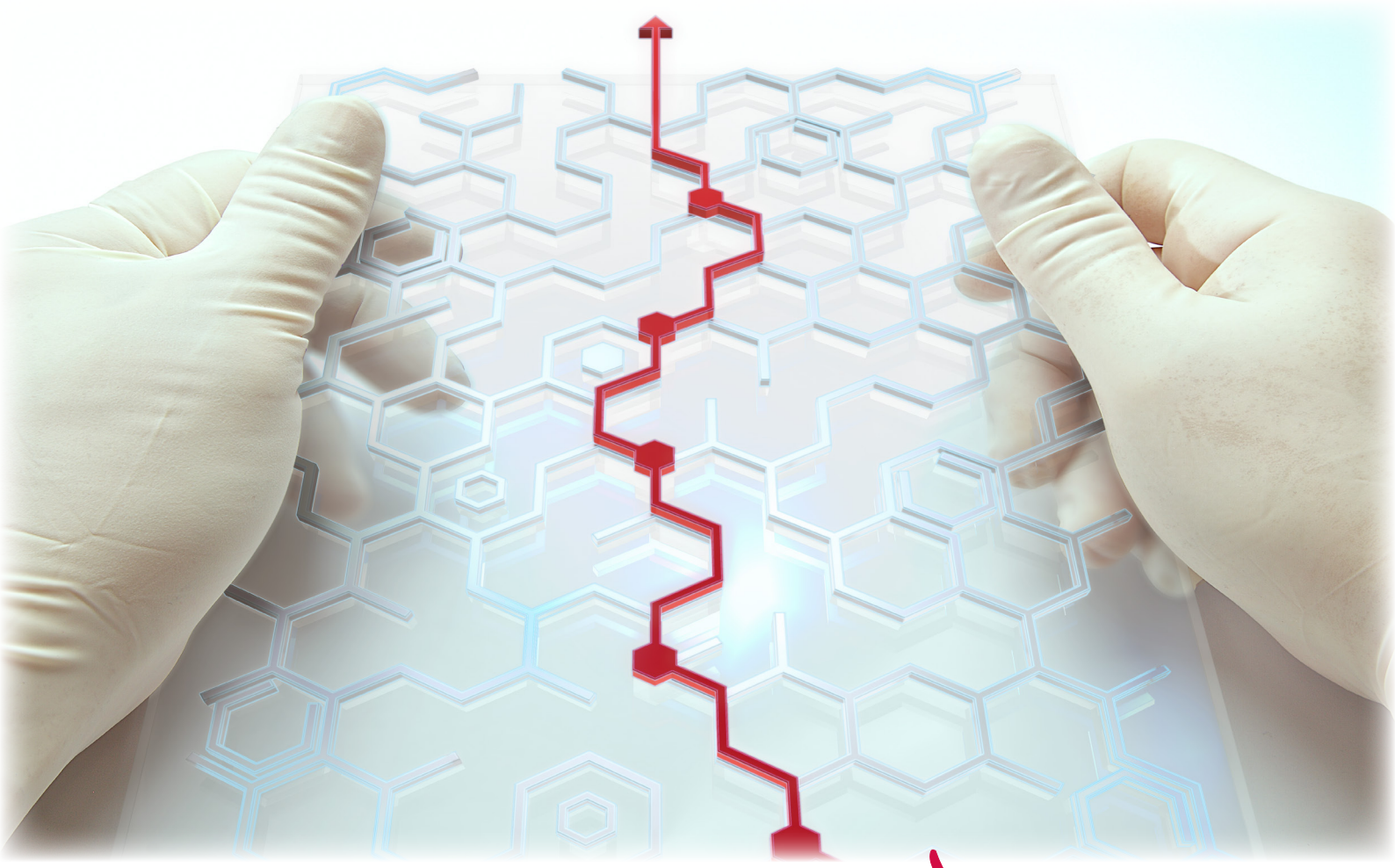

i-Tracker

High performance TDM assays for biologics

- Innovative CLIA technology
- Short turnaround time
- Validated on princeps and biosimilars
- Calibrated against WHO international standards

Theradiag
INNOVATION FOR BIOTHERAPIES

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i-Tracker

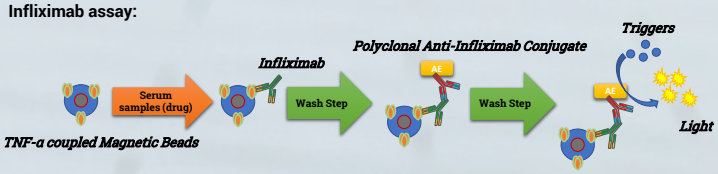
ACHIEVING EXCELLENCE IN THERAPEUTIC DRUG MONITORING

Therapeutic Drug Monitoring (TDM) of biologics entails the measurement of drug and anti-drug antibody concentrations, with subsequent possible dose adjustment to ensure optimized dosing for the patient. With its high performance and short turn around time, i-Tracker CLIA kits in combination with i-Track[10] random-access analyzer enable the clinician to take therapeutic decision in a timely manner. In giving access to rapid treatment adjustments, i-Tracker assays contribute to improve overall clinical outcomes for the patients while minimizing the cost of treatment.

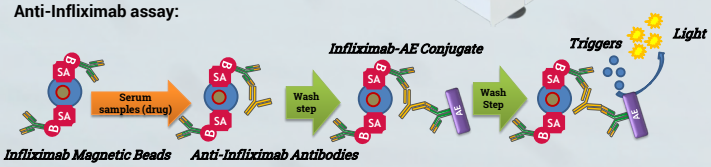
High Performance assays to achieve excellence

- Innovative CLIA technology
- Quantitative measurement of drug and anti-drug antibodies
- First results in less than 35 minutes, 60 results/hour
- Full compatibility with i-Track[10] random-access analyzer
- Standardization according to the NIBSC/WHO Infliximab (#16/170) and Adalimumab (#17/236) International standards
- Validated on princeps and biosimilars
- Controls and calibrators included

Infliximab assay:



Anti-Infliximab assay:



Serum samples are diluted and added to the coated magnetic beads suspension. Analytes are detected using an Ester Acridinium conjugate (AE). Relative Light Emissions (RLU) are detected and quantified by i-Track[10] chemiluminescent analyzer.

Measurement range			
Infliximab	0.3-24 µg/mL	Anti-Infliximab	10-2000 ng/mL
Adalimumab	0.5-24 µg/mL	Anti-Adalimumab	10-2000 ng/mL
Vedolizumab	1-60 µg/mL	Anti-Vedolizumab	10-2000 ng/mL
Ustekinumab	100-10000 ng/mL	Anti-Ustekinumab	1-250 UA/mL
Golimumab	0.3-8 µg/mL	Anti-Golimumab	10-2000 ng/mL
Rituximab	0.3-60 µg/mL	Anti-Rituximab	5-2000 ng/mL
Certolizumab Pegol	3-100 µg/mL	Anti-Certolizumab Pegol	10-1500 UA/mL

i-Tracker

Reference	Designation	Packaging
CTx 002-50/100	i-Tracker Drug	50 / 100 tests
CTx 003-50/100	i-Tracker Anti-Drug	50 / 100 tests

x = Infliximab 100 tests / Adalimumab 100 tests / Vedolizumab 50 tests / Ustekinumab 50 tests / Golimumab 50 tests / Rituximab 50 tests / Certolizumab Pegol 50 tests (Etanercept 50 tests, Tocilizumab 50 tests, Risankizumab 50 tests, Natalizumab 50 tests et Ocrelizumab 50 tests: in development)

i-Tracker Infliximab validated on Infliximab princeps Remicade® and Infliximab biosimilars SB2 (Flixabi®) and CT-P13 (Remsima® and Inflectra®)
i-Tracker Adalimumab Validated on Adalimumab princeps Humira® and Adalimumab biosimilars ABP 501 (Amgevita®) and SB5 (Imraldi®)

IMMUNO-TROL Internal Quality Control

A range of ready-to-use, internal Quality Control sera, CE marked, dedicated to the pharmacological dosage of biotherapies

Reference	Designation	Packaging
CTx 002-PC	Immuno-Trol i-Tracker Drug: Positive control two levels	2 x 500 µl
CTx 003-PC	Immuno-Trol i-Tracker Anti-Drug: Positive control two levels	2 x 1,5 ml

x = Infliximab / Adalimumab / Vedolizumab / Ustekinumab / Golimumab / Rituximab / Certolizumab Pegol (Etanercept, Tocilizumab, Risankizumab, Natalizumab et Ocrelizumab: in development)

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Read carrefully the instruction for use of the product insert before use. Pictures may differ from actual products.

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