

## i-Tracker%

## High performance TDM assays for biologics



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





## 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<sup>10</sup> 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<sup>10</sup> 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





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<sup>10</sup> 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	0.3-50 μg/mL	Anti-Rituximab	5-2000 ng/mL



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

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®)



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



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