

# i-Tracker

***High performance TDM assays for biologics***



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

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.

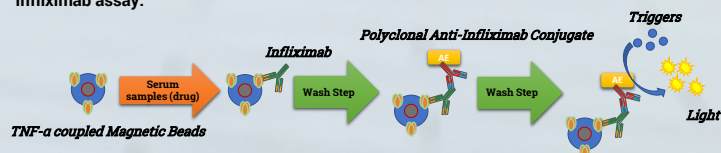


### High Performance assays to achieve excellence

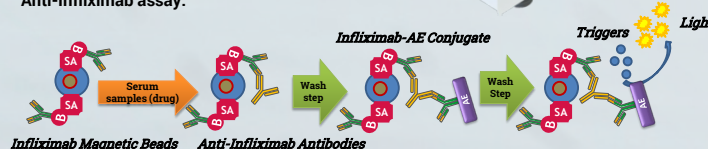
- Innovative CLIA technology
- Quantitative measurement of drug and anti-drug antibodies
- First results in less than 35 minutes, 60 results/hour
- Full compatibility with i-Track<sup>10</sup> random-access analyzer
- Standardization according to the NIBSC/WHO Infliximab (#16/170) and Adalimumab (#17/236)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



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<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  |
| Certolizumab Pegol | 3-100 µg/mL     | Anti-Certolizumab Pegol | 10-1500 UA/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 / 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 carefully the instruction for use of the product insert before use. Pictures may differ from actual products.