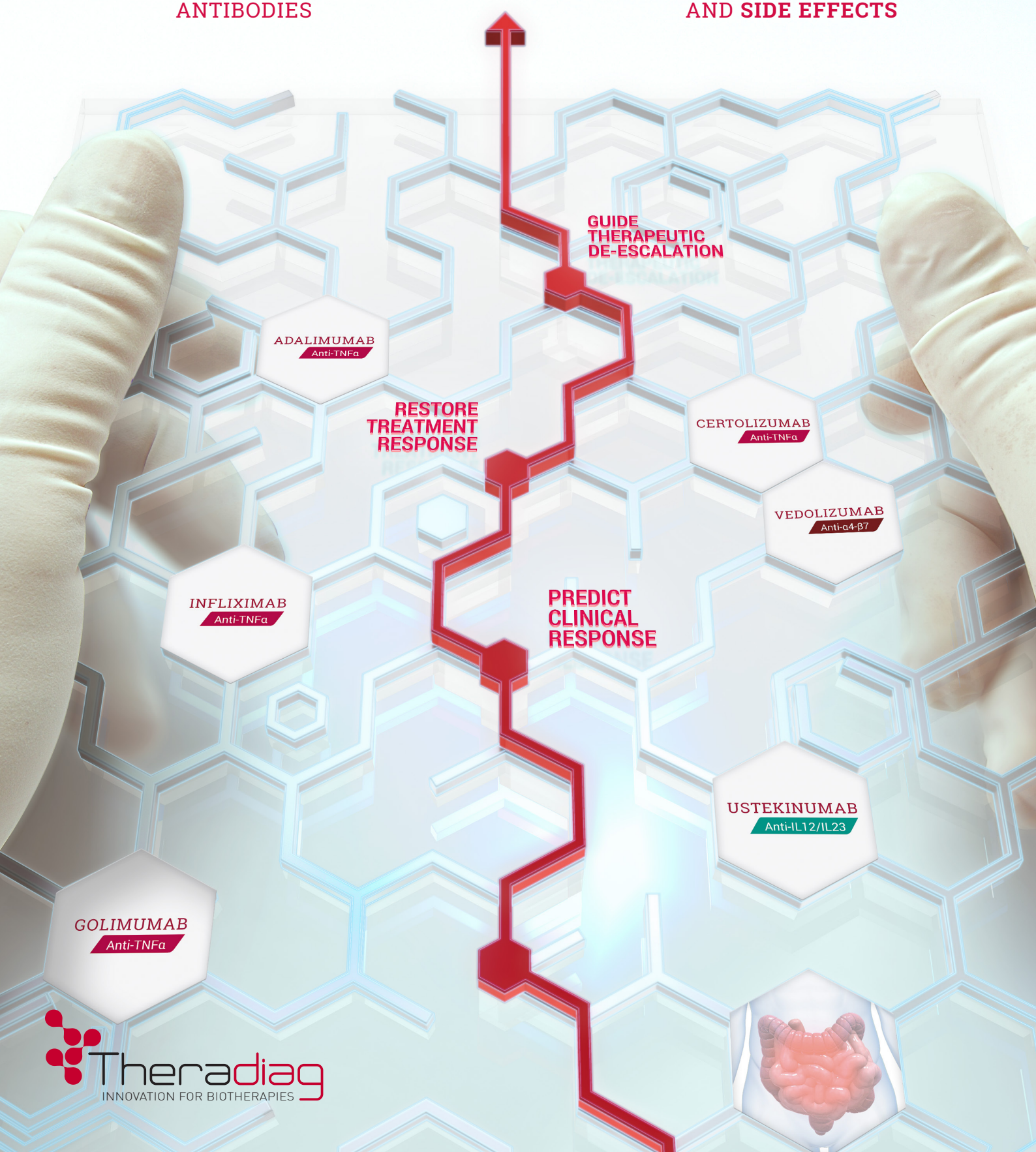
Tracker

THERAPEUTIC DRUG MONITORING IN INFLAMMATORY BOWEL DISEASES

MEASUREMENT OF **BIOLOGICAL DRUG** AND **ANTI-DRUG** ANTIBODIES

EXTEND TREATMENT RESPONSE WHILE **MINIMIZING COSTS** AND **SIDE EFFECTS**



Theradiag
INNOVATION FOR BIOTHERAPIES

Tracker

is your clinical decision-making tool for Inflammatory Bowel Diseases

CLINICALLY RELEVANT

- Numerous publications in peer-reviewed journals
- International decision algorithms validated with Tracker kits

UNIQUE TDM MENU

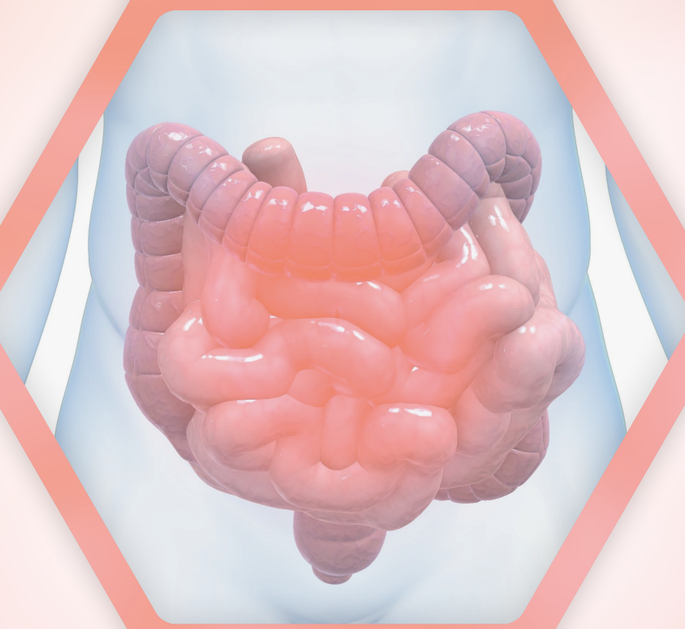
- Comprehensive menu in inflammatory diseases and oncology
- CE-IVD validation on serum and plasma samples
- Validation in accordance with the 1st WHO international standards (Infliximab and Adalimumab)
- Validation with Princeps and Biosimilars
- Continuous development on new parameters

Therapeutic Drug Monitoring (TDM) is a safe method to early measure drug level and detect anti-drug antibodies, guide the therapeutic procedure and optimize treatment efficacy

COST-EFFECTIVE

TDM strategy leads to major cost savings (28 to 50%) related to a biologic treatment[1]

- in Ulcerative Colitis (UC) and Crohn's Disease (CD)
- in patients in remission for treatment de-escalation[2]
- in patients with loss of response[3]



CLINICALLY VALIDATED

- Routine use tailored to your clinical practice
- Measurement ranges tailored to induction and maintenance treatment phases

ACCURATE

- Accurate quantitative measurement of drugs and of free and total anti-drug antibodies
- Detection of free anti-drug antibodies as recommended by international guidelines to fit patient's status
- Performance validated with both Originators and Biosimilars

EASY-TO-USE

- Ready-to-use reagents
- Standardized protocols from sample collection to results interpretation
- ELISA format validated on automated platforms (DS2, DSX, Evolis, etc.)
- CLIA format compatible with i-Track[10], IDS-iSYS and IDS-i10 random access instruments
- Point of Care format for near patient testing
- Validated with IMMUNO-TROL INTERNAL CONTROL

Therapeutic Drug Monitoring (TDM) strategy leads to major cost savings in IBD patients while maintaining appropriate efficacy[1]

Tracker

is a solution validated and supported by pharmaceutical companies to adapt patient treatment

THERAPEUTIC DRUG MONITORING TO IMPROVE CLINICAL OUTCOME AND SUPPORT THE PROPER USE OF DRUGS

NEARLY 20-30%

of patients do not respond to an anti-TNFα treatment[4]

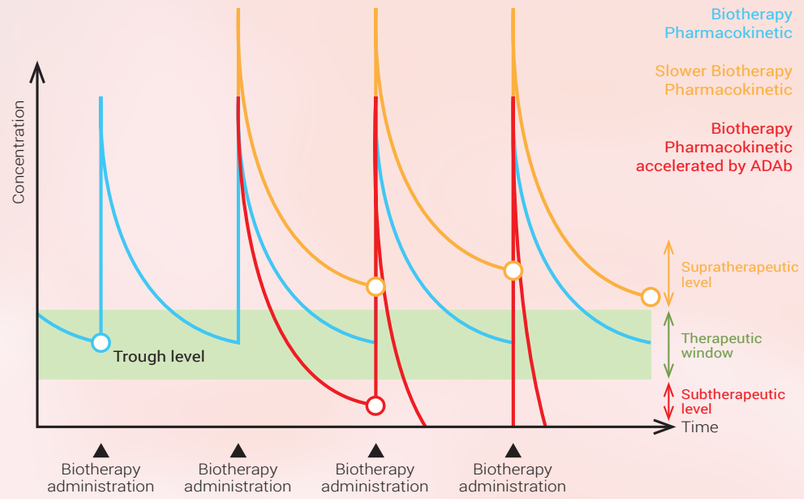
50% OF IBD PATIENTS

experience relapse in disease activity during maintenance therapy[5,6]

Pharmacokinetics and pharmacodynamics of biological therapies are highly variable among patients.

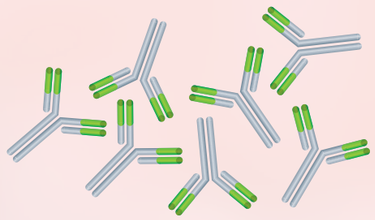
Patients with higher dose of drug or slower pharmacokinetics may have drug trough level above the therapeutic window (supratherapeutic).
Higher trough levels may increase side effects.

Patients with lower dose due to the presence of anti-drug antibodies or with low serum albumin concentration or high baseline CRP concentration may have drug trough levels below the therapeutic window (subtherapeutic), leading to reduced drug efficacy.



Therapeutic Drug Monitoring helps physicians **to make rational treatment decisions during the course of IBD**

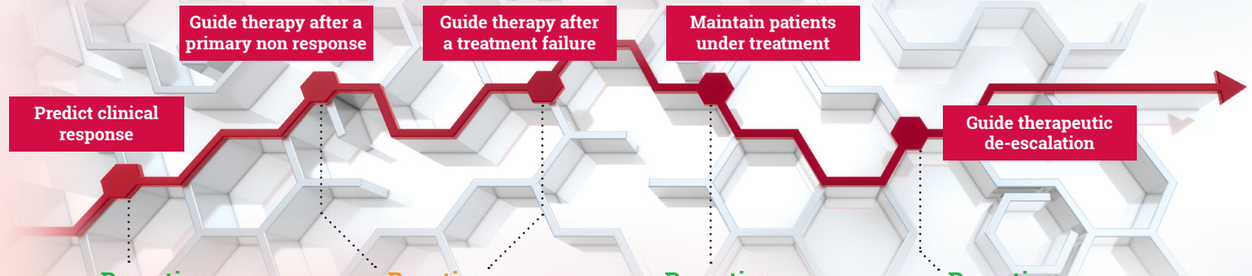
Immunogenicity of Biologics	Crohn's Disease	Ulcerative Colitis
Infliximab & Infliximab Biosimilar (CT-P13)	up to 83%[7]	up to 46%[7]
Adalimumab	up to 35%[7]	up to 5%[7]
Certolizumab Pegol	up to 25%[7]	up to 25%[7]
Vedolizumab	up to 3.7%[7]	up to 3.7%[7]
Ustekinumab	up to 1%[7]	up to 1%[7,9]
Golimumab	-	up to 19%[8]



Anti-drug antibodies rates vary widely among biologics regardless of the disease.

Assessment of the immunogenicity of these agents is an important consideration in the treatment decision making process.

WHEN TO PERFORM TDM?



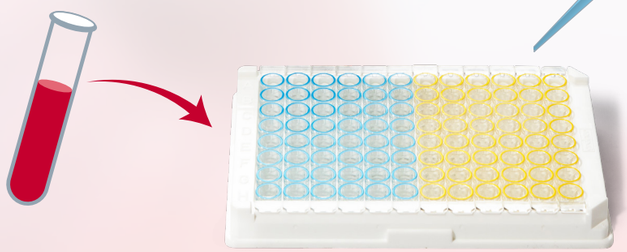
THERAPEUTIC THRESHOLDS[20]

		Induction		Post-induction		Maintenance	
		Reactive	Proactive	Reactive	Proactive	Reactive	Proactive[a]
Infliximab[b]	Recommendation	Consider	Consider	Recommend	Consider	Recommend	Recommend
	Target	Week 2 : 20 - 25 µg/mL Week 6 : 15 - 20 µg/mL		Week 14 : 7 - 10 µg/mL		5 - 10 µg/mL	
Adalimumab	Recommendation	Consider	Consider	Recommend	Consider	Recommend	Recommend
	Target	Week 4 : 8 - 12 µg/mL		Week 12 : 8 - 12 µg/mL		8 - 12 µg/mL	
Golimumab	Recommendation	N/A	N/A	Consider	Consider	Consider	Consider
	Target			3 - 7 µg/mL		1 - 3 µg/mL	
Certolizumab Pegol	Recommendation	N/A	N/A	Consider	Consider	Consider	Consider
	Target			32 - 36 µg/mL		13 - 15 µg/mL	
Vedolizumab[b]	Recommendation	Consider	Consider	Consider	Consider	Consider	Consider
	Target	Week 6 : 33 - 37 µg/mL		Week 14 : 15 - 20 µg/mL		15 - 20 µg/mL	
Ustekinumab	Recommendation	N/A	N/A	Consider	Consider	Consider	Consider
	Target			Week 8 : 3 - 7 µg/mL		1 - 3 µg/mL	

NOTE: Level recommendations are drawn from Cheifetz et al. These are broad targets, often based on limited evidence and, as per the main text, may need to be adjusted depending on disease phenotype and therapeutic goal.
N/A, not applicable due to lack of data
[a]At least once per year.
[b]Intravenous preparation.

WHEN TO COLLECT BLOOD ON PATIENTS?

- Timing of samples collection is key to interpret the result as the drug concentration varies during the interval between two injections
- Drug and anti-drug measurement is recommended to be performed at Trough Concentration (TC), just before the next dose, both during induction and mainenance:
  - Target ranges are defined using TC
  - Free anti-drug antibodies are mostly detectable at TC



INTERPRET DOSING INFORMATION

- Drug levels required to improve clinical outcomes may vary between patients and depend on the desired therapeutic endpoint
- In patients with undetectable drug levels, anti-drug antibody (ADAb) quantification helps to identify how to improve patient response
- In patients with high anti-drug antibodies levels, a switch in-class may be necessary
- In patients with low anti-drug antibodies levels, the addition of an immunosuppressive drug may improve clinical outcomes
- If your patients are good responders with higher drug trough levels, dose decrease may be possible without affecting clinical outcomes

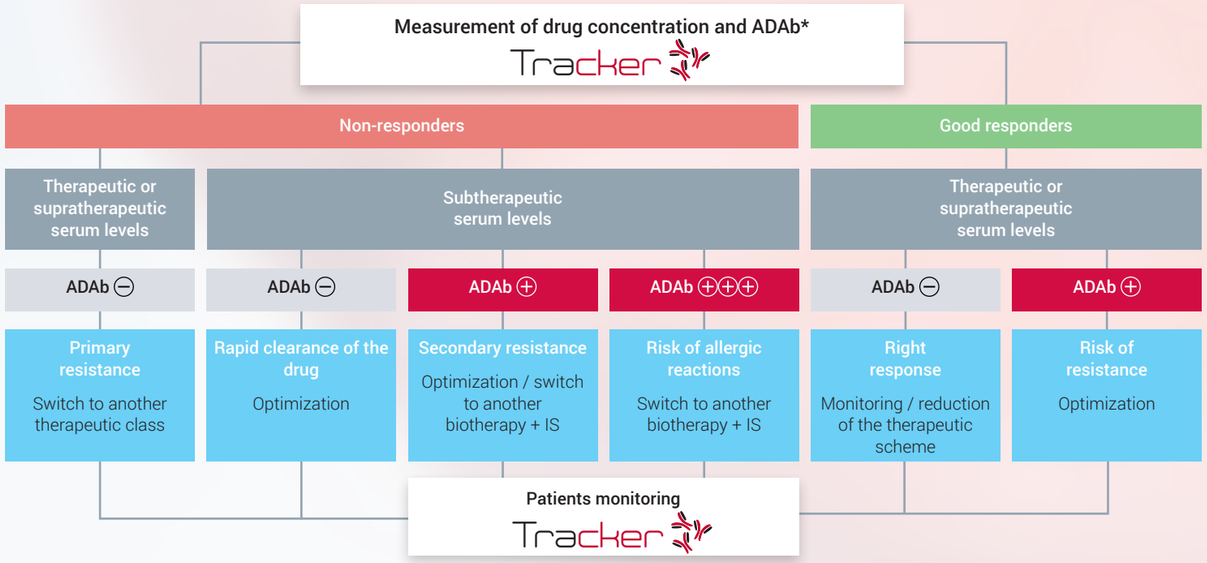
Example of therapeutic decision algorithm in patient with loss of response

	Negative Anti-drug Antibodies	Positive Anti-drug Antibodies
Therapeutic level of Drug	Switch out of therapeutic class	Retest
Subtherapeutic level of Drug	Treatment Optimization	Switch in-class

OptimAbs Tracker is a mobile application dedicated to clinicians, which aims at providing individual recommendations, based on literature and international guidelines, in the course of monitoring biotherapies of patients.

Download on the App Store

GET IT ON Google Play



IS = immunosuppressant

* These findings do not constitute a diagnosis in any case. They reflect information available in published peer-reviewed literature and guidelines and should be independently evaluated by the treating clinician and used to complete other clinical and biological information in accordance with clinician's independent medical judgment.

A **COMPLETE SOLUTION** ADAPTED TO YOUR MONITORING NEEDS

ez-Tracker: Rapid **immunofluorescence** Test

- Samples: whole blood, serum, plasma
- Result in 10 to 12 minutes depending on the parameter
- Excellent performance thanks to Time Resolved Fluorescence technology

LISA TRACKER: Automatable **ELISA** range

- Samples: serum, plasma
- Duo sets (drug and anti-drug)
- Ready-to-use reagents and standardized protocols
- Flexible test formats to adapt to the volume of activity

i-Tracker: **Random Access** CLIA solution

- Continuous loading of samples and reagents
- Samples: serum, plasma
- Result < 40 min
- System managed test protocol
- Ready-to-use reagents with system-managed sample dilutions
- High throughput analysis: 60 tests/hour
- STAT function
- Connectable to sample conveyors

- Assay of drugs and of free and total anti-drug antibodies
- Calibration on NIBSC / WHO international standards
- Validated on originator and biosimilars
- Validated through more than 100 clinical studies

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ORDERING INFORMATION

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)

LISA TRACKER

Reference	Designation	Packaging
LTx 005	LISA TRACKER Duo Drug + ADAb	2 x 48 tests
LTx 002-48	LISA TRACKER Drug	48 tests
LTx 003-48	LISA TRACKER Anti-Drug	48 tests
LTT 004-96	LISA TRACKER TNF	96 tests

x = Infliximab / Adalimumab / Etanercept / Certolizumab Pegol / Golimumab / Rituximab / Secukinumab / Tocilizumab / Bevacizumab / TRastuzumab / Ustekinumab / Vedolizumab

ez-Tracker

Reference	Designation	Packaging
ETx 002-24	ez-Tracker Drug	24 tests
ETx 003-24	ez-Tracker Anti-Drug Antibodies	24 tests
ETI 003T-24	ez-Tracker Infliximab Total Ab	24 tests

x = Infliximab / Adalimumab / Golimumab / Vedolizumab / Ustekinumab (Etanercept in development)

All Tracker products are validated on princeps molecules and associated biosimilars (when available).

IMMUNO-TROL Internal Quality Control

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

For i-Tracker

Reference	Designation	Packaging
CTx 002-PC	Immuno-Trol Drug: Positive control two levels	2 x 500 µl
CTx 003-PC	Immuno-Trol 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)

For LISA TRACKER

Reference	Designation	Packaging
LTx 002-PC	Immuno-Trol Drug: Positive control two levels	2 x 250 µl
LTx 003-PC	Immuno-Trol anti-Drug: Positive control two levels	2 x 1 ml

x = Infliximab / Adalimumab / Etanercept / Certolizumab Pegol / Golimumab / Rituximab / Secukinumab / Tocilizumab / Bevacizumab / TRastuzumab / Ustekinumab / Vedolizumab

For ez-Tracker

Reference	Designation	Packaging
ETx 002-C / ETx 003-C	ez-Tracker Drug / ADAs Controls	2 x 1 mL
ETx 002-CAL / ETx 003-CAL	ez-Tracker Drug / ADAs Calibrators	2 x 1 mL

x = Infliximab / Adalimumab / Golimumab / Vedolizumab / Ustekinumab (Etanercept in development)

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