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.

Measurement range

<table>
<thead>
<tr>
<th>Drug</th>
<th>Measurement range</th>
<th>Anti-drug range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab</td>
<td>0.3-20 µg/mL</td>
<td>10-200 ng/mL</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>0.3-20 µg/mL</td>
<td>10-160 ng/mL</td>
</tr>
<tr>
<td>Certolizumab Pegol</td>
<td>3-84 µg/mL</td>
<td>5-160 UA/mL</td>
</tr>
<tr>
<td>Etanercept</td>
<td>0.2-5 µg/ml</td>
<td>10-100 ng/ml</td>
</tr>
<tr>
<td>Vedolizumab</td>
<td>2-60 µg/mL</td>
<td>35-500 ng/mL</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>40-1000 ng/mL &amp; 0.4-10 µg/mL</td>
<td>3-100 UA/mL</td>
</tr>
<tr>
<td>Golimumab</td>
<td>0.1-8 µg/mL</td>
<td>5-80 ng/mL</td>
</tr>
<tr>
<td>Secukinumab</td>
<td>4-120 µg/ml</td>
<td>50-1000 ng/mL</td>
</tr>
<tr>
<td>Rituximab</td>
<td>2-50 µg/ml</td>
<td>5-100 µg/ml</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>10-300 µg/ml</td>
<td>3-60 ng/mL</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>10-200 µg/ml</td>
<td>10-120 ng/mL</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>1-50 µg/ml</td>
<td>5-100 ng/mL</td>
</tr>
</tbody>
</table>

A COMPLETE SOLUTION TAILORED TO YOUR MONITORING TESTING NEEDS

UNIQUE TDM MENU
- Comprehensive menu of inflammatory bowel diseases and oncology
- CE-IVD validation on serum plasma
- Validation in accordance with the 1st WHO international standards
- Validation with Princeps and Biosimilars
- Continuous development on new parameters

EASY-TO-USE
- Ready-to-use reagents
- Standardized protocols from sample collection to results interpretation
- Validated on automated platforms (DS2, DSX, Evolis, etc.)

CLINICALLY VALIDATED
- Routine use tailored to your clinical practice
- Measurement range tailored for induction and maintenance treatment phases

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- Comprehensive menu of inflammatory bowel diseases and oncology
- CE-IVD validation on serum plasma
- Validation in accordance with the 1st WHO international standards
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CLINICALLY RELEVANT
- Numerous publications with LISA TRACKER in peer-reviewed journals
- International decision algorithms validated with LISA TRACKER

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COST-EFFECTIVE
- TDM therapy leads to major cost savings (28 to 50%) related to a biologic treatment
- in Ulcerative Colitis (UC) and Crohn's Disease (CD)
- in patients in remission for treatment de-escalation
- in patients with loss of response

EASY-TO-USE
- Ready-to-use reagents
- Standardized protocols from sample collection to results interpretation
- Validated on automated platforms (DS2, DSX, Evolis, etc.)

TRUST OFFERED
- Informed consent
- Health-care professionals
- Therapeutic Drug Monitoring strategy leads to major cost savings in IBD patients while maintaining appropriate efficacy
THERAPEUTIC DRUG MONITORING TO MAINTAIN PATIENT UNDER TREATMENT AND SUPPORT THE PROPER USE OF DRUGS

WHEN TO PERFORM TDM?

- Individualisation of therapy is more effective
- Use of therapeutics is highly variable
- Visceral appendicitis
- Infliximab & Infliximab Biosimilar (CT-P13)
- Trough concentrations of infliximab guide dosing for
- Reduced drug efficacy
- Drug trough levels below the therapeutic window
- Presence of anti-drug antibodies or with
- Biotherapy

HOW TO EASILY PERFORM THE TEST?

- Detection of free anti-drug antibodies in accordance
- Biotinylated drug
- Biotinylated anti-drug
- Add biotinylated
- Wash of 300 µL wash of 300 µL
- Add substrate
- TMB
- Conjugated to Streptavidin
- Measurement of drug concentration and ADAb

INTERPRET DOSING INFORMATION

- Drug levels required to trigger clinical autoimmunity may vary
- Monitoring of adalimumab allows for detection of therapeutic response and
- Antibody concentrations in patients with inflammatory bowel disease
- Adalimumab in inflammatory bowel diseases
- A risk of

THERAPEUTIC THRESHOLDS

- Target ranges are defined using TC
- Next dose, both during induction and mainenance:
- Two injections
- Measurement of drug concentration and ADAb

WHEN TO COLLECT BLOOD ON PATIENTS?

- Detecting both drug and anti-drug antibodies
- Risk of
- Drug and anti-drug measurement is recommended to be
- Timing of samples collection is key to interpret the result as
- Between patients and depend on the desired therapeutic endpoint
- One or more assay may be necessary
- The addition of a confirmatory assay may impact clinical decisions.
- The table below shows the recommended doses and corresponding therapeutic thresholds.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Induction (week 2)</th>
<th>Postinduction (week 6)</th>
<th>Postinduction (week 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab</td>
<td>x 20</td>
<td>x 10</td>
<td>x 10</td>
</tr>
<tr>
<td>Vemurafenib</td>
<td>x 3</td>
<td>x 1</td>
<td>x 1</td>
</tr>
<tr>
<td>Certolizumab Pegol</td>
<td>x 15</td>
<td>x 10</td>
<td>x 10</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>x 1</td>
<td>x 1</td>
<td>x 1</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>x 1</td>
<td>x 1</td>
<td>x 1</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>x 1</td>
<td>x 1</td>
<td>x 1</td>
</tr>
<tr>
<td>Etanercept</td>
<td>x 1</td>
<td>x 1</td>
<td>x 1</td>
</tr>
<tr>
<td>Infliximab Biosimilar (CT-P13)</td>
<td>≥ 32</td>
<td>≥ 25</td>
<td>N/A</td>
</tr>
<tr>
<td>Certolizumab Pegol</td>
<td>≥ 7</td>
<td>≥ 4.5</td>
<td>≥ 1</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>≥ 1</td>
<td>≥ 1</td>
<td>≥ 1</td>
</tr>
</tbody>
</table>

*ADAb: Anti-drug antibodies

THERAPEUTIC WINDOW

- Level of Drug
- Interaction of Therapeutic or
- Monitoring is more cost-effective than a clinically-based approach
- Monitoring is more cost-effective than empiric dose escalation for patients with Crohn's disease

Example of therapeutic decision algorithm

- A switch in-class may be necessary
- De-escalation of infliximab therapy in patients with inflammatory bowel disease
- Cost effective than empiric dose escalation for patients with Crohn's disease
- Monitoring is more cost-effective than empiric dose escalation for patients with Crohn's disease
- Monitoring is more cost-effective than empiric dose escalation for patients with Crohn's disease

**Note:** The table above shows the recommended doses and corresponding therapeutic thresholds. These target ranges were those used in landmark studies or international guidelines and do not necessarily translate into general recommendations for individual patients.