Theradiag

# LISA TRACKER Duo Ustekinumab

English

REF **LTU 005**

2 x 48

**42 determinations**

## DEFINITION

**LISA-TRACKER Duo Ustekinumab** (Theradiag) is an enzyme linked immunoassay (ELISA) for the quantitative determination of Ustekinumab (antibody anti-Interleukin 12 and 23) and anti-Ustekinumab antibodies in human serum samples. These tests can be separatly or simultaneously done by following the standardized assay protocol.
For Ustekinumab determination, a double system of calibration (based on the dilution of the specimens) allows to cover two assay ranges adapted to the various therapeutic approaches.

## DIAGNOSTIC VALUE

Ustekinumab is indicated in the treatment of the moderate to severe plaque psoriasis, of the active psoriatic arthritis and the Crohn disease (requiring higher dose for injection). Ustekinumab is a human monoclonal antibody IgG1k directed against the subunit protein p-40 of the human cytokines IL-12 and IL-23. IL-12 and Il-23 are cytokines playing a central role in the induction of the inflammatory cascade and consequently the symptoms of the disease. During the treatment, some patients can develop antibodies against Ustekinumab.

**LISA-TRACKER Duo Ustekinumab** (Theradiag) allows the detection of 2 parameters: Ustekinumab and anti-Ustekinumab antibodies. This kit allows the physician to monitor the level of these 2 parameters in patient sera.

## SAMPLES COLLECTION AND HANDLING

- The test should be performed on serum or on plasma (EDTA, heparin or citrate collection tubes).
- Lipemic sera should be avoided, as well as samples which have been frozen and defrosted more than once.
- To avoid any non-specific binding, samples which have been frozen for more than 6 months or which are cloudy, should be centrifuged and filtered.

## ASSAY PRINCIPLE

### A. Dosage of Ustekinumab

The antibody anti-Ustekinumab (anti-idiotype) is coated onto a polystyrene microtiter plate (6 strips of 8 wells).

- First, the diluted sample is added to the antibody coated well, which allows to bind. After incubation, unbound proteins are removed by washing.
- Biotinylated antibody anti-Ustekinumab is added. After incubation, unbound antibodies are removed by washing.
- Then horseradish peroxydase labelled streptavidin is added. The streptavidin binds to the complex formed «anti-Ustekinumab / Ustekinumab / Biotinylated anti-Ustekinumab ». After incubation, the wells are washed again to eliminate any excess of conjugate.
- The bound enzyme is revealed by addition of substrate TMB (3,3',5,5' tetramethylbenzidin). The colour intensity is proportional to the amount of Ustekinumab.
- Adding $H_2SO_4$ (0.25M) allows to stop the enzymatic reaction.
- After stopping the reaction by $H_2SO_4$ (0.25M), the optical density is read by a spectrophotometer at 450nm.

A range of calibration allows to define the quantity of Ustekinumab of each patient samples expressed in µg/mL.

### B. Dosage of anti-Ustekinumab

The Ustekinumab is coated onto a polystyrene microtiter plate (6 strips of 8 wells).

- First, the diluted sample is added to the antibody coated well, which allows to bind. After incubation, unbound proteins are removed by washing.
- Biotinylated Ustekinumab is added. After incubation, unbound antibodies are removed by washing.
- Then horseradish peroxydase labelled streptavidin is added. The streptavidin binds to the complex formed with biotinylated Ustekinumab. After incubation, the wells are washed again to eliminate any excess of conjugate.
- The bound enzyme is revealed by addition of substrate TMB (3,3',5,5' tetramethylbenzidin). The colour intensity is proportional to the amount of anti-Ustekinumab antibodies.
- Adding $H_2SO_4$ allows to stop the enzymatic reaction.
- After stopping the reaction by $H_2SO_4$, the optical density is read by a spectrophotometer at 450nm.

A range of calibration allows to define the quantity of anti-Ustekinumab antibodies of each patient samples expressed in AU/mL.

## REAGENTS

3 reagent families :

| Color | Ustekinumab reagents | anti-Ustekinumab antibodies reagents | Common reagents |
|---|---|---|---|
| cap of vials | **Blue** | **Yellow** | **Green, White, Black or Purple** |
| microwells | **Blue** | **Yellow** | **-** |

## A) Specific reagents for the Ustekinumab determination

| | |
|---|---|
| Strips of individual breakaway blue wells coated with antibody anti-Ustekinumab. **MP** | 6 strips |
| 5 vials of « Ustekinumab » Standards, (µg/mL).<br>Ready to use.<br>The vials can be reused several times.<br>***The quantity of Ustekinumab is indicated on the vial label.***<br>***Blue caps*** **UST CAL n** | 5 x 1,5mL |
| «Positive control - Ustekinumab», (µg/mL).<br>To dilute. **UST CONTROL +**<br>The vials can be reused several times.<br>***The quantity of Ustekinumab is indicated on the vial label.***<br>***Blue cap*** **H** **L** | 2 x 250µL |
| Biotinylated antibody anti-Ustekinumab vial.<br>Ready to use. **UST Ab BIOT**<br>***Blue cap*** | 1 x 7,5mL |

## B) Specific reagents for the anti-Ustekinumab antibodies determination

| | |
|---|---|
| Strips of individual breakaway yellow wells coated with Ustekinumab. **MP** | 6 strips |
| 5 vials of « anti-Ustekinumab » Standards, (AU/mL). **A-UST CAL n**<br>Ready to use.<br>The vials can be reused several times.<br>***The quantity of anti-Ustekinumab is indicated on the vial label.***<br>***Yellow caps*** | 5 x 1,5mL |
| « Positive control – anti-Ustekinumab», (AU/mL).<br>To dilute. **A-UST CONTROL +**<br>The vial can be reused several times.<br>***The quantity of anti-Ustekinumab is indicated on the vial label.***<br>***Yellow cap*** | 1 x 1mL |
| Biotinylated antibody Ustekinumab vial.<br>Ready to use. **A-UST Ab BIOT**<br>***Yellow cap*** | 1 x 7,5mL |

## C) Common reagents

| | |
|---|---|
| HRP labelled Streptavidin.<br>Ready to use. **CONJ HRP**<br>***Green cap*** | 1 x 12mL |
| Phosphate-Tween Buffer pH 7.2 (10x) –<br>To reconstitute with distilled water.<br>***White cap*** **BUF WASH 10x** | 1 x 100mL |
| Substrate (TMB).<br>Ready to use. **SUBS TMB**<br>***Black cap*** | 1 x 12mL |
| Stop solution - $H_2SO_4$ (0.25 N).<br>Ready to use. **SOLN STOP**<br>***Purple cap*** | 1 x 15mL |

## MATERIAL REQUIRED BUT NOT PROVIDED

- distilled water
- precision pipettes
- microplate spectrophotometer with 450 nm filter
- 8 channel pipettes

## STABILITY AND STORAGE

- Store reagents and micro-wells at +2°C/+8°C in their own package.
- Do not use kits beyond the expiration date.
- Store unused strips into their plastic bag with the desiccant.
- Store all components immediately after use again at +2°C/+8°C.

## SETUP

Except the TDL, which can be prepare in advance, all reagents must be prepared extemporaneously.

***1. Dilution and Wash buffer (TDL)***

- Dilute concentrated Phosphate-Tween Buffer 1/10 in distilled water. **BUF WASH 10x**

- Shelf life : 3 months at +2°C/+8°C (avoid to use if signs of contamination or other visible changes occur).

*NB. If there are crystals in the concentrated solution, warm the bottle up to +37°C for 15 minutes before use.*

***2. Ustekinumab determination: preparation of samples and positive controls***

***a. UST100 determination (0.04 to 1 µg/mL assay range)***

**-** Dilute samples and positive control **L** to **1/101** in TDL (Ex : 10µL sample + 1mL TDL)
Vortex vigorously.

***b. UST1000 determination (0.4 to 10 µg/mL assay range)***

**-** Dilute samples and positive control **H** to **1/1001** in TDL (Ex : 5µL sample + 5mL TDL)
Vortex vigorously.

***3. Anti-Ustekinumab determination: preparation of samples and positive controls***

- Dilute samples and positive control to 1/2 in TDL (Ex : 130µL sample + 130µL TDL)
Vortex vigorously.

***4. Use of ready-to-use biotinylated antibody.***

- Estimate the amount required for handling and transfer to a tube.

***5. Use of ready-to-use HRP Streptavidin conjugate.***

- Estimate the amount required for handling and transfer to a tube.

***6. Use of ready-to-use substrate.***

- Estimate the amount required for handling and transfer to a dark tube.

## PRECAUTIONS

Unpack all reagents in order to let them warm at room temperature (+18°C/+25°C) at least half an hour before starting the test.

☝ The temperature of the reagents can impact the final result.

Check that all plates are well drained after each wash.

Avoid to use reagents if signs of contamination or other visible changes occur.

*Human sources for the preparation of standards and controls have been tested and found negative for antibody to HIV 1 and 2, antibody to hepatitis C virus and hepatitis B virus antigen. Nevertheless, no test can offer complete assurance that HIV, hepatitis B virus or other infectious agents are absent. Therefore, the reagents should be handled as potentially infective materials.*

Reagents in solution (except for substrate buffer and stop solution) contain <0.1% of sodium azide and <0.6% of ProClin® 300. Do not eat and avoid contact with skin and eyes. Azide can form explosive mixtures in copper or lead piping. Rinse thoroughly after flushing.

- ⚠ At this concentration, ProClin® 300 is irritating to eyes and skin, and may be detrimental if enough quantity is ingested. It is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

**LISA-TRACKER Duo Ustekinumab** (Theradiag) has been developed according EC regulation n°1272/2008 relating to the classification, packaging and labeling of dangerous preparations.

**LISA-TRACKER Duo Ustekinumab** (Theradiag) has been optimized for the use as describe in this procedure. Do not substitute other manufacter's reagents. Dilution or adulteration of these reagents may also affect the performance of the test. Close adherence to the test procedure will assure optimal performance.

For samples with a level lower or upper to the selected assay range, verify the system used:

**UST100 :** assay range from 0.04 to 1µg/mL + sample dilution 1/101 + positive control L
or
**UST1000 :** assay range from 0.4 to 10µg/mL + sample dilution 1/1001 + positive control H

## METHOD

### 1. *Preparing the test*

Use the work sheet to note the sample locations.

Set out:

- 5 "standard" wells
- 1 well for positive control H or L according the selected assay range
- 1 well for each sample

For a simultaneous testing of the 2 parameters, detach the exact number of wells needed. Return unused wells to plastic pouch provided in the kit, with the desiccant bag.

***Remark :***

If a dispensing/diluting device is used, place the specific wells in the following order : dosage of Ustekinumab then dosage of anti-ustekinumab.

### 2. *Samples, positive controls and standards incubation*

Add 100 µL of standards, diluted controls or samples.

Incubate for 60 minutes at room temperature (+18°C/+25°C).

*Wash step:*

Remove the content of the wells by rapid inversion.

Wash 3 times with 300µL of TDL buffer.

Dry the microplate by tapping it gently on an absorbent paper to eliminate the excess of liquid.

### 3. *Incubation of biotinylated antibody*

Add 100µL of **specific** biotinylated antibody in identified wells.

Incubate for 60 minutes at room temperature (+18°C/+25°C).

*Wash step:*

Remove the content of the wells by rapid inversion.

Wash 3 times with 300µL of dilution and washing buffer.

Dry the microplate by tapping it gently on an absorbent paper to eliminate the excess of liquid.

### 4. *Incubation of Conjugate*

Add 100µL of conjugate.

Incubate for 30 minutes at room temperature (+18°C/+25°C).

*Wash step:*

Remove the content of the wells by rapid inversion.

Wash 3 times with 300µL of dilution and washing buffer.

Dry the microplate by tapping it gently on an absorbent paper to eliminate the excess of liquid.

### 5. *Incubation of Substrate*

Add 100µL substrate into each well.

Incubate for 15 minutes at room temperature (+18°C/+25°C), in the dark.

### 6. *Stop of the reaction*

Add 100µL of $H_2SO_4$ to each well.

### 7. *Reading*

Read the optical density of each well at 450nm within 30 minutes after stopping reaction.

## RESULTS AND INTERPRETATION

- **A. Dosage of Ustekinumab** according the selected assay range UST100 or UST 1000
- The OD of the standard 1 should be at least 0.8.
- The positive control value should be comprised into the range indicated on the vial label.
- Trace a *polynomial standard curve* or a 4PL with plotting the units of the 5 standard points (µg/mL) along the abscissa (X axis) and the corresponding OD values along the ordinate (Y axis).
- The Ustekinumab value can be directly read on the curve.
- Samples with values greater than that of standard 1 may be diluted to obtain a more precise result. The number of units should be multiplied by the selected dilution.

**B. Dosage of anti-Ustekinumab**

- The OD of the standard 1 should be at least 0.8.
- The positive control value should be comprised into the range indicated on the vial label.
- Trace a *polynomial standard curve* with plotting the units of the 5 standard points (AU/mL) along the abscissa (X axis) and the corresponding OD values along the ordinate (Y axis).
- The anti-Ustekinumab value can be directly read on the curve.
- Samples with values greater than that of standard 1 may be diluted to obtain a more precise result. The number of units should be multiplied by the selected dilution.

## CHARACTERISTICS AND PERFORMANCE OF THE TEST

### *Limits of detection / threshold values*

Estimated on a population of healthy patient samples.

| Limit of detection<br>**Ustekinumab**<br>*Assay range*<br>*0.04 to 1 µg/mL* | Limit of detection<br>**Ustekinumab**<br>*Assay range*<br>*0.4 to 10 µg/mL* |
|---|---|
| 153 samples | 103 samples |
| 0.04 µg/mL<br>>99th percentile | 0.4 µg/mL<br>>99th percentile |

| Limit of detection<br>**anti-Ustekinumab** |
|---|
| 153 samples |
| 3 AU/mL<br>>99th percentile |

### *Assay range*

| **Ustekinumab**<br>UST100 | **Ustekinumab**<br>UST1000 |
|---|---|
| 0.04µg/mL – 1µg/mL | 0.4µg/ml – 10µg/ml |

| **anti-Ustekinumab** |
|---|
| 3 AU/ml - 100 AU/ml |

### *Interfering Substances Study*

**LISA-TRACKER Duo Ustekinumab** (Theradiag) was evaluated to assess potential cross reactivity to other antibodies and interference:
- on positive samples for several components (cryoglobulins, rheumatoid factors, heterophilic antibodies, high levels of triglycerides, bilirubin, IgG and/or IgM, and C1q proteins, autoantibodies),
- on a population of patients' serums presenting psoriasis,
- on samples completed with the following components: bilirubin (in 0.2mg/mL), haemoglobin (in 2mg/mL), triglycerides (in 10mg/mL) and rheumatoid factors (to 1000IU/mL).

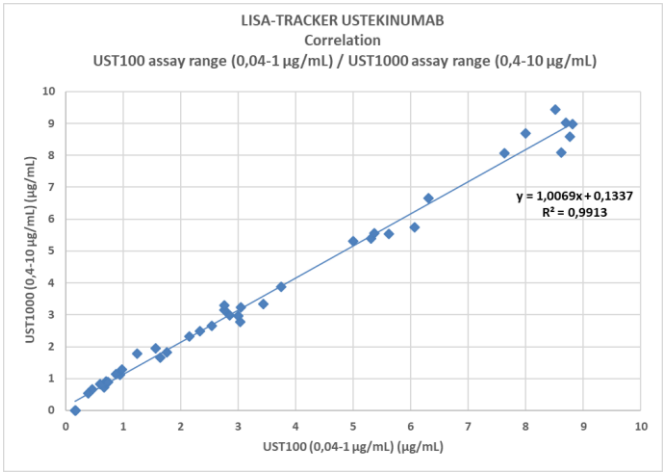
⇨ No interference was detected.

### *Precision*

| | Intra-run<br>*30 tests / assay<br>**10 tests / assay | | Inter-runs<br>*9 different assays<br>**6 different assays | |
|---|---|---|---|---|
| **Parameters** | **Mean** | **CV (%)** | **Mean** | **CV (%)** |
| **Ustekinumab* (µg/ml)**<br>Assay range<br>0.04 to 1µg/mL | 0.13 | 12.6 % | 0.13 | 10.3 % |
| | 0.48 | 10.6 % | 0.51 | 8.9 % |
| | 0.82 | 5.5 % | 0.85 | 3.5 % |
| **Ustekinumab** (µg/ml)**<br>Assay range<br>0.4 to 10µg/mL | 1.5 | 4.7% | 1.4 | 11.3% |
| | 3.7 | 8.7% | 4 | 7.9% |
| | 8.9 | 5.9% | 8.4 | 11.9% |
| **anti-Ustekinumab* (AU/ml)** | 10 | 11.1 % | 10 | 14 % |
| | 19 | 11.5 % | 22 | 11.2 % |
| | 43 | 5.9 % | 44 | 8.1 % |

### *Correlation*

The performances of the **Ustekinumab determination obtained with the assay range - UST1000 (0.4 to 10µg/mL)** were compared to the performances obtained with the **assay range - UST100 (0.04 to 1µg/mL)**. Samples outside assay ranges were diluted. A linear regression analysis of the two results showed that both are equivalent.




## LIMITS

The presence of biotin in patients' specimens can potentially impact the immunodosages using the Streptavidin-Biotin technology.

## QUALITY CONTROL

It is recommended to use internally and externally sourced control material for the different specificities. **Ustekinumab** or **anti-Ustekinumab IMMUNO-TROL** controls (Theradiag, Cat.n: LTU 002-PC or LTU 003-PC) contain Ustekinumab or antibodies directed against Ustekinumab. These materials are to be assayed in the same manner as the unknown samples.

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## SUMMARY OF METHOD

### A) Dilution

| | Ustekinumab | | anti-Ustekinumab |
|---|---|---|---|
| | **UST100 - 0.04 to 1µg/mL** | **UST1000 - 0.4 to 10µg/mL** | |
| **Samples** | 1/101 | 1/1001 | 1/2 |
| **Positive controls** | 1/101 L | 1/1001 H | 1/2 |

### B) Procedure

| Reagents | Procedure |
|---|---|
| Standards | 100µL / wells |
| Diluted positive controls | |
| Diluted samples | |
| Incubation | 1 h at room temperature |
| Washing* | Wash 3 times with TDL buffer : 3 x 300µL / wells |
| Biotinylated antibody | 100µL / wells **(specific reagents)** |
| Incubation | 1 h at room temperature |
| Washing* | Wash 3 times with TDL buffer : 3 x 300µL / wells |
| HRP-Streptavidin | 100µL / wells |
| Incubation | 30 minutes at room temperature |
| Washing* | Wash 3 times with TDL buffer : 3 x 300µL / wells |
| Substrate (TMB) | 100µL / wells |
| Incubation | 15 minutes at room temperature. Protect from light. |
| Stop solution | 100µL / wells |

* Dry the microplate by tapping it gently on a towel to eliminate the excess of liquid.

## C) Configuration of the assays

### a. 42 sera for Ustekinumab - Assay range UST 1000 - and anti-Ustekinumab

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | **Standard 5** | Sera 3 | Sera 11 | Sera 19 | Sera 27 | Sera 35 | **Standard 5** | Sera 3 | Sera 11 | Sera 19 | Sera 27 | Sera 35 |
| B | **Standard 4** | Sera 4 | Sera 12 | Sera 20 | Sera 28 | Sera 36 | **Standard 4** | Sera 4 | Sera 12 | Sera 20 | Sera 28 | Sera 36 |
| C | **Standard 3** | Sera 5 | Sera 13 | Sera 21 | Sera 29 | Sera 37 | **Standard 3** | Sera 5 | Sera 13 | Sera 21 | Sera 29 | Sera 37 |
| D | **Standard 2** | Sera 6 | Sera 14 | Sera 22 | Sera 30 | Sera 30 | **Standard 2** | Sera 6 | Sera 14 | Sera 22 | Sera 30 | Sera 30 |
| E | **Standard 1** | Sera 7 | Sera 15 | Sera 23 | Sera 31 | Sera 39 | **Standard 1** | Sera 7 | Sera 15 | Sera 23 | Sera 31 | Sera 39 |
| F | C+ (H) | Sera 8 | Sera 16 | Sera 24 | Sera 32 | Sera 40 | **C+** | Sera 8 | Sera 16 | Sera 24 | Sera 32 | Sera 40 |
| G | Sera 1 | Sera 9 | Sera 17 | Sera 25 | Sera 33 | Sera 41 | Sera 1 | Sera 9 | Sera 17 | Sera 25 | Sera 33 | Sera 41 |
| H | Sera 2 | Sera 10 | Sera 18 | Sera 26 | Sera 34 | Sera 42 | Sera 2 | Sera 10 | Sera 18 | Sera 26 | Sera 34 | Sera 42 |

Ustekinumab assay

anti-Ustekinumab assay

### b. 42 sera for Ustekinumab - Assay range UST 100 - and anti-Ustekinumab

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | **Standard 5** | Sera 3 | Sera 11 | Sera 19 | Sera 27 | Sera 35 | **Standard 5** | Sera 3 | Sera 11 | Sera 19 | Sera 27 | Sera 35 |
| B | **Standard 4** | Sera 4 | Sera 12 | Sera 20 | Sera 28 | Sera 36 | **Standard 4** | Sera 4 | Sera 12 | Sera 20 | Sera 28 | Sera 36 |
| C | **Standard 3** | Sera 5 | Sera 13 | Sera 21 | Sera 29 | Sera 37 | **Standard 3** | Sera 5 | Sera 13 | Sera 21 | Sera 29 | Sera 37 |
| D | **Standard 2** | Sera 6 | Sera 14 | Sera 22 | Sera 30 | Sera 30 | **Standard 2** | Sera 6 | Sera 14 | Sera 22 | Sera 30 | Sera 30 |
| E | **Standard 1** | Sera 7 | Sera 15 | Sera 23 | Sera 31 | Sera 39 | **Standard 1** | Sera 7 | Sera 15 | Sera 23 | Sera 31 | Sera 39 |
| F | C+ (L) | Sera 8 | Sera 16 | Sera 24 | Sera 32 | Sera 40 | **C+** | Sera 8 | Sera 16 | Sera 24 | Sera 32 | Sera 40 |
| G | Sera 1 | Sera 9 | Sera 17 | Sera 25 | Sera 33 | Sera 41 | Sera 1 | Sera 9 | Sera 17 | Sera 25 | Sera 33 | Sera 41 |
| H | Sera 2 | Sera 10 | Sera 18 | Sera 26 | Sera 34 | Sera 42 | Sera 2 | Sera 10 | Sera 18 | Sera 26 | Sera 34 | Sera 42 |

Ustekinumab assay

anti-Ustekinumab assay

## SYMBOLS USED

| | | | |
|---|---|---|---|
| CE | EC Declaration of Conformity | ▽ | Number of test |
| | ELISA Test | | Consult Instructions |
| REF | Catalogue number | | Temperature limitation |
| LOT | Lot Number | | Biological hazard |
| | Expiry Date | CONT $NaN_3$ | Contains sodium azide |
| IVD | *In vitro* Diagnostic device | RCNS | Reconsitute with |
| | Manufacturer | | Warning |


Theradiag

IVD

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