

INTENDED USE

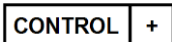
This reagent, prepared from human sera, is intended for use as an unassayed precision control with LISA-TRACKER procedures for determination of the following autoantibodies:

REF	PARAMETER	REF	PARAMETER
LTI 002-PC	Infliximab	LTI 003-PC	anti-Infliximab
LTA 002-PC	Adalimumab	LTA 003-PC	anti-Adalimumab
LTE 002-PC	Etanercept	LTE 003-PC	Anti-Etanercept
LTC 002-PC	Certolizumab	LTC 003-PC	anti-Certolizumab
LTV 002-PC	Vedolizumab	LTV 003-PC	anti-Vedolizumab
LTG 002-PC	Golimumab	LTG 003-PC	anti-Golimumab
LTT 002-PC	Tocilizumab	LTT 003-PC	anti-Tocilizumab
LTR 002-PC	Rituximab	LTR 003-PC	anti-Rituximab
LTB 002-PC	Bevacizumab	LTB 003-PC	anti-Bevacizumab
LTTR 002-PC	Trastuzumab	LTTR-003-PC	anti-Trastuzuma
LTU 002-PC	Ustekinumab	LTU 003-PC	Anti-Ustekinumab

DESCRIPTION

IMMUNO-TROL LISA-TRACKER reagents have been designed for use with LISA-TRACKER methods to monitor the precision of laboratory testing procedures for the analytes listed in this insert.

Each IMMUNO-TROL reagent lot is designed to produce a positive reaction for each autoantibodies above listed.



IMMUNO-TROL reagents have an assigned values for LISA-TRACKER kits. Each package includes two vials of control with a high level (identified by one H on the cap and the label) and a low level (identified by one L on the cap and the label).

However, each laboratory should establish its own target value for each marker and for each new lot on a minimum of 30 assays.

PACKAGING

LTI 002-PC	Pink cap	LTI 003-PC	Purple cap
LTA 002-PC	Green cap	LTA 003-PC	Orange cap
LTE 002-PC	White cap	LTE 003-PC	Black cap
LTC 002-PC	Red cap	LTC 003-PC	Yellow cap
LTV 002-PC	White cap	LTV 003-PC	Black cap
LTG 002-PC	Purple cap	LTG 003-PC	Pink cap
LTT 002-PC	Yellow cap	LTT 003-PC	Green cap
LTR 002-PC	Orange cap	LTR 003-PC	Red cap
LTB 002-PC	Black cap	LTB 003-PC	White cap
LTTR 002-PC	Green cap	LTTR 003-PC	Orange cap
LTU 002-PC	Pink cap	LTU 003-PC	Purple cap
Format : 2 x 250µL		Format : 2 x 1mL	

WARNING

Human sources for the preparation of this control have been tested and found negative for antibody to HIV 1 and 2,

antibody to hepatitis C virus or 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.

PROCEDURE

IMMUNO-TROL reagents should be analyzed in the same manner as patient samples, according to the instructions supplied by manufacturers of the kits used.

If the value of one parameter is out of the kit standard range, the reagent may be diluted following the kit's instruction for use.

STABILITY AND STORAGE

- Store the reagents at +2°C to +8°C when not in use.
- Do not use reagents beyond the expiration date.
- Open vial stability : 6 months at +2°C to +8°C.
- Do not freeze.

LIMITS

- IMMUNO-TROL reagents must not be substituted for the positive and the negative control reagents provided with manufacturer's tests.
- IMMUNO-TROL reagents are provided for quality assurance and must not be used for calibration.
- It is the responsibility of each laboratory to implement its own quality assurance program, to determine the suitability of IMMUNO-TROL reagents for its particular use and to establish guidelines for interpretation of results obtained with IMMUNO-TROL reagents.
- Adverse storage conditions or use of outdated reagents may produce erroneous results.
- IMMUNO-TROL reagents have been tested and showed a reactivity in test procedure of the following Theradiag kits: LISA-TRACKER.

SYMBOLS USED

	Biological risk		Temperature limitation
	Read instructions for use	REF	Catalog Number
	EC Declaration of conformity	LOT	Lot Number
	Manufacturer		Use by
	Warning	CONTROL +	Positive control