

INTENDED USE

These reagents are intended for use as quality controls with respective i-Tracker procedures for the quantification of the following parameters :

REF	PARAMETER	REF	PARAMETER
CTA 002-PC	ADALIMUMAB	CTA 003-PC	anti-ADALIMUMAB
CTC 002-PC	CERTOLIZUMAB	CTC 003-PC	anti-CERTOLIZUMAB
CTG 002-PC	GOLIMUMAB	CTG 003-PC	anti-GOLIMUMAB
CTI 002-PC	INFLIXIMAB	CTI 003-PC	anti-INFLIXIMAB
CTR 002-PC	RITUXIMAB	CTR 003-PC	anti-RITUXIMAB
CTU 002-PC	USTEKINUMAB	CTU 003-PC	anti-USTEKINUMAB
CTV 002-PC	VEDOLIZUMAB	CTV 003-PC	anti-VEDOLIZUMAB

DESCRIPTION

IMMUNO-TROL i-Tracker reagents have been designed for use with i-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 parameter above listed.

CONTROL	+
---------	---

IMMUNO-TROL reagents have an assigned values for i-Tracker kits. Each package includes two vials of control with a high level (identified by a red cap and the label with the letter H) and a low level (identified by a green cap and the label with the letter L).


PACKAGING

CTA 002-PC	Green cap (Low level) Red cap (High level)	CTA 003-PC	Green cap (Low level) Red cap (High level)
CTC 002-PC	Green cap (Low level) Red cap (High level)	CTC 003-PC	Green cap (Low level) Red cap (High level)
CTG 002-PC	Green cap (Low level) Red cap (High level)	CTG 003-PC	Green cap (Low level) Red cap (High level)
CTI 002-PC	Green cap (Low level) Red cap (High level)	CTI 003-P	Green cap (Low level) Red cap (High level)
CTR 002-PC	Green cap (Low level) Red cap (High level)	CTR 003-PC	Green cap (Low level) Red cap (High level)
CTU 002-PC	Green cap (Low level) Red cap (High level)	CTU 003-PC	Green cap (Low level) Red cap (High level)
CTV 002-PC	Green cap (Low level) Red cap (High level)	CTV 003-PC	Green cap (Low level) Red cap (High level)
Format : 2 x 500µL		Format : 2 x 1,5mL	

WARNING

- These reagents contain biological materials, it is recommended to handle them with the usual precautions and to dispose of them according to local environmental regulations.

- Reagents in solution contain <0.1% of sodium azide and <0.06% 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 i-Tracker 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.
- After opening, the reagents are stable 6 months at +2°C to +8°C. They can be kept on board for a maximum of 10 hours per day then stored, tightly closed, at +2°C / +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

 kits: i-Tracker.

SYMBOLS USED

	Biological risk		Warning
	Read instructions for use (edoc.theradiag.com)		
	Changes made on the previous version		



14 rue Ambroise Croizat
77 183 CROISSY BEAUBOURG
France

Tel : +33 (0)1 64 62 10 12
Fax : +33 (0)1 64 62 09 66

E-mail : support@theradiag.com
Internet : www.theradiag.com