

Instructions for Use

Life Science Kits & Assays



innuPREP TCT Target Concentration Kit Water

Order No.:

845-TC-0020010 10 reactions

845-TC-0020050 50 reactions

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It needs not necessarily agree with future versions. Subject to change!

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Manufacturer and Distributor:

IST Innuscreen GmbH Phone +49 30 9489 3380

Robert-Rössle-Straße 10 Fax +49 30 9489 3381

13125 Berlin · Germany

Made in Germany! info.innu@ist-ag.com

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1 Introduction

1.1 Intended use

The innuPREP TCT Target Concentration Kit Water was specifically developed for the concentration of biomolecules like circulating free DNA and RNA, viruses, bacteriophages, bacteria, algae, protozoa, bacteria and algae from water samples. Fresh water of different origins such as drinking water, surface water, process water, pool water, aquarium water etc. of different volumes (1 ml - 1000 ml) can be used. The kit is based on a novel and patent-pending technology that allows biomolecules contained in liquid samples to be concentrated and then made available for various other analysis methods. No filtration, ultrafiltration, ultracentrifugation, or PEG precipitation is required.

The concentrated sample can be used for subsequent extraction of DNA and RNA, for microbiological cultivation methods, immunological methods (lateral flow test, ELISA), cell assays, microscopy or spectroscopy, flow cytometry etc. Based on the high factor of concentration the sensitivity of any downstream application is significantly increased.



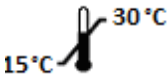





CONSULT INSTRUCTION FOR USE



This package insert must be read carefully before use. Package insert instructions must be followed accordingly. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.

1.2 Notes on the use of this manual and the kit

For easy reference and orientation, the manual and labels use the following warning and information symbols as well as the shown methodology:

Symbol	Information
	REF Catalogue number.
	Content Contains sufficient reagents for <N> tests.
	Storage conditions Store at room temperature, unless otherwise specified.
	Consult instructions for use This information must be observed to avoid improper use of the kit and the kit components.
	Expiry date
	Lot number The number of the kit charge.
	Manufactured by Contact information of manufacturer.
	For single use only Do not use components for a second time.
	Note / Attention Observe the notes marked in this way to avoid operating errors for obtaining correct results.

The following systematic approach is introduced in the manual:

- The chapters and figures are numbered consecutively.
- A cross reference is indicated with an arrow (e.g. →"Notes on the use of this manual" p. 3).
- Working steps are numbered.

2 Safety precautions

NOTE

Read through this chapter carefully before use to guarantee your own safety and a trouble-free operation.

Follow all the safety instructions explained in the manual, as well as all messages and information, which are shown.

All due care and attention should be exercised in handling the materials and reagents contained in the kit. Always wear gloves while handling these reagents and avoid any skin contact! In case of contact, flush eyes or skin with a large amount of water immediately.



FOR SINGLE USE ONLY!

This kit is made for single use only!

ATTENTION!

Don't eat or drink components of the kit!

The kit is designed to be handled only by educated personnel in a laboratory environment!

If the buffer bottles are damaged or leaking, wear gloves and protective goggles when discarding the bottles in order to avoid any injuries. This kit is to be used with potential infectious human samples. Therefore, all liquid waste must be considered as potentially infectious and must be handled and discarded according to local safety regulation.

Please observe the federal, state and local safety and environmental regulations. Follow the usual precautions for applications using extracted nucleic acids. All materials and reagents used for DNA should be free of DNases or RNases.

NOTE

Emergency medical information in English and German can be obtained 24 hours a day from:

Poison Information Center, Freiburg / Germany

Phone: +49 (0)761 19 240.

For more information on GHS classification on GHS classification and the Safety Data Sheet (SDS) please contact sds.innu@ist-ag.com.

3 Storage conditions

The kit is shipped at ambient temperature.

All components of the **innuPREP TCT Target Concentration Kit Water** should be stored dry at room temperature (15 °C to 30 °C). When stored at room temperature, the kit is stable until the expiration date printed on the label on the kit box.

If there are any precipitates within the provided solutions dissolve these precipitates by careful warming. Before every use make sure that all components have room temperature.

4 Functional testing and technical assistance

The IST Innuscreen GmbH guarantees the correct function of the kit for applications as described in the manual. This product has been produced and tested in an ISO 13485 certified facility.

We reserve the right to change or modify our products to enhance their performance and design. If you have any questions or problems regarding any aspects of the **innuPREP TCT Target Concentration Kit Water** or other IST Innuscreen GmbH products, please do not hesitate to contact us. For technical support or further information in Germany please contact info.innu@ist-ag.com. For other countries please contact your local distributor.

5 Product use and warranty

The kit is not designed for the usage of other starting materials or other amounts of starting materials than those, referred to in the manual (→ "Product specifications", p. 7). Since the performance characteristics of IST Innuscreen GmbH kits have just been validated for the application described above, the user is responsible for the validation of the performance of IST Innuscreen GmbH kits using other protocols than those described below. IST Innuscreen GmbH kits may be used in clinical diagnostic laboratory systems after the laboratory has validated the complete diagnostic system as required by CLIA' 88 regulations in the U.S. or equivalent regulations required in other countries.

All products sold by the IST Innuscreen GmbH are subjected to extensive quality control procedures and are warranted to perform as described when used correctly. Any problems should be reported immediately.

NOTE

The kit is for research use only!

6 Kit components

6.1 Included kit components

	Σ 10	Σ 50
REF	845-TC-0020010	845-TC-0020050
TCT Beads (1g)	5	25
TCT Beads (2g)	5	25
PBS, 1x	10 ml	50 ml
Manual	1	1

7 Product specifications

Starting material:

- Water (1 ml – 500 ml)

8 Protocol: Target concentration

1. Transfer the sample to a suitable bottle. The volume of the bottle should be about twice the volume of the sample.
2. Adding the appropriate amount of TCT Beads by combining different amounts of TCT Beads (1 g / 2 g → refer to table below). Shake the bottle vigorously. Incubate at room temperature until desired target volume is reached. The bottle can also be shaken briefly from time to time which slightly speeds up the process.

The table gives a few guide values that relate to initial volume, target volume and time. These are approximate values which may vary depending on sample type.

Sample volume	TCT Beads	Incubation time	Volume after incubation time
100 ml	2 g	1.5h	appr. 2 ml
100 ml	3 g	1h	appr. 5 ml
250 ml	5 g	2 h	appr. 4 ml
250 ml	10 g	30 min	appr. 10 ml
500 ml	5 g	2.5 h	appr. 100 ml
500 ml	5 g	Overnight	appr. 35 ml
500 ml	6 g	Overnight	appr. 15 ml
1000 ml	10 g	Overnight	appr. 80 -100 ml
1000 ml	12 g	Overnight	appr. 40 - 50 ml
1000 ml	15 g	Overnight	appr. 10 - 20 ml

IMPORTANT

- *The required amount of TCT Beads that are used depends on the desired concentration factor (according to the desired target volume) and the time in which the concentration is to take place.*
- *More beads can be used to reduce the time of the concentration process.*

- *It is also possible to run the concentration process overnight. The amount of beads can be adjusted in such a way that the desired target volume is available the next day.*
 - *It is also possible to perform a first concentration and then to further concentrate the resulting target volume in a second concentration step.*
 - *The amount of beads can also be set individually and can be determined e.g. by weighing. Also, the incubation time can be varied as desired and thus the volume of the concentrated sample can be specifically adjusted.*
 - *In addition, any other initial volume of the sample can be used (1-500ml).*
3. After concentration has been completed, the sample is transferred to a suitable vessel and is now available for further use.

IMPORTANT

In case all of the sample has been absorbed by the beads, only a small volume (2-3ml) of 1 x PBS Buffer needs to be added to the beads (alternatively, a small volume of the original sample can also be added). It is then shaken briefly, and the remaining volume should immediately be transferred to a new vessel.

The concentrated sample can be used for subsequent extraction of DNA and RNA. We recommend to use the innuPREP Anipath DNA/RNA kits for automated extraction and for manual extraction the innuPREP Sewage Water Kit. These kits are optimized for extraction of DNA/RNA from concentrated water samples for microbiological cultivation methods, immunological methods (lateral flow test, ELISA), cell assays, microscopy or spectroscopy, flow cytometry etc. Based on the high factor of concentration the sensitivity of any downstream application is significantly increased.

IST Innuscreen GmbH
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