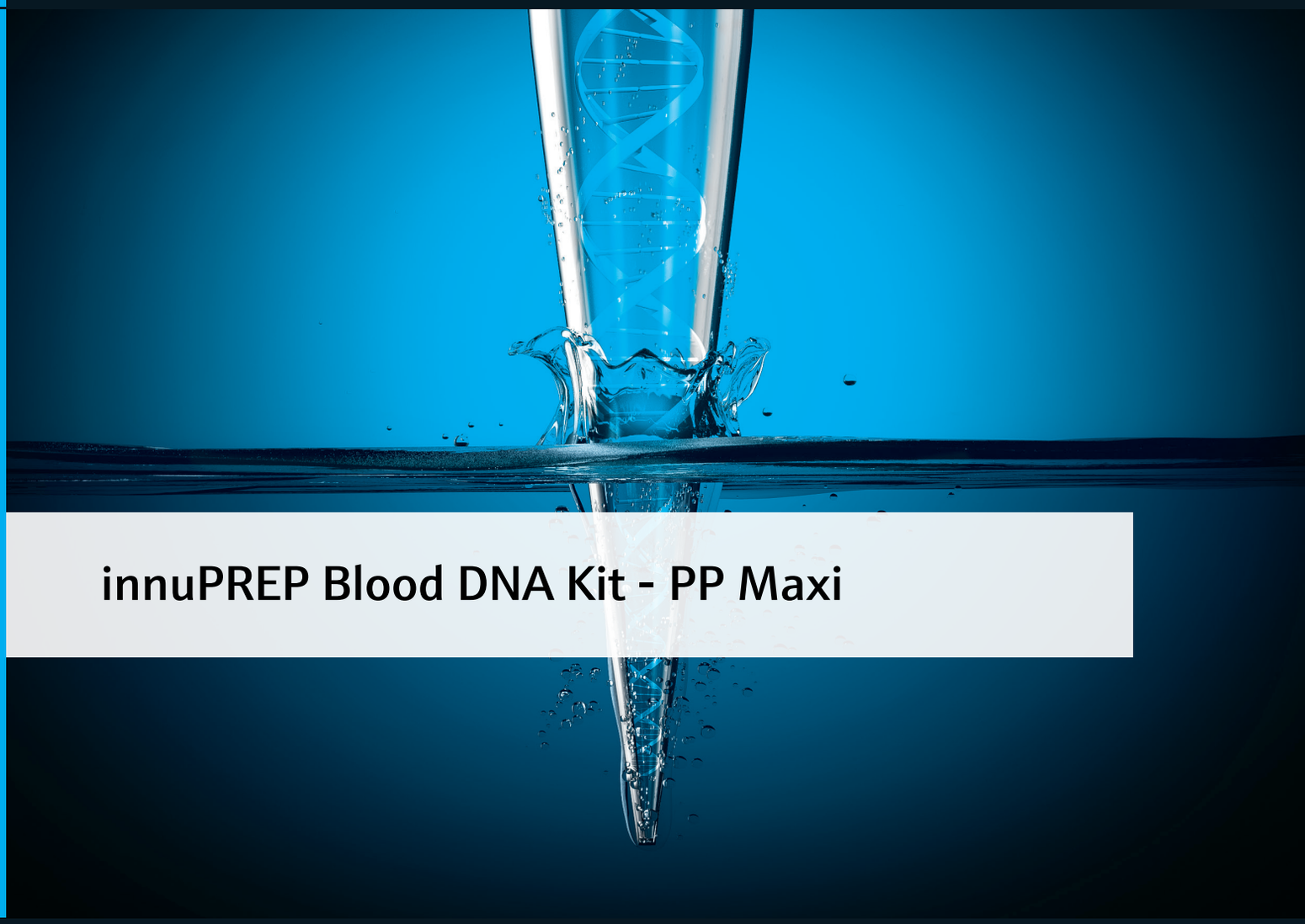
Instructions for Use
Life Science Kits & Assays



innuPREP Blood DNA Kit - PP Maxi

Innuscreen GmbH

Order No.:

845-PL-0040096	96 reactions
845-PL-0040960	960 reactions

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This documentation describes the state at the time of publishing.
It needs not necessarily agree with future versions. Subject to change!

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1 Introduction

1.1 Intended use

The **innuPREP Blood DNA Kit – PP Maxi** has been designed for the automated isolation of genomic DNA from whole blood on the PurePrep Maxi device. The extraction procedure is based on a new kind of chemistry.

The extraction procedure takes place on the magnetic particle processor PurePrep Mini and allows the parallel and flexible extraction of 1 up to 96 samples.

The extraction process starts with sample lysis on the PurePrep Maxi followed by binding of DNA on the surface of the magnetic particle. After washing the DNA is eluted in Elution Buffer.

The kit is intended for use by professional users. The kit has been designed to be used for a wide range of different downstream applications, like amplification reactions and further analytical procedures.

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	**REF** Catalogue number.
Σ N	**Content** Contains sufficient reagents for <N> reactions.
15 °C 30 °C	**Storage conditions** Store at room temperature or shown conditions respectively.
	Consult instructions for use This information must be observed to avoid improper use of the kit and the kit components.
	Expiry date
LOT	**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 ensure correct function of the kit and 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 and the kit“ 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 shall only be handled 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 could be used with potentially infectious 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 or RNA isolation should be free of DNases or RNases.

ATTENTION!
Do not add bleach or acidic components to the waste after sample preparation!

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 and the Safety Data Sheet (SDS) please contact sds.innu@ist-ag.com.

3 Storage conditions

All kit components are shipped at ambient temperature.

Upon arrival, store lyophilized and dissolved **Proteinase K** and **MAG Suspension F** at 4 °C to 8 °C.

All other components of the kit 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 are at 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 improve their performance and design. If you have any questions or problems regarding any aspects of the **innuPREP Blood DNA Kit – PP Maxi** 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. 8). Since the performance characteristics of IST Innuscreen GmbH kits have only 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 equivalents in other countries.

All products sold by 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

This kit is for research use only!

6 Kit components

6.1 Components included in the kit

	Σ 96	Σ 960
REF	845-PL-0040096	845-PL-0040960
Lysis Solution CBV (2x)	30 ml	320 ml
MAG Suspension F	2 x 250 µl	5 x 1.1 ml
Binding Solution SBS	30 ml	2 x 150 ml
Proteinase K	2 x for 1.5 ml working solution	16 x for 1.5 ml working solution
Washing Solution A	90 ml	850 ml
Washing Solution B2 (conc.)	80 ml	340 ml
Washing Solution ER	85 ml	2 x 450 ml
Elution Buffer	25 ml	2 x 110 ml
Manual	1	1

6.2 Components not included in the kit

- 96 %–99.8 % ethanol (molecular biology grade, undenatured)
- ddH_2O; ultrapure for dissolving Proteinase K
- 96 FlatWell plates, 96 DeepWell plate and tip combs for PP Maxi device (available from IST Innuscreen GmbH)

7 Product specifications

1. Starting material:

- 200 µl whole blood (EDTA / Citrate)

2. Time for automated extraction protocol on PurePrep Maxi:

- Appr. 60 minutes for air drying
- Appr. 50 minutes for ethanol removal with Washing Solution ER

8 Initial steps before starting

- Add 1.5 ml ddH_2O to each vial of **Proteinase K**, mix thoroughly and store as described above.
- Add the indicated volume of absolute ethanol to **Washing Solution B2 (conc.)** and mix thoroughly. Always keep the bottle firmly closed!

845-PL-0040096	Add 120 ml ethanol to 80 ml **Washing Solution B2**
845-PL-0040960	Add 510 ml ethanol to 340 ml **Washing Solution B2**.

- Avoid freezing and thawing of starting material.

9 Sample Preparation

9.1 Isolation of 200 µl whole blood

1. Label one Deep Well Plate “Lysis Plate”.
2. Transfer **200 µl** of the whole blood sample into the wells of the Deep Well Plate labeled “Lysis Plate”.
3. Add **300 µl Lysis Solution CBV (2x)** and add **20 µl Proteinase K** to each well used.
4. Proceed with “Extraction Protocol ” on p.11.

10 Extraction Protocol

10.1 Prefilling of Plates

Label and fill the 96 Well plates according to the table below.

Plate	Position	Label	Content
Deep Well	1	Tip Comb Plate	96 Well Tip Comb
Deep Well	2	Lysis Plate	Samples (including Lysis Solution CBV (2x) and Proteinase K)
Deep Well	3	Washing A	800 µl Washing Solution A
Deep Well	4	Washing B2	800 µl Washing Solution B2
Deep Well	5	Washing B2	800 µl Washing Solution B2
***Deep Well**	6	Washing ER	800 µl Washing Solution ER
Flat Well	8	Elution Plate	100 - 200 µl Elution Buffer

*optional, ethanol removal with Washing Solution ER instead of air drying

10.2 Loading the PurePrep Maxi with filled plates

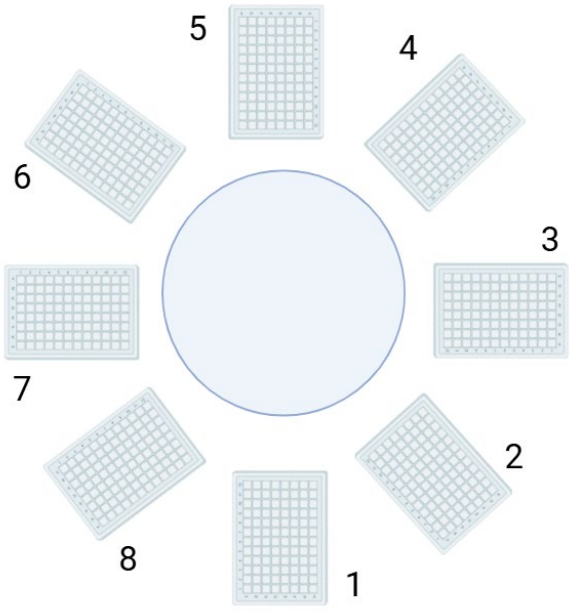

Fig. 1: Arrangement of the Plates in the device

1. Place the plates on the working table of the extraction device according to Fig.1.
2. Select the protocol “BloodPP96“ for airdrying or select “BloodPP96ER” for ethanol removal with Washing Solution ER and start the run.
3. The automated extraction process starts with sample lysis. After sample lysis the automated run stops.
4. After the device has stopped, take the Lysis Plate out of the device and add **5 µl** of well mixed **MAG Suspension F** and **285 µl** of **Binding Solution SBS** to the lysed samples.

NOTE

Mix the **MAG Suspension F** well by vortexing for 1 minute.

5. After adding **MAG Suspension F** and **Binding Solution SBS,** place the Lysis Plate back into the PurePrep Maxi and continue the extraction process by starting the device (you will find the instruction on the display of the PurePrep Maxi).
6. After finishing the extraction protocol, the Flat Well Plate contains the isolated DNA.

IMPORTANT NOTE

Store the DNA under adequate conditions.

We recommend storing the extracted DNA at −22 °C to −18 °C.

If the eluate contains carryover of magnetic particles, place the plate on a magnet or centrifuge the plate at maximum speed for 3 minutes. Pipet the supernatant with DNA into a new plate.

11 Troubleshooting

Problem / probable cause	Comments and suggestions
Low amount of extracted DNA	
Insufficient lysis	Prolong lysis time. Reduce amount of starting material.
Low concentration of extracted DNA	
Too much Elution Buffer	Elute the DNA in a lower volume of Elution Buffer (min. 80 µl).

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