

Instructions for Use

Life Science Kits & Assays



innuPREP FFPE DNA Kit - IPC16

Order No.:

845-IPS-5916016 16 reactions
845-IPP-5916016 16 reactions
845-IPS-5916096 96 reactions
845-IPP-5916096 96 reactions
845-IPP-5916480 480 reactions

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

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1 Introduction

1.1 Intended use

The **innuPREP FFPE DNA Kit – IPC16** has been designed for automated isolation of genomic DNA from formalin-fixed, paraffin-embedded (FFPE) samples using the **InnuPure C16 touch**. The extraction procedure is based on a new patented chemistry.

The procedure starts with an external lysis step without the need for a deparaffinization step using toxic and hazardous components like octane or xylene. After the external lysis and incubation step the **MAG Suspension F** and the samples are transferred into the **Reagent Strips** or **Reagent Plate** of the kit, which is already prefilled with all extraction reagents needed for the extraction process. The following extraction process runs automatically on the **InnuPure C16 touch**. The extraction process is based on binding of the DNA to surface-modified magnetic particles. After washing steps the nucleic acid is eluted from the magnetic particles with RNase-free water and is now ready to use. The extraction chemistry in combination with the **InnuPure C16 touch** protocol is optimized to get maximum yield and quality.



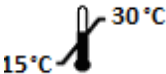





CONSULT INSTRUCTION FOR USE



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 ensure correct function of the device 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 to 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. IST Innuscreen GmbH has not tested the liquid waste generated during using the kit for potential residual infectious components. This case is highly unlikely, but cannot be excluded completely. 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

The kit is 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 **innuPREP FFPE DNA Kit – IPC16** 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.

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

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 FFPE DNA Kit – IPC16** 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 (→ "Intended use" p. 2) (→ "Product specifications" p. 10). 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.

6 Kit components

6.1 Components included in the kit

	 16	 96	 480
REF	845-IPS-5916016 ^a 845-IPP-5916016 ^b	845-IPS-5916096 ^a 845-IPP-5916096 ^b	845-IPP-5916480 ^b
MAG Suspension F	0.25 ml	1.1 ml	5 × 1.1 ml
Lysis Solution BC	2 × 2 ml	2 × 12 ml	2 × 60 ml
Solution QPS	2 × 2 ml	25 ml	2 × 60 ml
Proteinase K	For 3 × 0.3 ml working solution	For 3 × 1.5 ml working solution	For 13 × 1.5 ml working solution
Reagent Strip I ^a	16 (pre-filled, sealed)	96 (pre-filled, sealed)	--
Reagent Plate I ^b	2 (pre-filled, sealed)	12 (pre-filled, sealed)	60 (pre-filled, sealed)
Filter Tips	2 × 16	2 × 96	10 × 96
Elution Tubes (0.65 ml)	16	2 × 48	10 × 48
Elution Caps (Stripes)	2	12	5 × 12
Elution Strips	2	12	5 × 12
Manual	1	1	1

6.2 Components not included in the kit

- ddH₂O for dissolving Proteinase K
- 1.5 ml tubes
- 2.0 ml tubes, optional

- Piercing Tool (12 well Piercer; 845-PTS-0000005, IST Innuscreen GmbH, Germany)

7 Initial steps before starting

- Add the indicated amount of ddH₂O to each vial of **Proteinase K**, mix thoroughly and store as described above.

845-IPS-5916016	Add 0.3 ml ddH ₂ O to lyophilized Proteinase K.
845-IPP-5916016	

845-IPS-5916096	Add 1.5 ml ddH ₂ O to lyophilized Proteinase K.
845-IPP-5916096	

845-IPP-5916480	Add 1.5 ml ddH ₂ O to lyophilized Proteinase K.
-----------------	--

- Heat thermal mixer or water bath to 65 °C and 90 °C.
- Centrifugation steps should be carried out at room temperature.
- Invert the Reagent Plate / Reagent Strips for 3–4 times and thump it onto a table to collect the prefilled solutions at the bottom of the wells.

8 Product specifications

1. Starting material:
 - FFPE tissue samples
 - Approx. $2 \times 5 \mu\text{m}$; optional more starting material

2. Time for isolation:

Preliminary steps: approx. 3.75 hours

Extraction protocol	Protocol on InnuPure C16 <i>touch</i>	Time InnuPure C16 <i>touch</i>	Elution volumes
External Lysis 200 μl – 05	200 μl	52 min	20–500 μl
External Lysis 200 μl – Fast – 05	200 μl	41 min	20–500 μl

3. Typical yield:
 - Depending on amount and quality of starting material.

9 Protocol: Lysis of FFPE tissue samples

NOTE

The lysis of the starting material is a preliminary manual step. Heat two thermomixers or water baths to 65 °C and 90 °C, respectively.

1. Place the FFPE tissue sample (approx. 2x 5 µm or 1x 10 µm; optional more starting material) into a 2.0 ml reaction tube, close the cap and centrifuge the reaction tube at max. speed for 1 minute.
 2. Open the reaction tube and add **200 µl Lysis Solution BC** and **40 µl Proteinase K** to the sample and mix vigorously by pulsed vortexing for 10 seconds. Centrifuge briefly to remove drops from the lid of the tube.
-

NOTE

The FFPE tissue sample must be covered by **Lysis Solution BC** completely!

3. Incubate the reaction tube at 65 °C for 2.5 hours in a thermal mixer under continuous shaking at 1,000 rpm.
-

NOTE

Overnight incubation at 65 °C may increase the DNA yield. However, for most types of FFPE tissue sample the incubation at 65 °C for 2.5 hours is sufficient.

We recommend using a shaking platform (thermomixer, water bath or another rocking platform) for a continuous shaking of the sample. Vortex the sample optionally during incubation.

4. After the lysis step place the sample into a second thermal mixer pre-heated to 90 °C and incubate the sample for 1 hour.

NOTE

Do not place the sample into the thermal mixer, before the temperature of 90 °C is achieved!

We recommend using a shaking platform (thermomixer, water bath or another rocking platform) for a continuous shaking of the sample. Vortex the sample optionally during incubation.

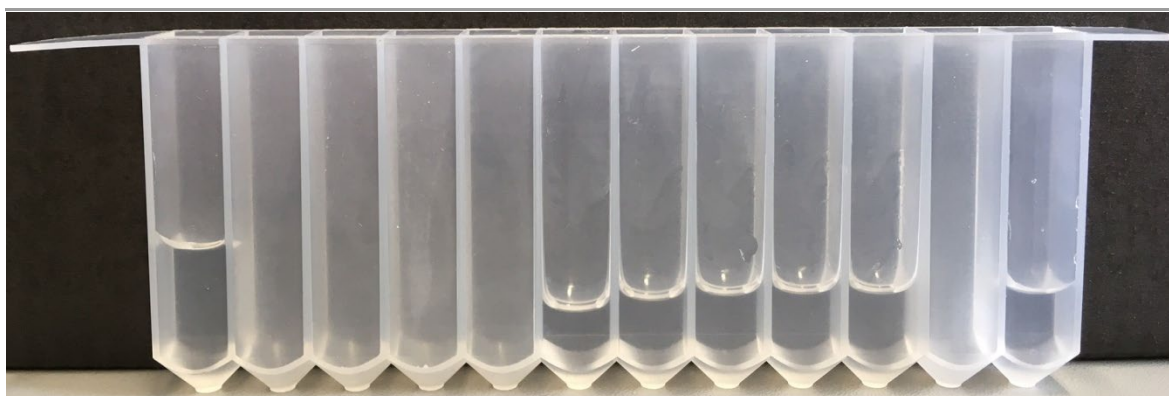
-
5. Open the reaction tube and add **200 µl Solution QPS** to the sample, mix vigorously by pulsed vortexing for 5 seconds.
 6. Centrifuge the reaction tube at max. speed for 1 minute.
 7. Proceed with automated extraction (→ "Preparing Reagent Plate / Strip for automated extraction", p. 13).

NOTE

If there is a thin film of paraffin above the sample, pierce this film carefully with pipette and carefully remove the sample.

10 Preparing Reagent Plate / Strip for automated extraction

10.1 General filling scheme of reagent reservoir



Cavity 1:	RNase-free Water	Cavity 7:	Washing Solution
Cavity 2:	Empty	Cavity 8:	Washing Solution
Cavity 3:	Empty	Cavity 9:	Washing Solution
Cavity 4:	Empty	Cavity 10:	Washing Solution
Cavity 5:	Empty	Cavity 11:	Empty
Cavity 6:	Binding Solution	Cavity 12:	Elution Buffer

10.2 Unpacking of Reagent Plate or Reagent Strip

NOTE

According to transport regulations Reagent Reservoirs are wrapped into plastic bags only when transported by airplane.



Reagent Plates or Reagent Strips are delivered wrapped into plastic bags for transport protection.

Carefully open the overpack of Reagent Plates or Strips by using scissors.

10.3 Piercing of sealing foil of Reagent Plate or Reagent Strip

NOTE

Before using Reagent Plates or Strips the sealing foil has to be pierced manually. Always wear gloves while piercing of the foil!



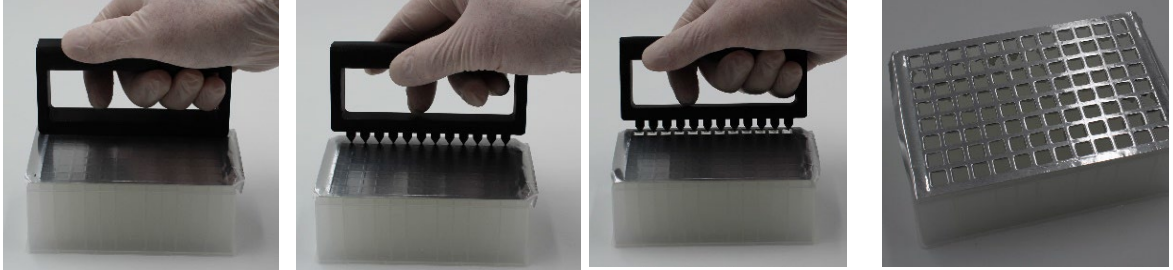
Reagent Plates or Strips are prefilled with extraction reagents and are sealed with a foil. Prior to use this foil has to be pierced manually, by using the piercing tools (12 well piercer).

Keep the Reagent Plates or Strips in a horizontal position to avoid spilling of the reagents while piercing of the foil.

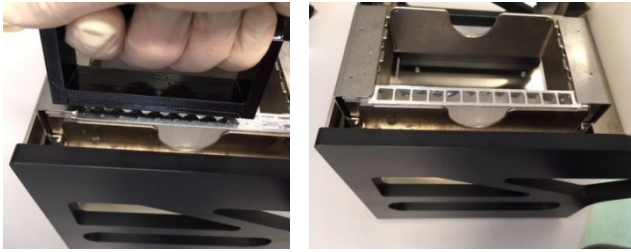
Open all cavities (one row per sample).

Preparing Reagent Plate / Strip for automated extraction

Using Reagent Plates



Using Reagent Strips



10.4 Loading the sample to Reagent Plate or Reagent Strip

NOTE

It is important to mix the **MAG Suspension F** by vigorous shaking or vortexing before use (approx. 30 seconds)!

Ensure the foils of Reagent Plate or Reagent Strips have been pierced (→ „Preparing Reagent / Strip for automated extraction“ p. 13).

1. Transfer **10 µl** of **MAG Suspension F** directly into the liquid of the **first cavity** of Reagent Plate or Reagent Strip.
-

NOTE

It is important to mix the **MAG Suspension F** by vigorous shaking or vortexing before use (approx. 30 seconds).

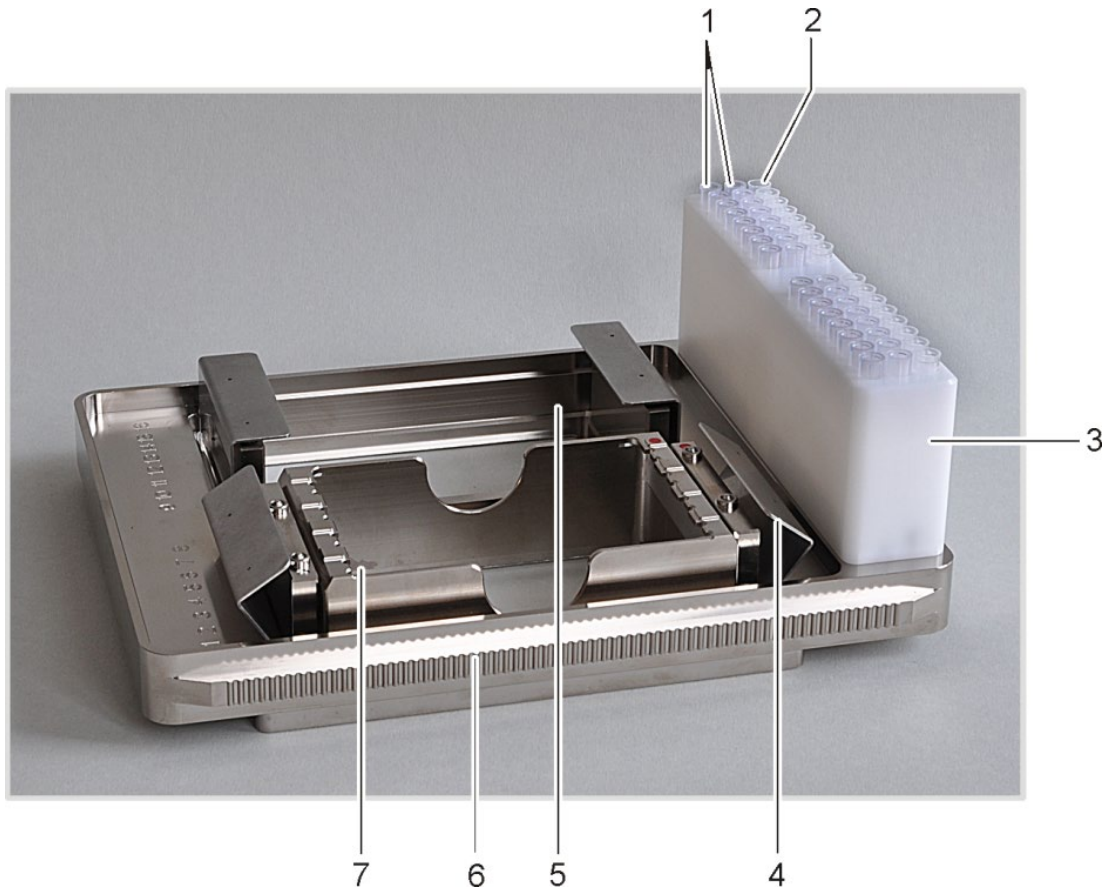
2. Transfer **400 µl** of the **lysed sample** into the **third cavity** of Reagent Strip or Reagent Plate. Avoid carry-over of residual FFPE material!
-

NOTE

The sample will be processed using the InnuPure C16 *touch*. Please follow the instructions of chapter 11 p. 17.

11 Automated extraction using InnuPure C16 *touch*

11.1 Sample tray of InnuPure C16 *touch*



No. 1: Filter tips

No. 2: Elution vessels for purified samples

No. 3: Tip block

No. 4: Holding-down clamp

No. 5: Sample block for reagent plates or adapter for reagent strips

No. 6: Guide rail

No. 7: Adapter for reagent strips

11.2 Preparing sample tray of InnuPure C16 touch

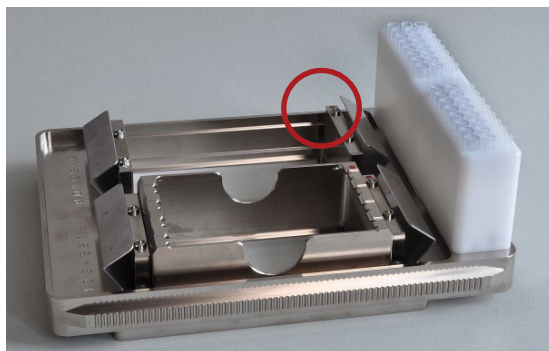
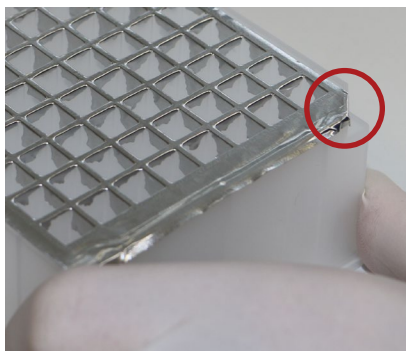
NOTE

The needed number of Reagent Strips or Reagent Plates is depending on the number of samples, which have to be processed. Don't use more strips as number of samples!

1. Place the InnuPure C16 touch sample tray into the priming station and fold the holding-down clamp at the sample tray upwards!
2. Place the Reagent Plate or an adapter with Reagent Strips into the holder of the sample tray. Using Reagent Plates, the notched corner of the Reagent Plate has to align with the colored dot at the holder. Using adapters and Reagent Strips, the colored dot of the adapter has to align with the colored dot at the holder and Reagent Strips have to be inserted in a way that the "AJ" labels are arranged at the side of the adapter which is more distant from the tip block.

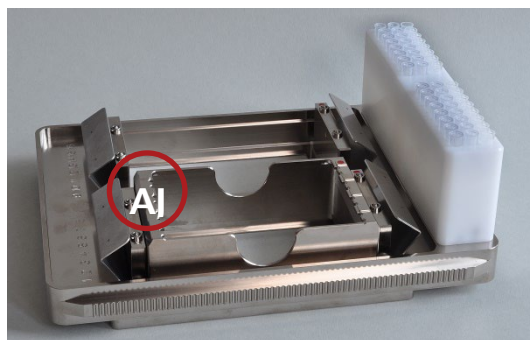
Reagent Plate

The notched corners of the Reagent Plate must point to the colored dot on the holder.



Reagent Strips

Place the strips into the adapter. The long tab marked with the label "AJ" must point to the side of the adapter which is more distant from the tip block.



CAUTION

Both holders have to be equipped with a Reagent Plate or Reagent Strips. If applicable use an empty or dummy plate for the respective holder.

3. Fold down the holding-down clamp to prevent the Reagent Plates and Reagent Strips to be pulled out of the holder during the extraction process.
 4. For each extracted sample place two filter tips in the smaller drill holes of the tip block.
 5. Place the Elution Tubes into the wider drill hole at the edge of the tip block. Empty sample positions do not need to be filled.
-

NOTE

Especially with the Reagent Strips make sure that for every strip the tips and the elution vessel are in the corresponding positions in the tip block!

IMPORTANT NOTE

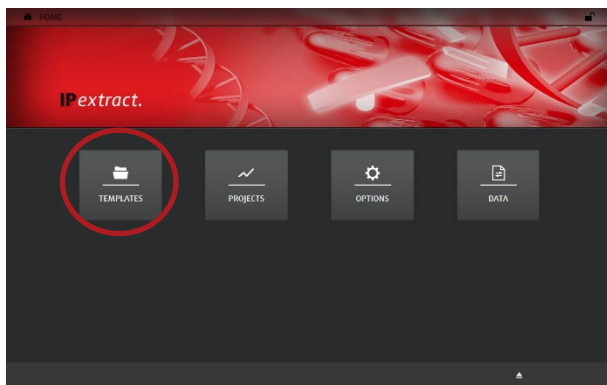
It is possible to select between two different elution vessels! For small elution volumes up to 200 µl use Elution Strips (0.2 ml). For high elution volumes up to 500 µl use Elution Tubes (0.65 ml) with corresponding Elution Caps (Stripes).

11.3 Starting the InnuPure C16 touch

NOTE

The following instructions describe the necessary steps for the start of the InnuPure C16 touch. For further features and data entry (e.g. opening templates, entering sample setups, saving projects) refer to the manual of the InnuPure C16 touch.

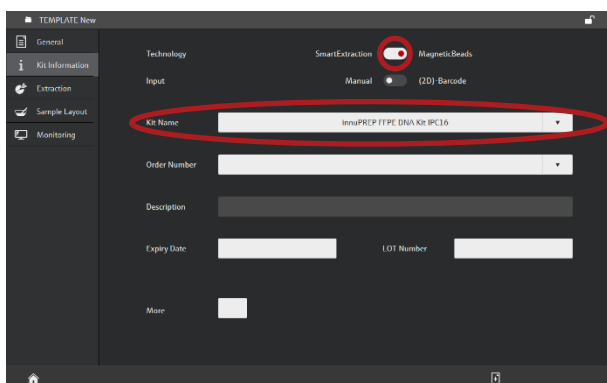
1. Switch on the InnuPure C16 touch and the tablet computer. Wait until the home screen of IPextract is displayed on the tablet screen.



NOTE

Home screen of IPextract

2. Choose [TEMPLATES] → [New Template] → [Kit-based].
3. Enter optional information in the tab "General".
4. Choose the tab "Kit Information" and switch the "Technology" to "MagneticBeads"!
5. Choose your desired kit from "Kit Name"!



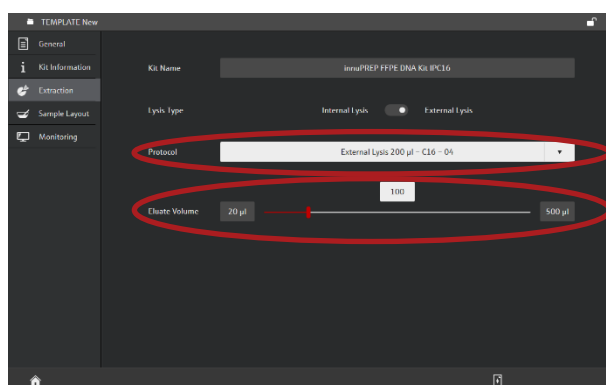
NOTE

"Kit Information" tab

6. Enter optional information in the tab "Kit Information"
7. Choose the tab "Extraction" and choose the desired "Protocol"

Extraction procedure	Protocol on InnuPure® C16 <i>touch</i>
Standard (maximum yield, approx. 52 minutes)	External Lysis 200 µl - 05
Fast (time-optimized, approx. 41 minutes)	External Lysis 200 µl - Fast - 05

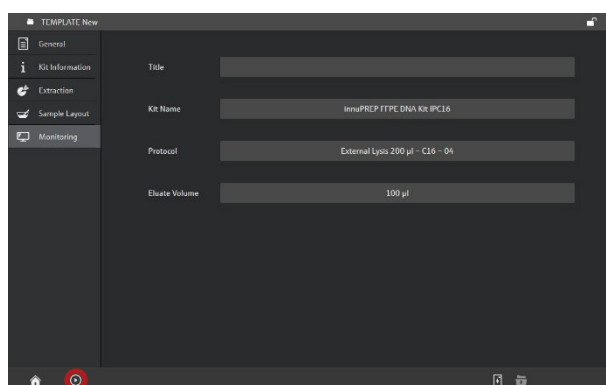
8. Adjust your desired "Eluate Volume" using the slider or the text field.



NOTE
"Extraction" tab

The recommended elution volume is 100 µl.

9. Choose the tab "Monitoring" and start the protocol by tapping the start button.



NOTE
"Monitoring" tab

10. Follow the instructions displayed on the tablet screen.
11. Completion of the protocol is indicated by a message on the tablet screen. Follow the instructions on the screen to remove the sample tray from the device.

12. The Elution Tubes contain the extracted DNA. Close the lids and store the DNA under proper conditions.
-

NOTE

Store the DNA under adequate conditions. We recommend storing the extracted DNA at -22 °C to -18 °C!

12 Troubleshooting

Problem / probable cause	Comments and suggestions
Low amount of extracted genomic DNA	
No extracted DNA	No magnetic beads added to cavity 1. Please add 10 µl MAG Suspension F to cavity 1 prior the extraction procedure. Ensure Mag Suspension F has mixed well before use.
Poor quality of extracted DNA	Avoid carryover of residual FFPE material when transferring lysed sample to cavity 3 of Reagent Plate/Strip.
Insufficient lysis of starting material	Perform lysis at 65 °C for at least 2.5 hours. Ensure to use the required volume of Proteinase K and Lysis Solution BC .
Elution volume too high	Decrease the elution volume. The suggested elution volume is 100 µl. Please note that lowering the elution volume will not necessarily increase the yield proportional!

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