INVITEK
Molecular

USER MANUAL
InviMag® FFPE DNA Kit/ IG

for fully automated purification of genomic DNA from FFPE samples with magnetic beads

REF 2432120100

Invitek Molecular GmbH · D-13125 Berlin

Instruction for InviMag® FFPE DNA Kit/ IG

The **InviMag® FFPE DNA Kit/ IG** combines the advantages of the innovative InviMag® technology with easy handling of paramagnetic particles of high purity in combination with the InviGenius® robotic platform.

The **InviMag® FFPE DNA Kit/ IG** in combination with the InviGenius® is the ideal tool for a walk-away automated isolation of highly pure genomic DNA.

The nucleic-acid-binding paramagnetic particles are characterized by a specific surface, a uniform size distribution and good suspension stability.

The **InviGenius®** is a compact walk-away DNA extraction platform with full in-process control, including the following modules e.g. like a pipettor, heat incubator, barcode reader, magnet tool, PC and touch screen, barcode labelled sample racks for primary tubes and barcode labelled reagent racks, which helps to deliver premium quality nucleic acid for routine laboratories by eliminating human errors, standardizing the extraction process, and offering an integrated Para-X Solution, data storage, backup and archiving using unique bar codes for samples and reagents to avoid unwanted transpositions.

Due to the high purity, the isolated DNA is ready to use for a broad panel downstream applications or can be stored at –20°C for subsequent use.

Contents

Kit contents of InviMag® FFPE DNA Kit/ IG

Component	8 x 12 reactions	Reagent sufficient for
Catalogue No.	2432120100	
Para-X Solution*	2 x 8.2 ml	
Lysis Buffer HLT	30 ml	96 samples (in max. 12 runs)
Proteinase S/ IG	4 x 3 ml	24 samples (in max. 3 runs/ tube)
MAP Solution B/ IG	2.6 ml	96 samples (in max. 12 runs)
SNAP Solution	2.6 ml	96 samples (in max. 12 runs)
Binding Solution (fill with 99.7% Isopropanol)	empty bottle (final volume 70 ml)	96 samples (in max 12 runs)
Ethanol (fill with 96-100% Ethanol)	empty bottle (final volume 125 ml)	96 samples (in max 12 runs)
Wash Buffer II	60 ml	96 samples (in max. 12 runs)
Elution Buffer M	100 ml	96 samples (in max 12 runs)
Incubation Plate A	4	2 runs per plate
Working Plate B	4	2 runs per plate
Elution Plate E	1	8 runs per plate
Microtube Caps	8	
Sheath Box	1 (2 racks á 48 sheaths)	4 runs per rack
Sealing Foils	4	
Incubator Stripe Foils	2	
Initial steps	Add 70 ml of **99.7% Isopropanol** (molecular biologic grade) into the empty bottle labelled **Binding Solution** Add 125 ml of 96-100% **Ethanol** to the bottle **Ethanol.**	

***If Para-X-Solution is solid please wait and leave it at room Room Temperature until the whole liquid is dewed.**

Symbols


Manufacturer


Lot number


Catalogue number


Expiry date


Consult operating instructions


Temperature limitation


Do not reuse


Humidity limitation

Attention: *Do not combine components of different kits, unless the lot numbers are identical!*

Storage

All buffers and kit contents of the **InviMag® FFPE DNA Kit/ IG** should be stored at room temperature and are stable for at least 12 months.

Room temperature (RT) is defined as range from 15 - 30°C.

Before every use, make sure that all components have room temperature. If there are any precipitates within the provided solutions solve these precipitates by warming carefully (up to 30°C).

All bottles and tubes should be appropriately sealed after the run and stored at room temperature.

Quality Control and product warranty

Invitek Molecular warrants the correct function of the **InviMag® FFPE DNA Kit/ IG** for applications as described in this manual. Purchaser must determine the suitability of the product for its particular use. Should any product fail to perform the applications as described in the manual, Invitek Molecular will check the lot and if Invitek Molecular investigates a lot connected problem, the product will be replaced free of charge.
Invitek Molecular reserves the right to change, alter, or modify any product to enhance its performance and design at any time.
In accordance with Invitek Molecular's EN ISO 13485 certified Quality Management System, the performance of all components of the **InviMag® FFPE DNA Kit/ IG** have been tested separately against predetermined specifications routinely on lot-to-lot to ensure consistent product quality.
In case of any questions or problems regarding any aspects of **InviMag® FFPE DNA Kit/ IG** or other Invitek Molecular products, please do not hesitate to contact us. A copy of Invitek Molecular's terms and conditions can be obtained upon request or are presented at the Invitek Molecular webpage.

For technical support or further information, please contact:

from Germany: +49-(0)30-9489-2901/ 2910
from abroad: +49-(0)30-9489-2907

or contact your local distributor.

Intended use

The **InviMag® FFPE DNA Kit/ IG** is designed for fully automated extraction and purification of DNA from 12 samples per run by using paramagnetic beads in combination with the **InviGenius® Plus**. All utilities you need additional to the **InviMag® FFPE DNA Kit/ IG** see page 9.

The nucleic acid isolation protocol is suitable for routinely walk-away automated preparation of genomic DNA from FFPE samples. For an efficient extraction the appropriate sample storage is essential (see “Sampling and storage of the starting material”, page 7).

The procedure of the **InviMag® FFPE DNA Kit/ IG** is optimized for the isolation of nucleic acids from FFPE material.

THE PRODUCT IS INTENDED FOR USE BY PROFESSIONALS SUCH AS TECHNICIANS, PHYSICIANS AND BIOLOGISTS TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES. It is designed to be used with any downstream application employing enzymatic amplification or other enzymatic modifications of DNA followed by signal detection or amplification. Any diagnostic results generated by using the sample preparation procedure in conjunction with any downstream diagnostic assay should be interpreted with regard to other clinical or laboratory findings. To minimize irregularities in diagnostic results, adequate controls for downstream applications should be used.

Product use limitation

The kit is validated for FFPE material. Related applications will need a separate validation. Extraction of other than human DNA from FFPE material has not been evaluated with this kit.

Differing of starting material may lead to inoperability. Therefore, neither a warranty nor guarantee in this case will be given, implied or expressed. The included chemicals are only useable once.

The user is responsible to validate the performance of the Invitek Molecular product for any particular use. Invitek Molecular does not provide validations of performance characteristics of the product with respect to specific applications.

Invitek Molecular products may be used e.g. in clinical diagnostic laboratory systems under following conditions:

- If used in the US, based on the condition that the complete diagnostic system of the laboratory has been validated pursuant to CLIA’ 88 regulations.
- For other countries based on the condition that the laboratory has been validated pursuant to equivalents according to the respective legal basis.

All products sold by Invitek Molecular are subject to extensive quality control procedures (according to EN ISO 13485) and are warranted to perform as described herein. Any problems, incidents or defects shall be reported to Invitek Molecular immediately upon detection thereof.

The chemicals and the plastics are for laboratory use only. They must be stored in the laboratory and must not be used for other purposes than intended.

The product with its contents is not suitable for consumption.

Safety information

When and while working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles!

Avoid skin contact! Adhere to the legal requirements for working with biological material!

For more information, please consult the appropriate material safety data sheets (MSDS). These are available online in convenient and compact PDF format at www.invitek-molecular.com for each Invitek Molecular product and its components. If buffer bottles are damaged or leaking, **WEAR GLOVES AND PROTECTIVE GOGGLES** when discarding the bottles in order to avoid any injuries.

Invitek Molecular has not tested the waste generated by the **InviMag® FFPE DNA Kit/ IG** procedures for residual infectious materials. Contamination of the waste with residual infectious materials is unlikely, but cannot be excluded completely. Therefore, the waste has to be considered infectious and should be handled and discarded accordingly to local safety regulations.

Subsequently European Community risk and safety phrases for the components of the **InviMag® FFPE DNA Kit/ IG** are listed.

Lysis Buffer HLT

Warning

H302-H315-H319, P280-P305+P351+P338

Proteinase S

Danger

H317-H318-P280-P305+P351+P338

Para-X Solution

Danger

H304, P301+P310, EUH066

H302: Harmful if swallowed.
H304 May be fatal if swallowed and enters airways
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
EUH066: Repeated exposure may cause skin dryness or cracking.

Emergency medical information can be obtained 24 hours a day from infotrac:

outside of USA: 1 – 352 – 323 – 3500
inside of USA : 1 – 800 – 535 – 5053

Product characteristics of the InviMag® FFPE DNA Kit/ IG

The **InviMag® FFPE DNA Kit/ IG** is the ideal tool for an efficient and fully automated DNA extraction and purification from FFPE samples using paramagnetic beads in combination with the InviGenius® robotic platform.

Starting Material	Yield	Time for preparation
FFPE slides FFPE material fixed on a specimen holder	depending on sample (storage and source)	about 225 min per run (12 samples)

The DNA isolation process is based on the deparaffination step and the interaction of nucleic acids with silica coated paramagnetic particles in optimal buffer conditions.

The InviGenius® PLUS will automatically perform all lysis, washing and elution steps of reagent distribution. The DNA purification procedure is performed without any user intervention, except any sample pretreatment and the initial loading of the system. Sample cross-contamination and reagent cross-over is effectively eliminated. The usage of unique bar codes for samples and reagents avoids unwanted transpositions.

The InviGenius® PLUS uses magnetic rods to transport the DNA-binding paramagnetic particles through the various extraction phases: deparaffination-lysis-bind-wash-elute. Eliminating the direct liquid handling and increasing the automation level results in a fast, reliable and robust technique.

After deparaffination and a sample specific lysis using **Lysis Buffer HLT** and **Proteinase S**, optimal binding conditions are adjusted by the addition of **Binding Solution.** The DNA binds to the added and combined paramagnetic particles **(MAP Solution B** and **SNAP Solution)** and is separated from the solution by magnetic rods controlled by the InviGenius® Plus.

Subsequent to three washing steps of the particle bound nucleic acids, the DNA is finally eluted in **Elution Buffer M**.

Due to the high purity, the eluted total DNA is ready-to-use in a broad panel of respective downstream applications.

Sampling and storage of starting material

Starting material for nucleic acid purification should be freshly cut sections of FFPE tissue, each with a maximal thickness of 20 µm. Thicker sections may result in lower yields, due to inefficient lysis. Up to 3 sections, each with a thickness of 10 µm and a surface area of up to 200 mm^2 each,
or 1 sections each with a thickness of 20 µm and a surface area of up to 200 mm^2 each,
can be combined for one preparation.
Material amount should not exceed 6 mm^3 in volume or 6 mg in weight for paraffin and sample together. If you have only FFPE tissue without paraffin, around 1 to 2 mg is enough for good results. More tissue may lead to reduced quality and yields.

If fixed in buffered formalin and embedded appropriately in paraffin DNA isolation works from FFPE material, but formalin fixation leads to reduced DNA quality (fragmented DNA). In addition, an improper contact of the tissue with formalin will reduce dramatically the yield of DNA.

For reproducible and high yields, the appropriate sample storage is essential. Yields may vary from sample to sample depending on thickness of sample slides, sample age, kind of sample, transport and storage conditions.

Invitek Molecular will be released of its responsibilities if other sample materials as described in the chapter “Intended Use” are processed or if the sample preparation protocols are changed or modified.

Principle and procedure

The **InviMag® FFPE DNA Kit/ IG** procedure comprises following steps:

- deparaffination
- lysis and protein digestion
- binding of the DNA to the paramagnetic beads
- washing the paramagnetic beads bound DNA and elimination of alcohol
- elution of DNA

After deparaffination and lysis, the nucleic acid binds to the paramagnetic beads whereas contaminations and enzymatic inhibitors are efficiently removed during the following three washing steps.

Deparaffination and Lysis
FFPE samples are deparaffinated by **Para-X Solution** while the tissue is lysed at elevated temperatures in the presence of **Lysis Buffer HLT** and **Proteinase S.**

Binding of the genomic DNA
After addition of **Binding Solution, MAP Solution B** and **SNAP Solution** (both paramagnetic beads) to the lysate, the DNA is bound to the surface of the beads.

Removing residual contaminants
Contaminants are efficiently removed by washing steps while the DNA remains bound to the paramagnetic beads.

Elution
The DNA is finally eluted in **Elution Buffer M**. The eluted DNA is ready-to-use in different subsequent downstream applications e.g. for PCR amplification, digestion with restriction enzymes, Southern hybridizations, HLA typing etc.

Yield and quality of genomic DNA from FFPE

The amount of purified genomic DNA in the **InviMag® FFPE DNA Kit/ IG** procedure from FFPE material depends on the sample source, thickness of slides, transport, storage and age.

Yield and quality of isolated DNA are suitable for any molecular-diagnostic detection system.

Different amplification systems vary in efficiency depending on the total amount of nucleic acid present in the reaction.

The kit is suitable for downstream analysis with NAT techniques, for examples PCR, qPCR, RT-qPCR, LAMP, LCR. Diagnostic assays should be performed according to the manufacturer's instructions.

Important notes

Important points before starting a protocol

Immediately upon arrival of the product, inspect the kit and its components as well as the package for any apparent visible damages and correct quantities. If there are any unconformities, please notify Invitek Molecular in writing with immediate effect upon inspection thereof. If buffer bottles are damaged, contact the Invitek Molecular Technical Services or your local distributor. In case of liquid spillage, refer to "Safety Information" (see page 6). Do not use damaged kit components, since their use may lead to poor kit performance.

- When working with chemicals, always wear a suitable lab coat, disposable gloves and protective goggles
- Discard contaminated gloves immediately
- Do not combine or merge components from kits
- Avoid microbial contaminations of the kit reagents
- To minimize the risk of infections from potentially infectious material. This kit should only be used by trained personnel

Preparing reagents and buffers

Before starting a run, equilibrate all reagents to room temperature. Where necessary, gently mix and re-dissolve any precipitates by incubation at 30°C. Swirl gently to avoid foaming.
Para-X Solution, Lysis Buffer HLT, Proteinase S, MAP Solution B, SNAP Solution, Wash Buffer II and Elution Buffer M are ready-to-use. The empty bottles have to be filled like shown in the following table.

8 x 12 DNA-extractions
Add 70 ml of 99.7% Isopropanol to the bottle **Binding Solution.** Add 125 ml of 96 - 100% Ethanol to the bottle **Ethanol**.

Reagents and equipment to be supplied by user

When working with chemicals, always wear a suitable lab coat, disposable gloves and protective goggles. For more information, please consult the appropriate material safety data sheets (MSDS). (See our webpage: www.invitek-molecular.com)

- measuring cylinder (250 ml)
- **conductive pipette tips**
- Disposable gloves
- Vortex
- *Optional*: Shaker for 96 well plates
- **96-100% Ethanol**
- **99.7 % Isopropanol*** (molecular biological grade)

*The **InviMag® FFPE DNA Kit/ IG** is validated with 2-Propanol; Rotipuran >99.7%, p.a., ACS, ISO (Order no. 6752) from **Carl Roth.**

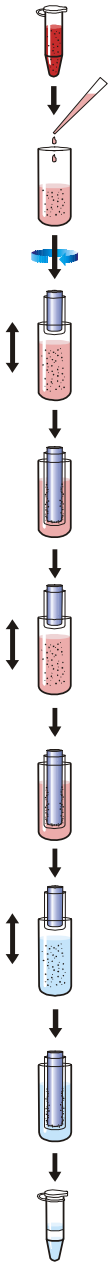
Possible suppliers for Isopropanol

Carl Roth
2-Propanol
Rotipuran >99.7%, p.a., ACS, ISO
Order no. 6752

Applichem
2-Propanol für die Molekularbiologie
Order no. A3928

Sigma
2-Propanol
Order no. 59304-1L-F

Scheme of the InviMag® FFPE DNA Kit/ IG

Add the Buffers to the Buffer loading rack.	
	Put the **FFPE slides** into the wells of lane **A** of the **Incubation Plate A**.(see page 11) Add **160 µl of Para-X Solution** to each sample, place the plate on a Plate-Shaker if available and shake until the plate is loaded to the instrument. Switch on the InviGenius® PLUS and load the instrument (see page 11-12; 19). Please do not forget to load the **Incubation Plate A with the samples**. Start the Assay. The samples are mixed with Para-X Solution, Lysis Buffer and Proteinase. Incubation at elevated temperature is performed for 150 min. In the next Lane (B) of the Incubation Plate Binding Solution and paramagnetic beads are added to the lysate. Nucleic acid binds to the paramagnetic beads. Magnetic separation Washing of the paramagnetic beads bound DNA with three Wash Buffers mixed by the machine Magnetic separation Heated elution in Elution Buffer Magnetic separation and removal of paramagnetic beads The final elution volume is about 50 µl.

Preparing the samples for processing on the InviGenius®PLUS

Please read the instructions carefully and conduct the prepared procedure.

For questions please contact: +49 30 94892901/ 10 or 2907, E-Mail: info@invitek-molecular.com

If you are unfamiliar with the DNA extraction of FFPE samples, please call us beforehand to get practical advice.

Important Note: *The protocol has been optimized for the isolation of gDNA from formalin-fixed-paraffin-embedded samples. (FFPE)*

For better sample transfer into the Incubation Plate A, FFPE slides stored in tubes can be frozen at -20°C for at least half an hour. If the tube is too warm, the paraffin sample will stick to the tube.

Prevention of cross-contamination

To comply with the demanding guidelines of *in-vitro* diagnostics we programmed the InviGenius® PLUS to route the pipettor in such a way that possible contamination-risks are minimized.

Preparing samples and plates

Incubation Plate A: Please use every Incubation Plate A **only for two runs** to avoid contaminations and for better handling with the samples

First run for the Incubation Plate A (first use):

The machine will use the first two lanes (A and B)

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Samples and Para-X Solution

Binding Lane

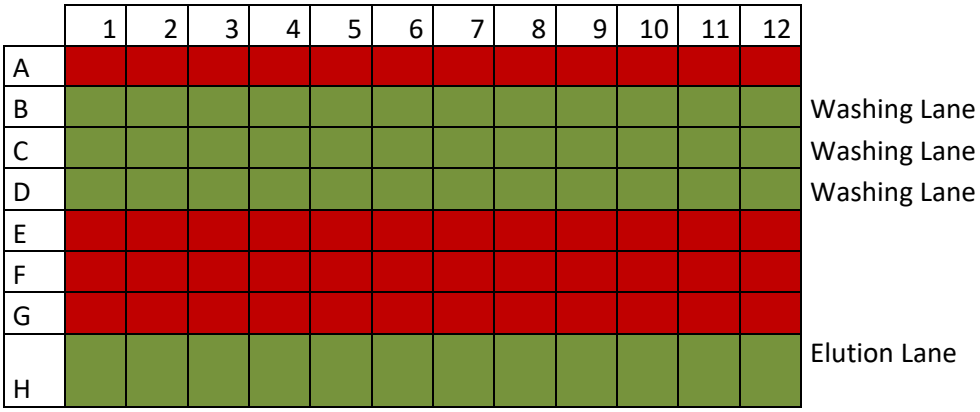
Please fill the FFPE samples into the wells of lane **A** (dark blue line, as shown above), beginning with well A1 and pipet **160 µl** of the **Para-X Solution** onto each of the samples. Place the **Incubation Plate A** on a plate shaker if available and leave it there while starting the InviGenius® Plus.

Lane A will be used for lysis step, lane B will be used for binding step by the machine.

Working Plate B: The Working Plate B can be used **for two runs**.

First run for the Working Plate B (first use):

The machine will use lanes B, C, D and H. (green)

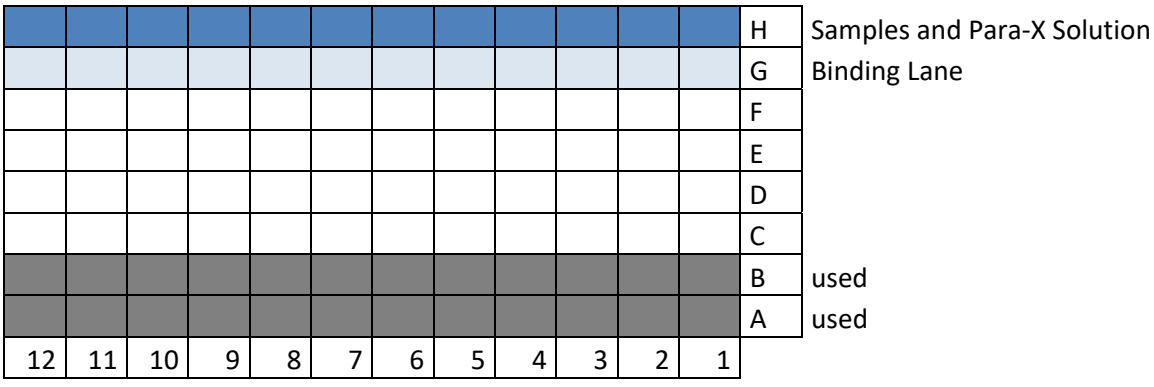


After the first run please save the two plates for the second use.

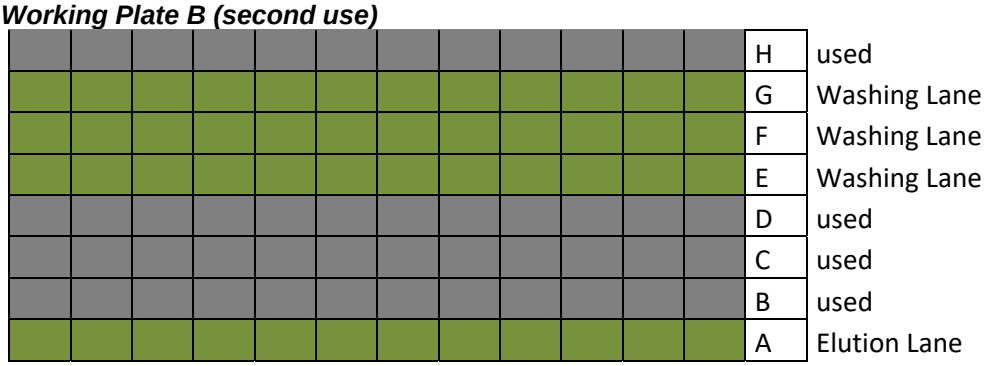
Second run for the Incubation Plate A and the Working Plate B (second use):

Please turn both plates around 180°. (In the software of InviGenius Plus load for every run a new Incubation Plate A and a new Working Plate B – see page 19)

Incubation Plate A (second use)



Working Plate B (second use)



General overview of the InviGenius® PLUS

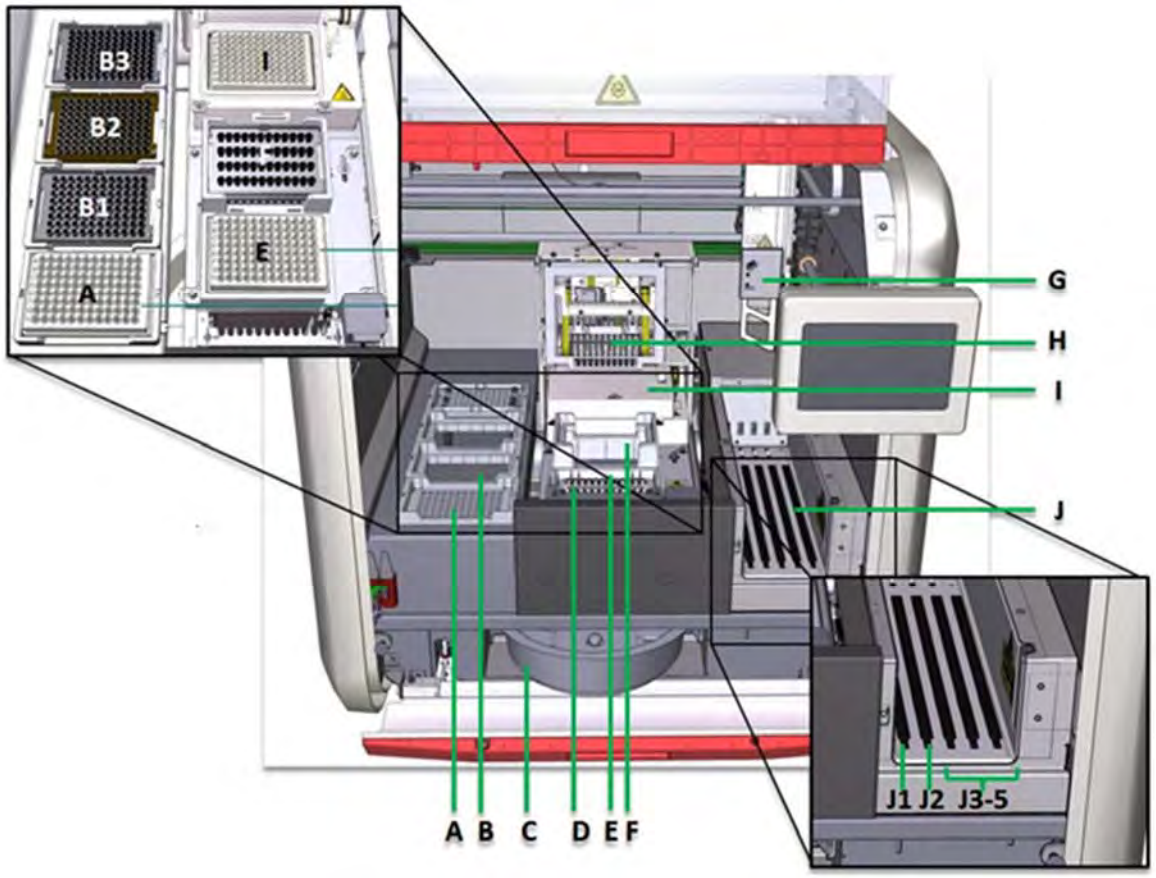


Figure 1: Frontal view of the InviGenius® PLUS

Figure 1 shows the plate positions **A** (elution position), **E** (working position) and **I** (incubation position). Disposable tips are placed on position **B1-B3** and disposable sheaths on **F**. The waste tray (must be ordered separately from Invitek Molecular GmbH) **C** is located on the lower side of the **InviGenius® PLUS** behind the red flap. The waste shaft **D** is completely stainless steel and easily removable for autoclaving.

The loading bay is divided into sample loading bay **J1,** eluate loading bay **J2** and reagent loading bay **J3-5**. The magnetic separator head (MSH) **H** is located on top of the incubator **I** and can reach all necessary positions. The single head pipettor **G** starting positions are in the right front of the machine. All movable parts only work when the **InviGenius® PLUS** is closed and locked.

Preparing and loading of the InviGenius® PLUS

Preparing the reagents

Before you start a new kit, add Ethanol to **Ethanol bottle** and Isopropanol to **Binding Solution bottle.**

Preparing the InviGenius® PLUS

Switch on the InviGenius® PLUS using the power switch located on the right side of the back part of the instrument. The InviGenius® PLUS software will be automatically loaded after the system has booted up. Please keep the door of the InviGenius® PLUS closed during system initialization.

After initialization of the InviGenius® PLUS a login screen appears (Figure 2). Log-in with the provided user name and password.

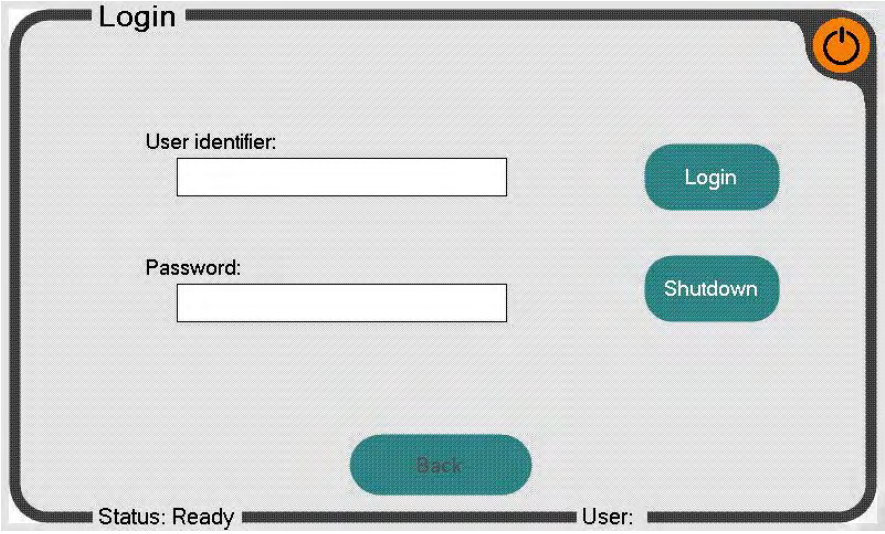


Figure 2: Login screen of the InviGenius® software

After logging in the main screen of the InviGenius® PLUS software appears (Figure 3). Select “Loading” to start with the loading procedure of the system and prepare. Go directly to “Processing” to define and run an assay if the system has been already loaded.

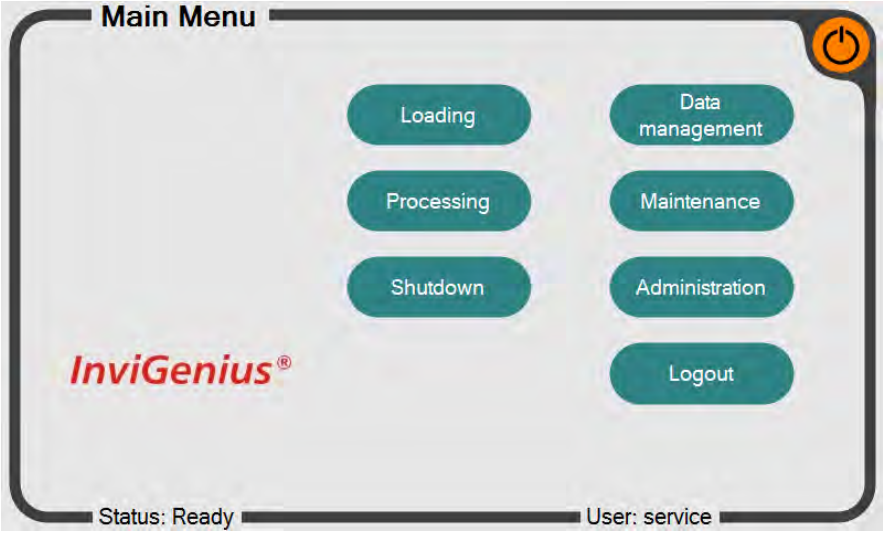


Figure 3: Main menu of the InviGenius® PLUS software

Sample Loading

After selecting “Loading” the sample loading screen appears.

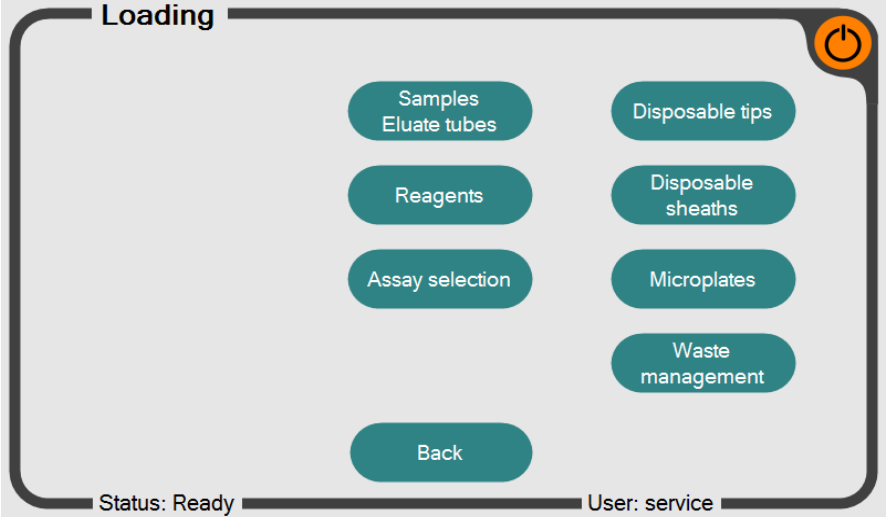


Figure 4: Loading screen of the InviGenius® PLUS software

Select “Samples” to proceed with the sample-loading-screen.

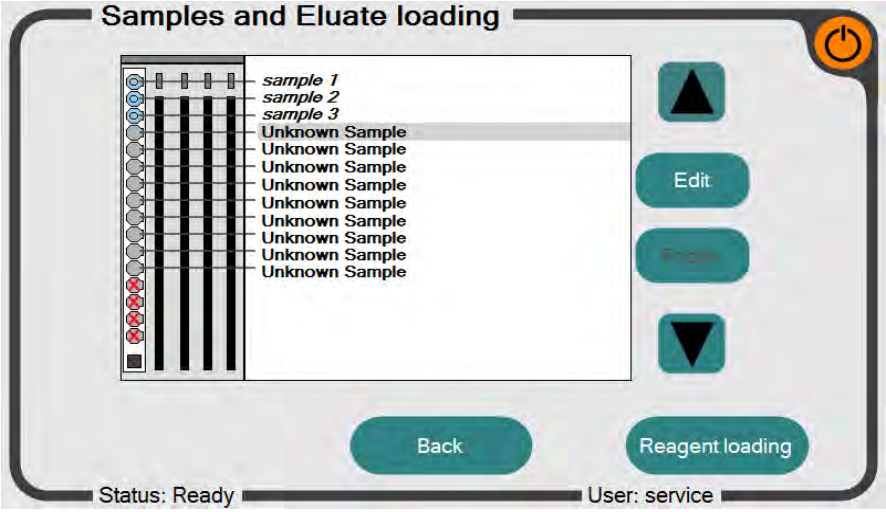


Figure 5: “Sample-loading” screen of the InviGenius® PLUS software

Please add the samples to the Incubation Plate A as shown on page 11. Add 160 µl of Para-X Solution to each sample and put the Plate with the samples on a Plate Shaker if available.

Insert the sample rack without samples into the machine as shown on the screen.

After inserting the sample rack in the very left lane of the loading bay, please push the button “Edit” to scan the barcodes of the samples or to name samples by selecting the corresponding sample by using the arrow fields, followed by pushing the “Edit” button for the next sample name (every sample needs at least 3 letters or numbers). An updated screen will show the identifiers from the samples (Figure 5).

After a certain time (app. 5 min), the bar code scanner is deactivated. In that case, the user has to restart the scanner with the “Focus” button if the loading procedure was not finished.

After successful loading of the samples proceed with reagent loading by selecting “Reagent loading” on the bottom right hand side of this screen.

Reagent Loading

The reagent loading process is analogous to the sample loading procedure.

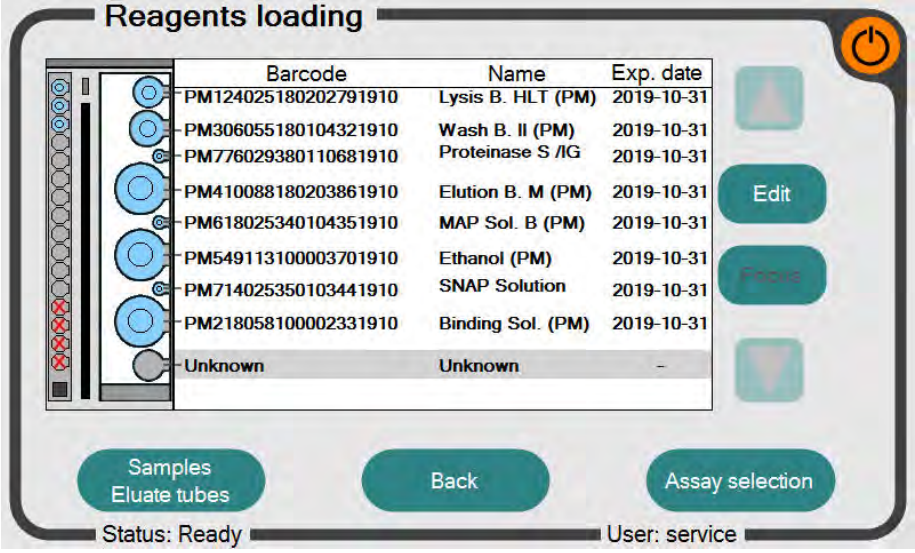


Figure 6: "Reagent-loading" screen of the InviGenius® PLUS software

Insert all provided reagents into the reagent rack of the InviGenius® Plus. Verify that the bar code labels face to the right side of the loading bay and decap the bottles and tubes. The order of the inserted reagents is not crucial because the type and position of a reagent is identified by the unique bar code. However, the possible loading positions are limited by the size of the bottles. After rack insertion, the loading status of the reagents will be shown. In case of unsuccessful reagent allocation, remove the rack, check the bar code orientation and try again slowly.

Assay Selection

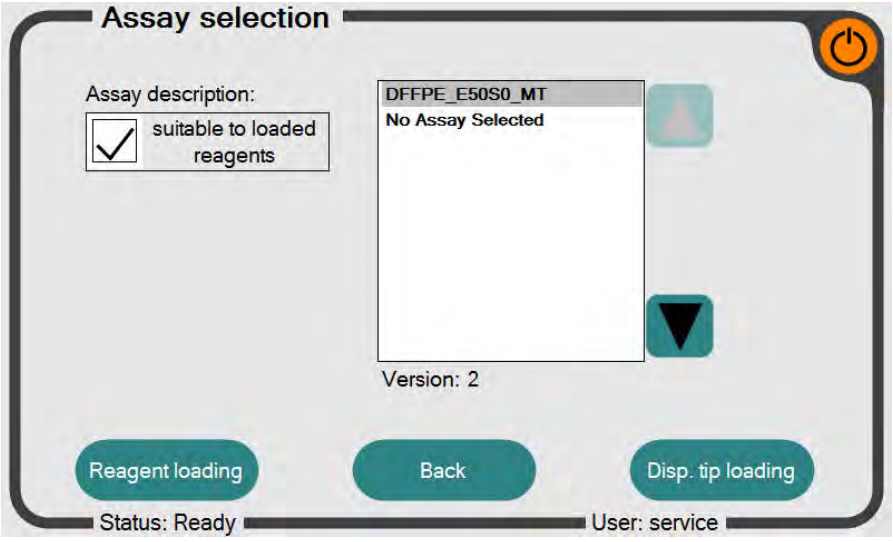


Figure 7: "Assay Selection" screen of the InviGenius® PLUS software

Select the appropriate assay and proceed with disposable tip loading. After assay selection, the system will check the availability of the buffers, shelf live, and buffer volume. If reagents are missing that are required for the run, no assay will be visible or selectable.

Disposable Tip Loading

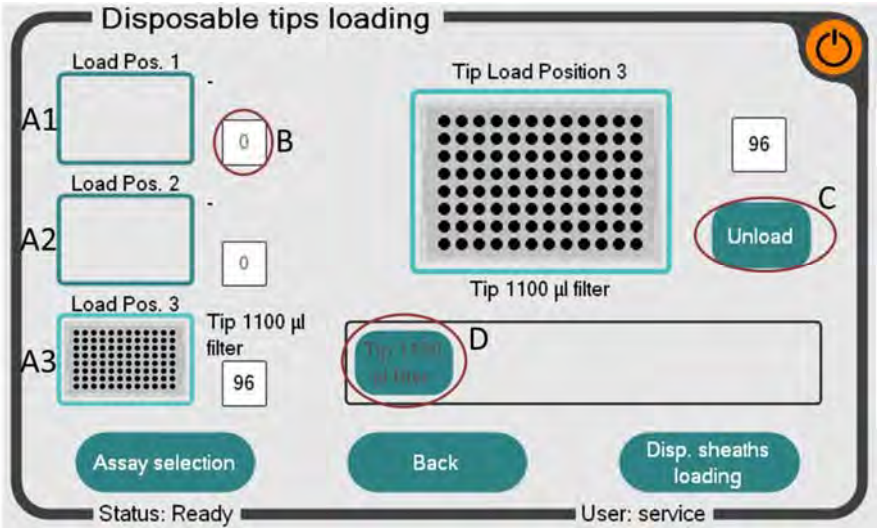


Figure 8, Disposable tip loading screen

There are three tip rack positions on the InviGenius® PLUS (Fig. 8, A1-A3). Remaining tip-numbers are shown in field (B). Tip-numbers can be changed by pressing the number-field directly.

Empty tip-racks can be unloaded and reloaded by:

1.) Pressing the Loading-Position directly (The software will focus the corresponding loading position on the main screen)

2.) Pressing the Unload-Button (C)

3.) The loading-position can be refilled with a new tip-rack by pressing on the corresponding tip-rack (D)

All protocols should be used in combination with filter tips to ensure efficient prevention of sample or reagent cross-contaminations. Invitek Molecular will give no guarantee or responsibility if contaminations occur due to the use of non-filtered tips.

Note: ***Disposable tips are not supplied within the kit. We recommend the use of validated conductive tips, which can be ordered at Invitek Molecular. See page 25. Be sure that conductive tips are used otherwise the tip detection unit, installed in the pipetting unit, will reject the tips and no run is possible.***

Disposable Sheaths Loading

The sheaths are used as protection devices for the magnetic rods. They are automatically picked up during the run.

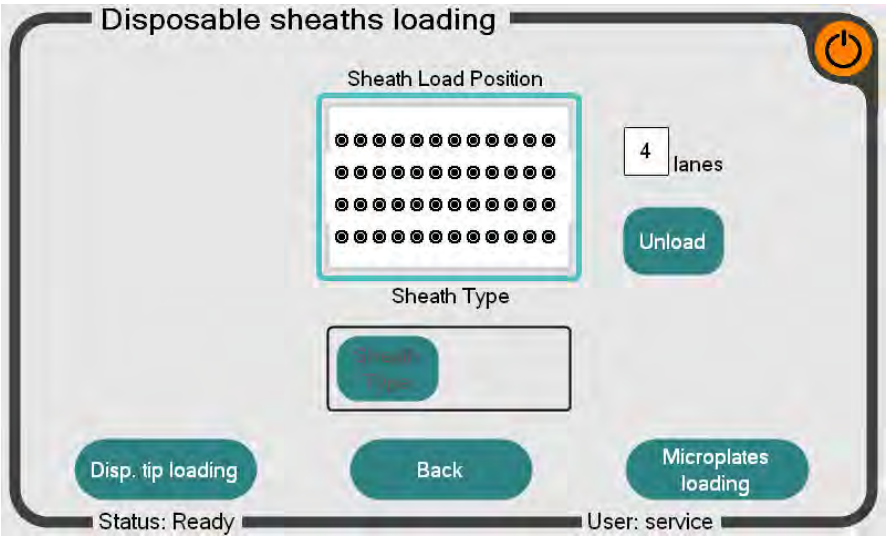


Figure 9, Disposable sheaths loading screen

The loading procedure of the disposable sheaths works analogous to the disposable tip loading screen. For a run, always 12 disposable sheaths (one row in the sheaths rack) are used, regardless of the processed sample numbers. This is done, to assure that the rods are always protected against contaminations.

In general, the number of sheaths supplied within the kit is sufficient for the amount of runs imprinted on the kit package. If you are lacking sheaths, they can be ordered separately at Invitek Molecular see page 25. Comparable to the disposable tips loading it is possible to define the number of rows left in the tip rack by pressing on the displayed number area. Make sure that the disposable sheaths are loaded (and displayed) consistent to the manually loaded sheaths in the rack to ensure correct sheaths pick up. Do not remove single disposable sheaths within a row of the sheaths rack if less than 12 samples are processed within one run. There is a sheaths detection sensor installed in the device. If less than 12 sheaths are picked up by the instrument a warning will be displayed and all picked up sheath are discarded into the waste container before the next row of sheaths are picked up for verification.

To avoid unwanted contaminations, we strongly recommend not washing / reusing any disposed sheaths!

Plate Loading

Analogous to the previous loading screens, the incubation, working and elution plate are loaded within the plate-loading screen (Figure 10).

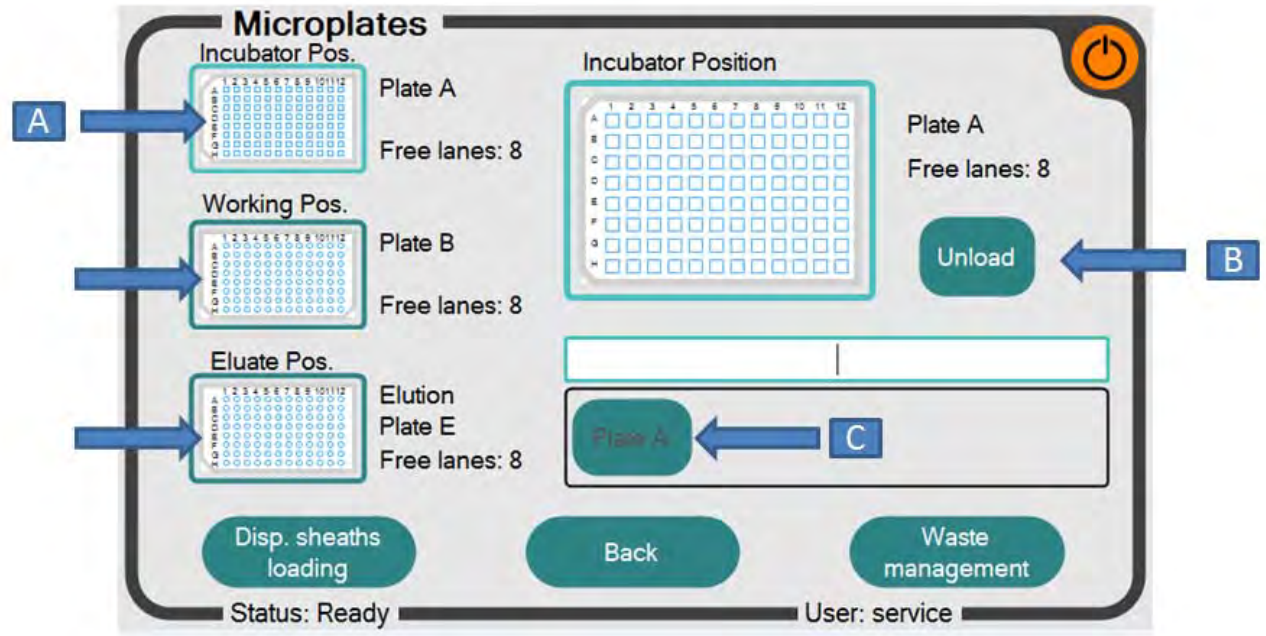


Figure 10, Plate loading screen

The Incubation Plate A is used at the Incubator Position, Working Plate B at the Working Position whereas Elution Plate E at the Eluate Position is used.

Used plates can be unloaded and reloaded by:

1.) Pressing the plate position directly on the sceen. The software will focus at the plate position on the main screen (A).

2.) Pressing the “Unload” button (B)

3.) The plate can be reloaded by pressing at the offered plate below (C)

For a successful run the InviGenius®PLUS needs **two free lanes in the Incubator Plate A**, **four free lanes in the Working Plate B** (please **see page 12**) and **one free lane in the Elution Plate**.

Attention:

Please make sure that the depicted lanes shown on the monitor are consistent with the real lanes in the corresponding positions.

In the software: for every new FFPE run unload the used Incubation Plate A and the used Working Plate B and load (on the sceen) a new one.

In reality: For every **first run,** you take a new Incubation Plate A and a new Working Plate B**.**

For every **second run, both plates have to be turned around 180° (see page 12).** (In the software the machine needs a new plate, see above)

After the second run, please discard both Plates.

The Elution Plate will be used for eight runs.

To avoid contaminations, we strongly recommend **not** wash/ reuse disposed plates!

Waste management

Please make sure that the waste trays capacity is sufficient for the planned assay. If the capacity is not sufficient, empty the solid waste.

Note: The waste is potential infectious.

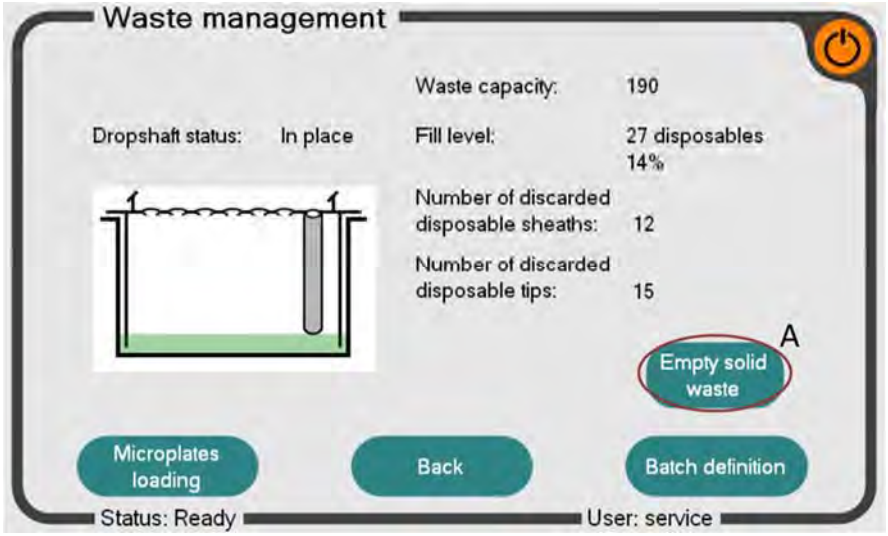


Figure 11; Waste management screen

If the waste tray was renewed, please click on the “Empty solid waste” button (A).

Batch definition

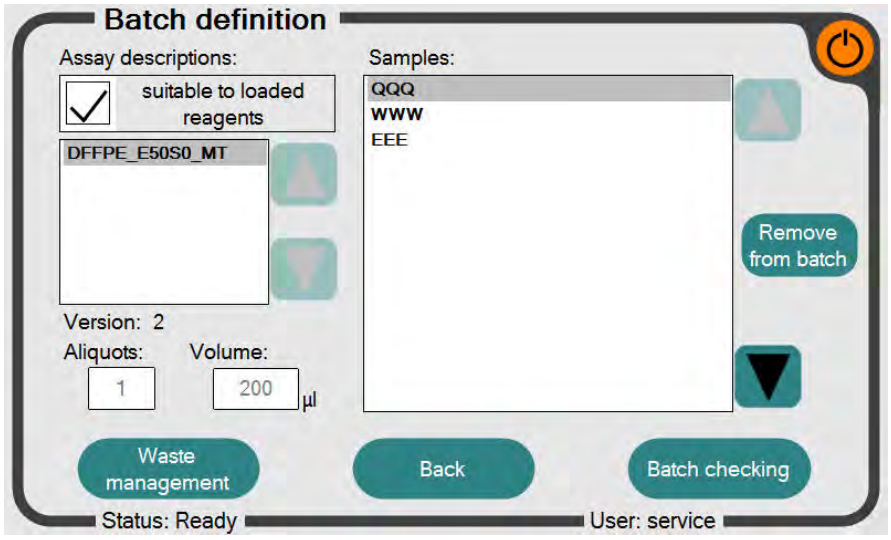


Figure 12; Batch definition-screen

Please select the desired assay and recheck the allocated samples that should be processed in this run.

Batch checking

This screen shows a summary of all verified positions such as disposables, samples and reagents in one informational screen. Please ensure that all required components are loaded properly. In case of any error, the corresponding field will be highlighted in red color. In case that no error is displayed, proceed by pressing the button “Batch processing”.

To solve any error, directly click on the red highlighted field and follow the instructions printed on the instrument screen.

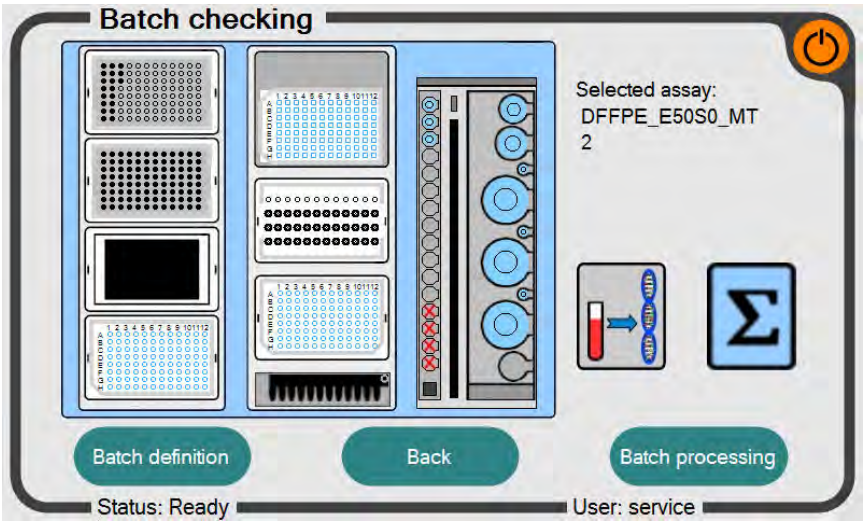


Figure 13; Batch checking screen

Please do not forget to load the Incubation Plate A with the samples if it is on the Plate Shaker.

Batch processing

After closing the system-door, the assay can be started by pressing the “Start”-Button (A). The door will be locked during the run and the system will start with sample processing. The door will only be unlocked after a run has been successfully finished or if an error occurs that requires user interaction. Do not try to force open the door during a run. This will cause an abort of the run!

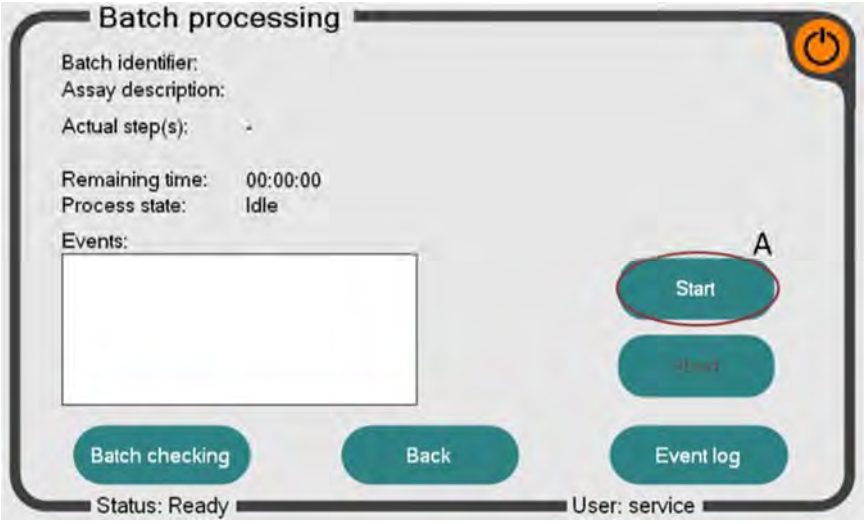


Figure 14; Batch processing screen

At the end of the process, the nucleic acid containing eluates are located in the appropriate eluate position and can be used for any further downstream application.

Note: ***The complete process in the InviGenius® PLUS will take approximately 220 minutes for 12 samples.***

After a run

After a run is completed and no additional run shall be started, unload all plates and reagents and store them according to GLP guidelines. Please keep in mind, that the plates could contain infectious material.

As with all medical/clinical and diagnostically equipment, all waste (liquids, tips, sheaths and plates) should be treated as potentially dangerous bio-hazard waste.

Daily maintenance (UV decontamination)

The InviGenius® PLUS is equipped with an internal UV lamp (254 nm wavelength) that should be used daily either at the end of the working day or in the morning before a run is started. The suggested decontamination time is about 20 min. To start the UV decontamination go to the main menu of the InviGenius software and select “Maintenance”.

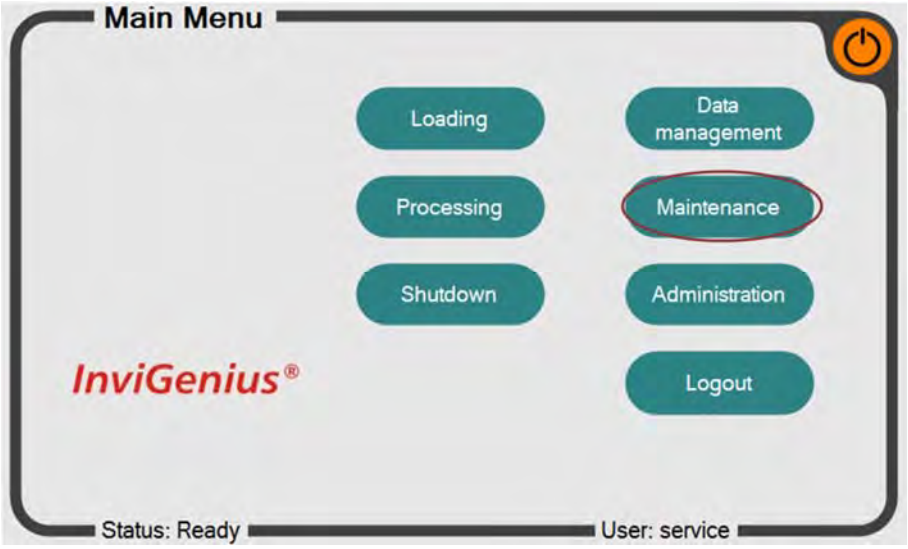


Figure 15: Main screen of the InviGenius® software

When the sub item “Maintenance” is opened, select “UV decontamination”

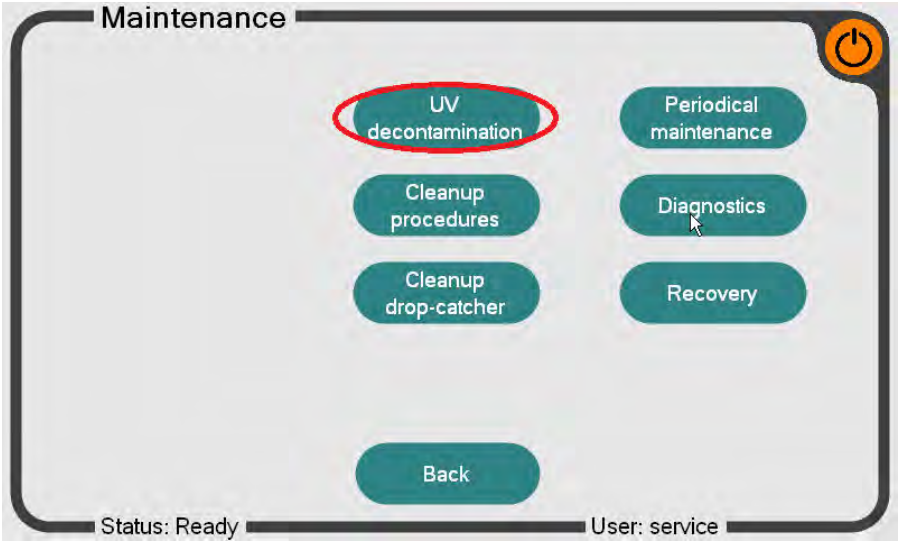


Figure 16: Maintenance screen of the InviGenius® software

In the UV decontamination menu adjust the exposure time (A) and finally press the “Start” button (B). During the decontamination process, the instrument door will be locked to prevent any UV radiation release in the lab.

Warning: ***UV radiation is harmful. It causes serious burns of the skin and leads to irreparable damage of the eyes and skin. Ensure that no lab personnel is submitted to direct UV light. Do not try to force open the instrument door during the decontamination process.***

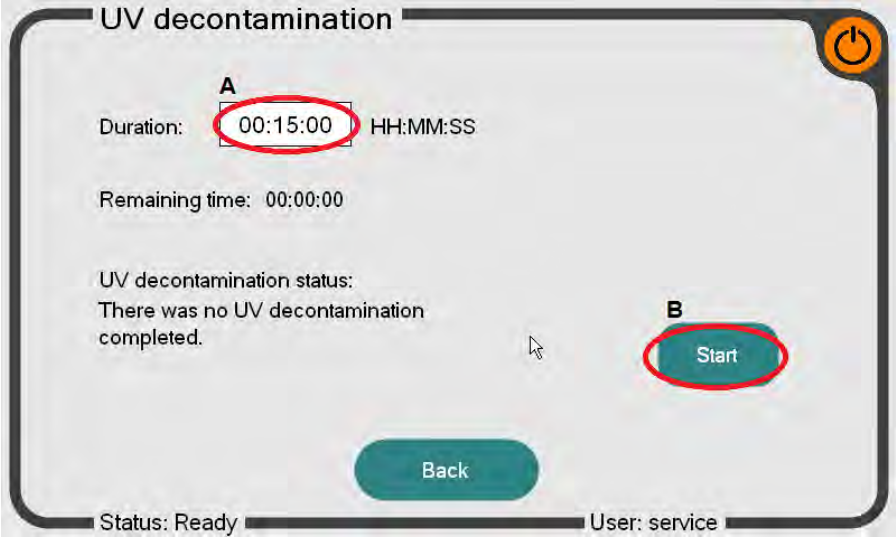


Figure 17: UV decontamination screen

When the decontamination is finished, go back to the main menu by using the “Back” button. The device is now decontaminated and can be either switched off or used for sample processing. We recommend decontaminating the instrument daily.

Appendix

General notes on handling DNA

Nature of DNA

The length and delicate physical nature of DNA requires careful handling to avoid damage due to shearing and enzymatic degradation. Other conditions that affect the integrity and stability of DNA include acidic and alkaline environments, high temperature, and UV irradiation. Careful isolation and handling of high molecular weight gDNA is necessary to ensure its functionality in various downstream applications. Damaged DNA could perform poorly in applications.

Troubleshooting

Problem	Probable cause	Comments and suggestions
pipetting distribution errors	reagent / buffer transfer failed / incomplete	ensure that the supplied empty bottles **Ethanol / Binding Solution** are filled up properly with either ethanol or isopropanol do not reuse bottles more often than described in Tab.1 because they will be rejected by the system
low concentration of extracted DNA	to small amount of starting material	Use two or more slides of FFPE sample
degraded DNA the DNA out of FFPE samples normally is a little bit degraded caused in the pretreatment	incorrect storage of starting material	ensure that the storage of starting material is correct
	old material	old material may contain degraded DNA sometimes caused by not buffered Formalin
no assay selectable	combination of reagents from different kits / missing required reagent	ensure that only and all reagents belonging to one kit type are used. a combination of reagents belonging to different kit types is not supported
eluted nucleic acids are brownish colored	Residual paramagnetic particles are left in eluate	centrifuge the eluate at full speed for 1 min and transfer supernatant to a new tube

For questions please contact: +49 30 94892901/ 10 or 2907, E-Mail: info@invitek-molecular.com

Ordering information

Product	Package size	Catalogue No.
InviMag® FFPE DNA Kit/ IG	8 x 12 preps	2450120100

Related Products	Package size	Catalogue No.
Invisorb® Spin Tissue Mini Kit	250 preparations	1032100300

InviGenius®PLUS and consumables

InviGenius®PLUS	1 unit	5011100000
Starting Box I/ IG:	1 box	2400110100
Sheath Box Conductive filter tips, 1 ml; 2 x 2 rack/ pack (384 pieces) 5 Waste Trays 120 sample tubes		
Sheath Bundle	10 x 48 pieces	5011100300
Sheaths	1000 pieces	5011100200
Conductive filter tips, 1 ml	10 x 96 pieces	5011100400
Waste tray/ IG	25 pieces	5011100100

Possible suppliers for Isopropanol

Carl Roth
2-Propanol
Rotipuran >99.7%, p.a., ACS, ISO
Order no. 6752

Applichem
2-Propanol für die Molekularbiologie
Order no. A3928

Sigma
2-Propanol
Order no. 59304-1L-F

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0062432120 V-01-2020