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NOTICE of CHANGE dated 25/09/2025

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

« ELITe InGenius® SP RNA»
Ref. INT034SPRNA

This new revision of the Instruction for Use (IFU) contains the following changes:

- *Update of hazard statements*

Composition, use and performance of the product remain unchanged.

PLEASE NOTE

	LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT
	LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT

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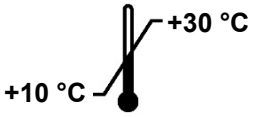
ELITe InGenius® SP RNA

reagents for Nucleic Acid Extraction

REF INT034SPRNA

CE

IVD



UDI 03661540900075

TABLE OF CONTENTS

INTENDED USE

The **«ELITe InGenius® SP RNA»** is a cartridge ready-to-use containing reagents for extraction and purification of high-quality total RNA for single test.

«ELITe InGenius® SP RNA» (ELITechGroup S.p.A., ref. INT034SPRNA) is used in association with the **«ELITe InGenius®»** (ELITechGroup S.p.A., ref. INT030) and «**ELITe BeGenius®**» (ELITechGroup S.p.A., ref. INT040) instrument and constitutes, together with ELITechGroup Real Time PCR assays, the **ELITe InGenius o ELITe BeGenius System**, fully automated molecular diagnostics systems performing extraction, purification, amplification, detection and results interpretation.

The high-quality total RNA isolation protocol is based on magnetic beads and designed for automated preparation (extraction and purification) from lympho-monocyte suspensions and leukocyte suspensions (~1 x 10^7 cells) isolated from peripheral blood collected in EDTA or sodium citrate.

«ELITe InGenius SP RNA» does not provide diagnostics results by itself. To obtain diagnostic results, this

product must be used with a RNA based amplification assay and **ELITe InGenius or** «**ELITe BeGenius**» System. The **«ELITe InGenius»** or «**ELITe BeGenius**» instrument is intended to perform One-Step Real-Time PCR after RNA extraction. This product is intended for use by professionals such as technicians, physicians and biologists trained in molecular biological techniques. It can be used with downstream assays based on Nucleic Acid Amplification Technologies (NAT assay). The use of this product in association with any downstream diagnostic assay must be validated. Any diagnostic results generated using the extracted nucleic acids in association with any downstream diagnostic assay should be interpreted taking into account other clinical or laboratory findings. Adequate controls for downstream assays should be used in order to mitigate risk of incorrect diagnostic results.

ASSAY PRINCIPLES

The **«ELITe InGenius SP RNA»** is the reagent set for automated RNA extraction and purification from lympho-monocyte suspensions and leukocyte suspensions isolated from peripheral blood collected in EDTA or sodium citrate of clinical samples in association with the **«ELITe InGenius»** and «**ELITe BeGenius**». The reagent set has been optimized for the isolation of nucleic acids from 0.2 mL samples. The resulting nucleic acid extracted is then available for One-Step Real-Time PCR application with **«ELITe InGenius»**. and «**ELITe BeGenius**»

The RNA isolation process is based on the Magtration® Technology, an automated extraction technology based on magnetic beads, as shown in Figure A below.

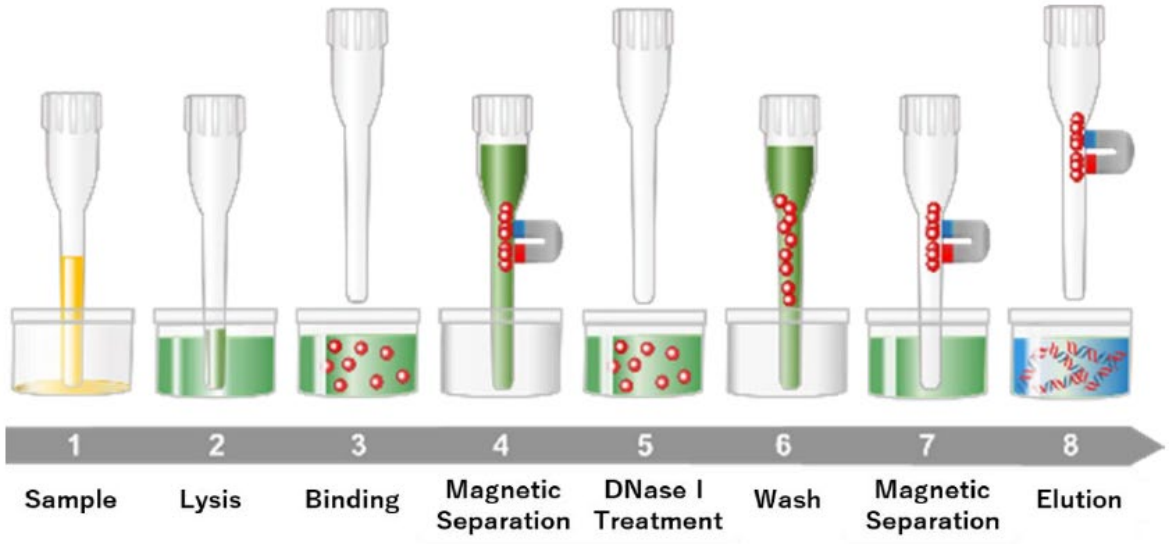


Figure A: Extraction Workflow

The **«ELITe InGenius»** and «**ELITe BeGenius**» automatically perform sample dispensing from extraction tubes. The RNA purification procedure is carried out without user involvement, except the initial loading of the instrument, thus allowing safe handling of potentially infectious samples. Sample cross-contamination and reagent cross-over is effectively reduced.

The resulting highly purified nucleic acids are eluted with distilled water. The extraction process on 9 samples takes approximately 75 minutes.

The purified nucleic acids are ready to use for downstream assays based on One-Step Real Time PCR. Otherwise, the purified nucleic acids can be stored at -20 °C or -70 °C for subsequent use.

The kit provides reagents for **48 extractions** (e.g. 16 runs x 3 samples).

Note: The minimum number of samples to be processed per run with the **«ELITe InGenius»** is 1, the maximum number is 9,
The minimum number of samples to be processed per run with the **«ELITe BeGenius»** is 1, the maximum number is 6,

MATERIALS PROVIDED

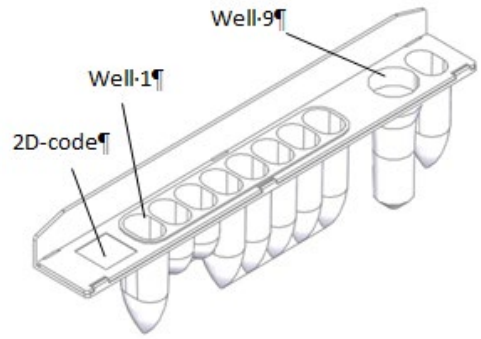


Figure B: Total RNA Extraction Cartridge

The kit contains 48 unitary prefilled Total RNA extraction cartridges.

Each Total RNA extraction cartridge contains:

Well No.	Reagent name	Quantity	H-code/P-code
1	Reductant solution	100 µL	H225, H302, H314, H315, H318, H319, H332, H334, H336, H412 P210, P261, P264, P273, P280, P301+310, P304+340, P302+P352, P305+P351+P338, P310, P312, P332+P313, P337+P313, P342+P311, P362+P364, P403+P233
2	PK solution	80 µL	
3	Carrier solution	80 µL	
4	Magnetic particles	200 µL	
5	Binding buffer	1200 µL	
6	Wash buffer 1	1200 µL	
7	Wash buffer 2	700 µL	
8	Distilled water	1200 µL	
9	Lysis solution	800 µL	

Material Storage

The **«ELITe InGenius SP RNA»** extraction cartridge should be stored at room temperature (+10 / +30 °C). For the expiration date, please refer to the product label.

Do not freeze. Keep the extraction cartridge away from high temperatures, humidity, and vibration.

Avoid exposure with direct sunlight.

Store the extraction cartridge with the sealed side up.

Material Quality Controls

ELITechGroup S.p.A. (EGSpA) guarantees the performance characteristics of the **«ELITe InGenius SP RNA»** for applications as described in the manual.

In accordance with the EGSpA certified Quality Management System, the **«ELITe InGenius SP RNA»** has been tested against established acceptance criteria to ensure consistent product quality.

MATERIALS REQUIRED BUT NOT PROVIDED

The following equipment and reagents are not provided:

- Disposable powder free gloves in nitrile or similar material.
- Laminar airflow hood.
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips.
- Vortex mixer.
- Bench microcentrifuge (~ 13,000 RPM).
- Bench centrifuge (5,000 RPM).

Sample tubes for samples are not provided. To run samples on the **ELITe InGenius System** and on the **ELITe BeGenius System**, the user should use the secondary tubes listed below.

Sample Tubes for ELITe InGenius and ELITe BeGenius. Systems
Secondary tubes
Sarstedt 2 mL tube (Sarstedt #72.694.006) only for ELITe BeGenius
Extraction tube (ELITechGroup S.p.A., ref. INT032CS)

Disposable filter tips and solid waste box are not supplied within the kit. The required consumables are reported below and can be ordered individually from ELITechGroup S.p.A.

Component	Code	Quantity	Description
300 µL Filter Tips Axygen (for ELITe InGenius only)	TF-350-L-R-S	1 box x 10 racks with 96 tips	Standard Volume Tips (300 µL) with filter
1000 µL Filter tips Tecan (for ELITe BeGenius only)	30180118 or 30000631	1 box x 24 racks with 96 tips (2304pcs)	Liquid Handling (LiHa) disposable tips (1000 µL) with filter
ELITe InGenius® Waste Box	F2102-000	20 box / pack	Disposable plastic containers

OTHER PRODUCTS REQUIRED

This product must be used in association with the **«ELITe InGenius»** instrument (ELITechGroup S.p.A., ref. INT030) and «**ELITe BeGenius**» ELITechGroup S.p.A., ref. INT040), with the **«ELITe InGenius® SP 200 Consumable Set»** (ELITechGroup S.p.A., ref. INT032CS), and with the **«ELITe InGenius DNase I» (**ELITechGroup S.p.A., ref. INT034DNASE), the **«ELITe InGenius DNase tube adapter kit» (**ELITechGroup S.p.A., ref. G6431-000).

The consumable set, the DNase I and the tube adapter kit can be ordered separately using the code ELITechGroup S.p.A., ref. INT032CS, INT034DNASE, G6431-000.

The consumables necessary to carry out the extraction procedure are included in the «**ELITe InGenius SP 200 Consumable Set**».

The consumable set components are listed below:

Component	Quantity	Description
Extraction tube	48	Disposable tube to be placed in the extraction position. It can also be used as secondary tube for loading samples
Tip cassette	4 x 12	Cassette containing a piercing tip and a pipette tip used during the extraction procedure
Elution tube	50	0.5 mL tube and cap used to collect the extracted Nucleic Acid (NA)

WARNINGS AND PRECAUTIONS

This product is exclusively designed for *in-vitro* use.

General warnings and precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. All materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards.

After receiving the kit, check the kit components for damage. If extraction cartridges are damaged, contact ELITechGroup Technical Services or your local distributor. In the case of liquid spillage, refer to “Warnings and precautions for specific components” and to the appropriate Safety Data Sheets (SDS).

The chemicals and plastic parts are for laboratory use only; they must be stored in the laboratory and are not to be used for purposes other than intended.

Wear suitable protective clothes and gloves and protect eyes and face.
Discard gloves if they get contaminated.
Never pipette solutions by mouth.
Do not eat, drink, smoke or apply cosmetic products in the work areas.
Carefully wash hands after handling samples and reagents.
Dispose of leftover reagents and waste in compliance with local regulations.
Carefully read all the instructions provided in the product before running the assay.
While running the assay, follow the instructions provided with the product.
Do not use the product after the indicated expiry date.
Do not use damaged kit components.
Only use the reagents provided in the product and those recommended by the manufacturer.
Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acid extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or contamination of the samples by amplification products.

The samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled in a Class II Biological Safety Cabinet. Pipettes used to handle samples must be exclusively used for this specific purpose and should be cleaned after each use. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be both DNase and RNase free, and DNA and RNA free.

Warnings and precautions specific for the components

«ELITe InGenius SP RNA» cartridge is for single use.

The following components of the **«ELITe InGenius SP RNA»** contain hazardous reagents. GHS Hazard and Precautions statements applied to those components are listed below.

Please, note that hazard labeling is not necessary for quantities less than 125 g or 125 mL.

Lysis Solution
Contains Guanidinium thiocyanate and Sodium N-lauroylsarcosinate

Danger

H302:	Harmful if swallowed
H314:	Causes severe skin burns and eye damage
H332:	Harmful if inhaled
H412:	Harmful to aquatic life with long-lasting effects
P264:	Wash th skin thoroughly after handling.
P273:	Avoid release to the environment.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P301+310:	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P304+P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Binding Buffer, Wash Buffer 1 and Wash Buffer 2
Contains 2-propanol

Danger

H225:	Highly flammable liquid and vapour.
H319:	Causes serious eye irritation.
H336:	May cause drowsiness or dizziness
P210:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261:	Avoid breathing dust/fume/ gas/mist/vapours/spray.
P264:	Wash the hands thoroughly after handling.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.

Reductant Solution
Contains sodium dodecyl sulfate

Danger

H315:	Causes skin irritation
H318:	Causes serious eye damage
P264:	Wash the hands thoroughly after handling.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352:	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313:	If skin irritation occurs: Get medical advice/attention.
P337+P313:	If eye irritation persists: Get medical advice/ attention.

For further information, please, see Material Safety Data Sheets.

No other component of the **«ELITe InGenius SP RNA»** contains hazardous reagents that require European Community Risk and Safety phrases and GHS Hazard and Precautions phrases.

Do not reuse extraction cartridge or tip rack.

Do not damage or obscure the 2D code.

When liquid drops are present on the wall of the cartridge well, shake gently without creating bubbles to move the drops down to the bottom of the tube.

Elution is performed with distilled water, the eluate final volume may be affected by residues on the magnetic beads, on the tip surface or evaporation.

The use of an internal control is recommended to obtain reliable diagnostic results.

Warnings and precautions specific for ELITe InGenius and «**ELITe BeGenius**» **System**

In the case of an instrument error message, please refer to instrument Operator's Manual (ELITechGroup S.p.A., ref. INT030).

SAMPLES AND CONTROLS

For reproducible and high yields of extraction, appropriate sample collection, transport and storage is essential. Yields may vary from sample to sample depending on factors such as the patient, the sample age and the type of sample.

EDTA or sodium citrate, can be used to collect the samples to be used with the **«ELITe InGenius SP RNA»**.

Note: Samples should not contain clots or other solid materials. Mix the sample to ensure a homogenous resuspension before loading onto the instrument.

Peripheral blood collected in EDTA or sodium citrate

The peripheral blood collected in EDTA or sodium citrate, used for RNA extraction, must be collected according to laboratory guidelines, transported at +2 / 8 °C and stored at +2 / 8 °C for a maximum of 48 hours prior to purification.

Do not freeze peripheral blood in order to prevent degradation of RNA.

When starting with peripheral blood it is advisable to separate leukocyte according to laboratory guidelines.

Interfering substances

Whole blood samples **must not contain heparin**, as it is a powerful inhibitor of DNA polymerase enzymes (such as thermostable DNA polymerases and reverse transcriptase) and leads to invalid or incorrect results in downstream assays performed on the extracted RNA.

Any inhibitory effect caused by drugs that may be contained in the starting sample will have to be evaluated each time by the user in account of downstream assays performed on the extracted RNA.

Extraction quality controls

Extraction quality controls may be used for training, proficiency testing and external QC of the System. External controls may be used in accordance with guidelines or requirements of local regulations or accreditation organizations.

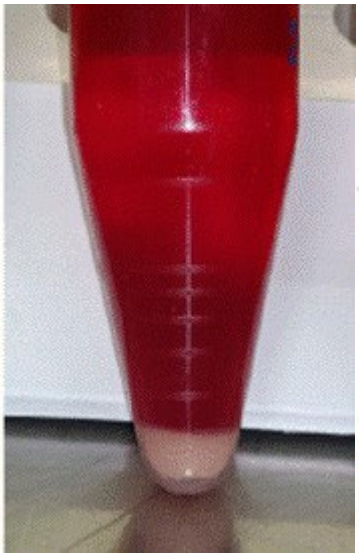
As a negative specimen processing control, the laboratory can use a negative sample that has already been tested with the downstream assay or carry out a simulated extraction using molecular biology grade water in place of the sample.

As a positive specimen processing Control, the Laboratory can use a positive sample that has already been tested with the downstream assay or a certified reference material.

PROCEDURE FOR THE PREPARATION OF THE SAMPLE.

When starting with peripheral blood, it is mandatory to separate leukocytes according to the following indications.

	A. Pre-treatment procedure for leukocyte isolation with Buffy Coat	**B. Pre-treatment procedure for leukocyte isolation with Direct Lysis**
1	Prepare 15 mL tubes and 2 mL tubes needed and label them with a permanent marker.	Prepare 50 mL tubes and 2 mL tubes needed and label them with a permanent marker.
2	Not applicable	Dispense **Cell Lysis Solution** (Promega, ref. A7933) into a 50 mL tube: use **15 mL** if starting from 5 mL of blood or **30 mL** if starting from 10 mL of blood (3:1 ratio).
3	Mix peripheral blood samples collected in EDTA or sodium citrate thoroughly by inversion.	
4	Transfer **5 - 10 mL of fresh peripheral blood** into the 15 mL tube.	Transfer **5 - 10 mL of fresh peripheral blood** into the 50 mL tube.
5	Centrifuge for **10 minutes at 3,000 RCF** (with no brake applied).	Not applicable
6	Dispense **5 mL of Cell Lysis Solution** (Promega, ref. A7933) into a new 15 mL tube.	Not applicable
7	With a 1 mL pipette, **remove the buffy coat** obtained after centrifugation and transfer it into the 15 mL tube containing the Cell Lysis Solution. Wash the tip in the solution until it is free of cells.	Not applicable
8	Incubate at **room temperature for 10 minutes** mixing by inversion (no vortex) at least 3-4 times.	
9	Centrifuge for **10 minutes at 3,000 RCF**.	

10	**NOTE** The ideal quantity of white cells is represented, in 1:1 scale, in the following picture.   • If the pellet is equal to or smaller than the one shown above, remove the supernatant, resuspend the pellet in **1.5 mL of Cell Lysis Solution** and transfer it into a 2.0 mL tube. If the pellet is bigger than the one shown above, remove the supernatant, resuspend the pellet in **3 mL of Cell Lysis Solution** and transfer 1.5 mL into two different 2.0 mL tubes.
11	Centrifuge again for about **2 minutes at 3,000 RCF**.
12	Carefully **remove the supernatant** (attention to remove traces of red cells above the white cells pellet).
13	Carefully lyse the pellet in **200 µL of Homogenization Solution** (1 mL of RNA Lysis Buffer, Promega, ref. Z3051 + 20 µL of 1-Thioglycerol, Promega, Ref. A208B-C) by pipetting.

PREPARATION OF SAMPLES

- Transfer 10 – 14 mL of fresh peripheral blood collected in EDTA or sodium citrate into a 15 mL tube after mixing it thoroughly by inversion.
- Centrifuge for 10 minutes at 3000 RCF;
- add 5 mL of Cell Lysis Solution (Promega, Ref. A7933) into a new 15 mL tube;
- with a 1 mL pipette, remove the buffy-coat obtained after centrifugation and transfer it to the 15 mL tube containing the lysis solution Wash the tip in the solution until it is free of cells.
- aspirate and release until the cells are inside the tube and the pipette is free of material;
- incubate at room temperature for 10 minutes and mix by inversion (NO VORTEX) at least 3-4 times
- centrifuge at 3000 RCF for 10 minutes; remove the supernatant and resuspend in 2 mL of Cell Lysis Solution by transferring it into a 2 mL tube
- centrifuge again for about 2 minutes at 3000 RCF

- carefully remove the supernatant and resuspend the pellet in 200 µL of Lysis Solution (1 mL of Lysis Buffer, Promega, Ref. Z3051 + 20 µL of 1-Thioglycerol, Promega, Ref. A208B-C).

Samples must be transferable by pipette; ensure there are no clots or other solid materials.

Volume of samples in the Extraction tubes

The pre-treated sample can be directly loaded into the system using the extraction tubes (**«ELITe InGenius SP 200 Consumable Set»**, ELITechGroup S.p.A., ref. INT032CS).

DESCRIPTION OF THE EXTRACTION PROCEDURE ON ELITE INGENIUS AND ON ELITE BEGENIUS.

Extraction with the **«ELITe InGenius SP RNA»** reagent cartridge is performed automatically by the **ELITe InGenius and ELITe BeGenus System**. The procedure includes the following steps:

1. Switch on the instrument.
2. Select functions from the system screen. It is possible to perform a session for “Extraction Only” or “Extraction plus PCR”.
3. Select the assay to be run.
4. Put the total RNA extraction reagent cartridge, DNase I, DNase I tube adapter, tip set included in the consumable set, and sample in positions as indicated on the GUI.

Hole	Consumable, Reagent
S	Sample tube (Micro tube 1.5mL)
T2	DNase I (Lyophilized) DNase I tube adapter
T1	Tip & Sheath
E	Elution tube (Micro tube 1.5mL)

5. Examine if the reagent sticks to the interior wall of the cartridge before use. Shake lightly to allow the drops to fall without making bubbles. If DNase I powder sticks to the cap or interior wall of the vial, spin down briefly. Make sure to put DNase I into the DNase I tube adapter and remove the cap before placing into the instrument.
   Reagent and consumable required for one sample extraction are listed as follows. Put them into the instrument according to the GUI guidelines of the instrument.
   - ELITe InGenius SP RNA cartridge 1 pc
   - DNase I 1 pc
   - DNase I tube adapter 1 pc
   - Tip set 1 pc
   - Elution tube 1 pc
   - Extraction tube 1 pc

6. Close the door at the front of the instrument.
7. Press the Start button to begin the total RNA extraction process.
8. Once the process is complete, open the door following the instructions displayed on the system display.

The extracted RNA will be used directly in PCR if the ‘Extraction plus PCR’ mode has been selected.

Otherwise, the extracted RNA can be stored in the 0.5 ml elution tube. At the end of the session, close the tube with the screw cap and store the sample for future use.

General overview of the ELITe InGenius working area and the ELITe BeGenius working area

The **ELITe InGenius System** has been developed and validated for specific *in-vitro* diagnostic (IVD) applications by ELITechGroup S.p.A. in combination with IVD extraction kits and IVD Real Time PCR kits.

An overview of the **«ELITe InGenius»** instrument is shown in Figure 1.

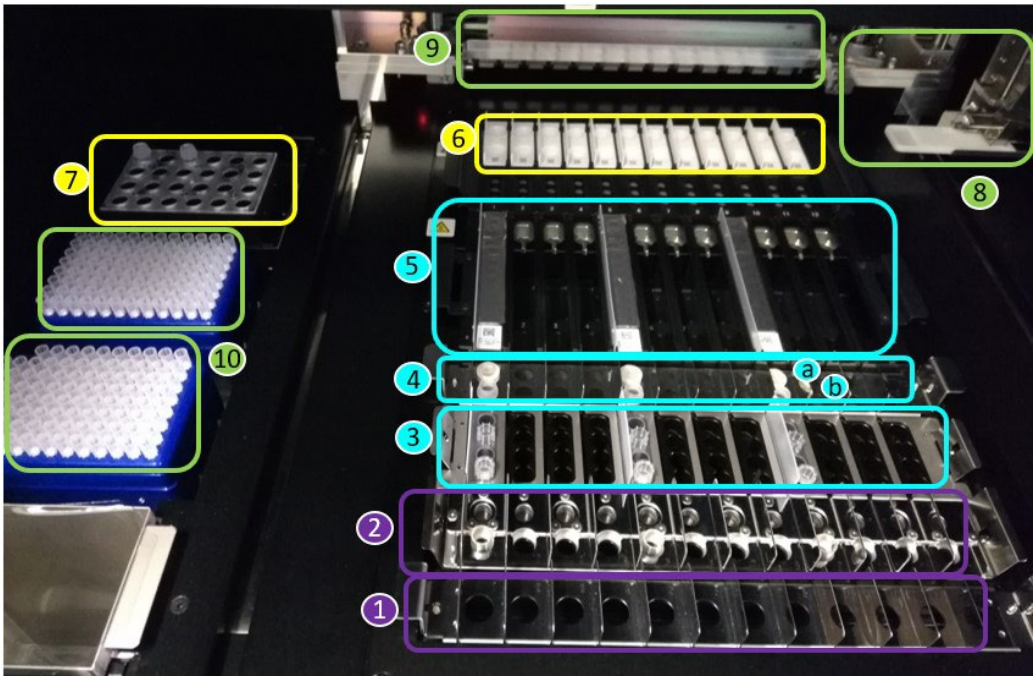


Figure 1: The **«ELITe InGenius»** loading area

Figure 1 shows: Primary tube rack position (**1**), Extraction tube rack position (**2**), Tip rack position (**3**), Elution tube rack position (Dnase I tube + tube adapter (a) and Elution tube (b)) (**4**), Extraction cartridge rack position (**5**) and PCR cartridge rack position (**6**), PCR and Internal Control reagent block (inventory manager) position (**7**), sample and reagent dispensing (**8**, **9**), the waste box (left-bottom) and tips positions (**10**).

The single head pipettor (**8**) starting positions is in the right back of the machine. All movable parts work only when the **«ELITe InGenius»** instrument is closed and locked.

The **ELITe BeGenius System** has been developed and validated for specific *in-vitro* diagnostic (IVD) applications by ELITechGroup S.p.A. in combination with IVD extraction kits and IVD Real Time PCR kits.

An overview of the **«ELITe BeGenius»** instrument is shown in Figure 2.

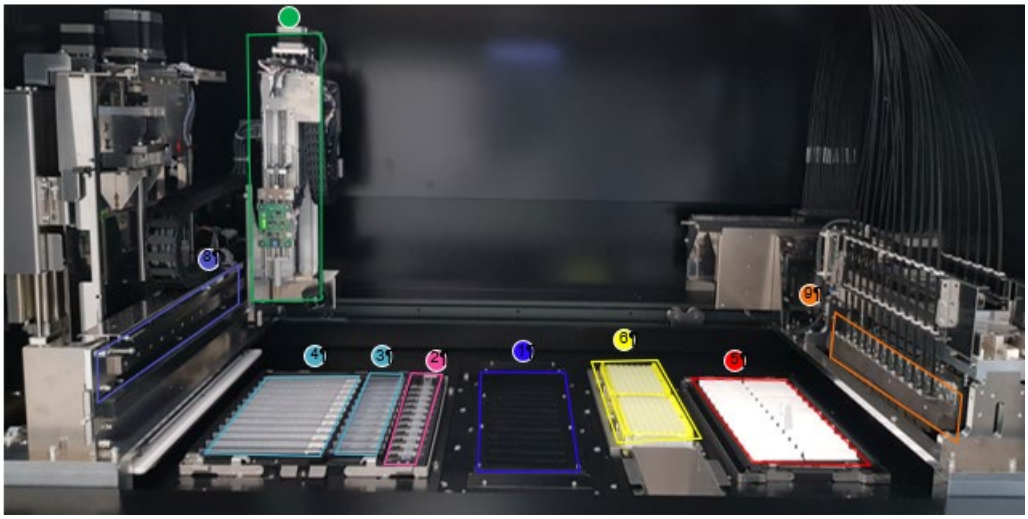


Figure 2*: ELITe BeGenius instrument – Working Area view*

1. Cooler unit
2. Extraction tubes
3. Extraction Tip cassettes
4. Extraction cassette
5. Universal PCR cassette and caps
6. Filter tips racks (1000 µL)
7. Single nozzle pipettor arm
8. Twelve nozzles pipettor arm
9. Twenty-four RT-PCR heads

Loading of the «ELITe InGenius» instrument

Refer to the **«ELITe InGenius»** operator's manual.

Switch on the **«ELITe InGenius»** instrument using the power switch located on the right side of the instrument. The **«ELITe InGenius»** instrument software will be automatically loaded after the system has booted up. Please keep the door of the instrument system closed during system initialization.

Instrument set-up

After logging in by "Open" or "Close" modality (IVD certified), the main screen "Home" appears (Figure 2).

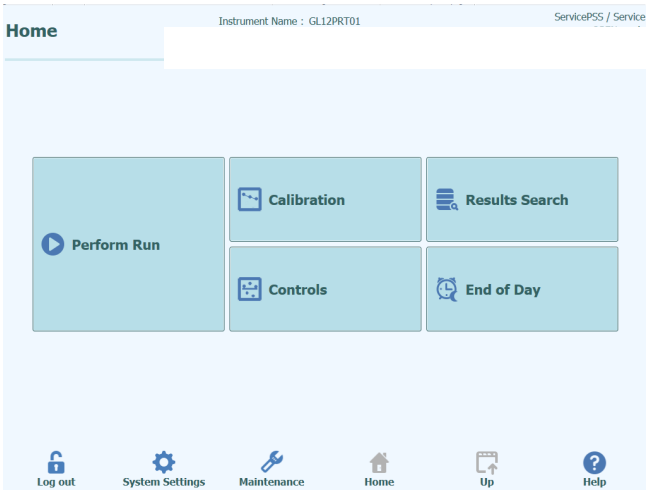


Figure 3: «ELITe InGenius» Home screen

1. Select “Perform Run” to start loading the system and prepare for starting a run.

The Perform Run screen appears (Figure 4).

Figure 4: “Perform Run” screen

"Input Volume" (Treated Volume) depends on the extraction reagents. The volume of treated sample is 200 µL.

“Elute Volume” depends on specific assays. Possible elution volumes are 50, 100, 200 µL.

Sample ID (SID) and Assays to be performed must be specified. The picture below shows an example (Figure 5).

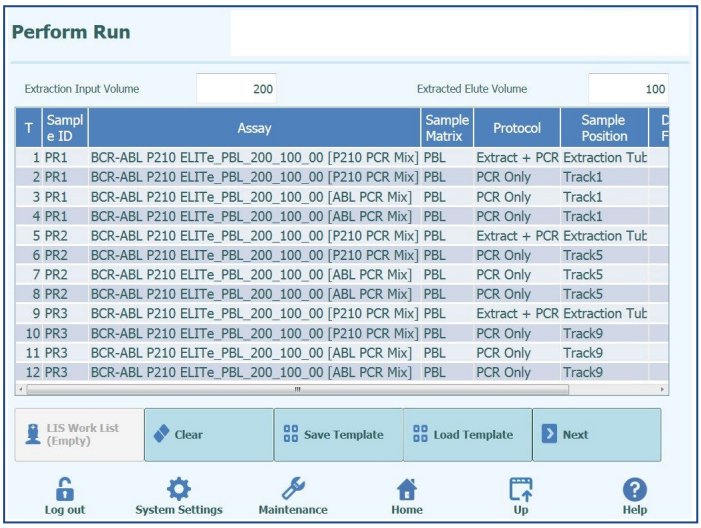


Figure 5: Example of Sample ID and Assay specification

2. Select “SID”. Enter the sample ID using the keypad or barcode scanner.
3. Select “Assay”. Choose the assay from the list.

The system screen will be updated according to the assay selected.

4. Select “Protocol” to define “Extraction only” or “Extraction plus PCR” methods.

At this point, sample positions can be saved to create a panel template. For instructions on how to save the settings refer to the **«ELITe InGenius»** operator’s manual.

Note: with ELITe InGenius SP RNA kit, samples can only be loaded into the Extraction tube.

5. Press the “Next” button to proceed with the disposable-loading.

The “Load / Unload Inventory” screen appears (Figure 6).

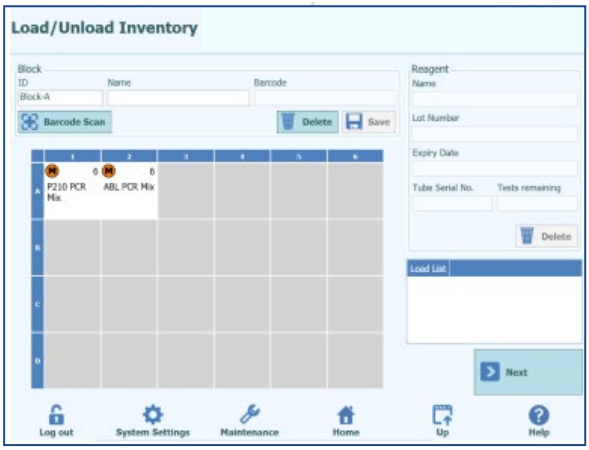


Figure 6: “Load / Unload Inventory” screen

This screen allows the user to confirm reagent and control loading according to the settings defined in the “Perform Run” screen.

6. To confirm that sufficient reagents for the number of tests selected are placed in the inventory manager position 7 (cfr. page 10, Figure 1) as indicated on the screen, press the “Next” button.

Note: “Next” button is enabled when there are sufficient reagents/controls for the run.

The “Load / Unload Inventory” screen for Tip rack loading appears (Figure 7).

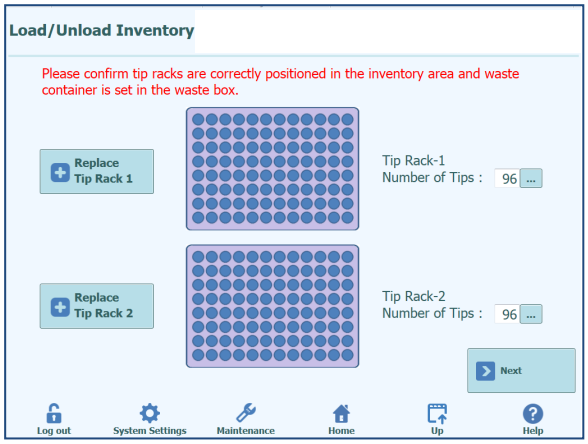


Figure 7: The “Load / Unload Inventory” screen confirms tip rack placement

7. Place sufficient Tips racks in position 10 (cfr. page 10, Figure 1).
8. Press the “Next” button.

Note: The “Next” button will not be enabled until there are sufficient Single Tips loaded for the run.

The “Disposable” screen appears to guide the user during the disposables loading. The first screen is related to the PCR Rack loading (Figure 8).

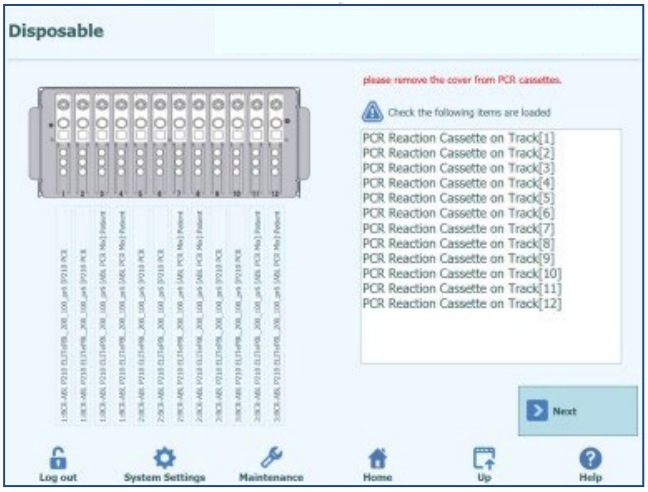


Figure 8: The “Disposable” screen is used to confirm loading PCR racks

When “Extraction plus PCR” Protocol has been selected in the “Perform Run” screen:

9. Place the PCR cassettes indicated in position 6 (cfr. page 10, Figure 1).
10. Press the “Next” button.

Note: If the Extraction only protocol was selected in the "Perform Run" screen, the PCR Cassette don’t have to be loaded.

The “Disposable” screen for Extraction Rack loading with Extraction Cartridge appears (Figure 8).

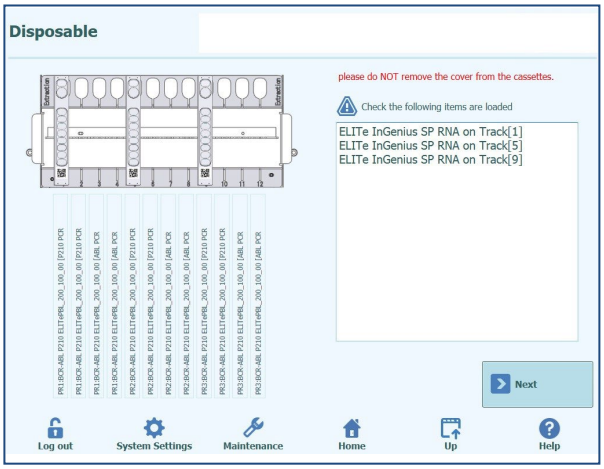


Figure 9: The “Disposable” screen is used to confirm Extraction Rack loading

11. Place the Extraction cartridge cassette(s) indicated in position 5 (cfr. Page 10, Figure 1).
12. Press the “Next” button.

Note: The “Next” button is enabled when there is sufficient number of Extraction cartridge for the run are loaded.

The “Disposable” screen for DNase I, into the DNase I tube adapter, loading with Elution Tube Rack appears (Figure 9).

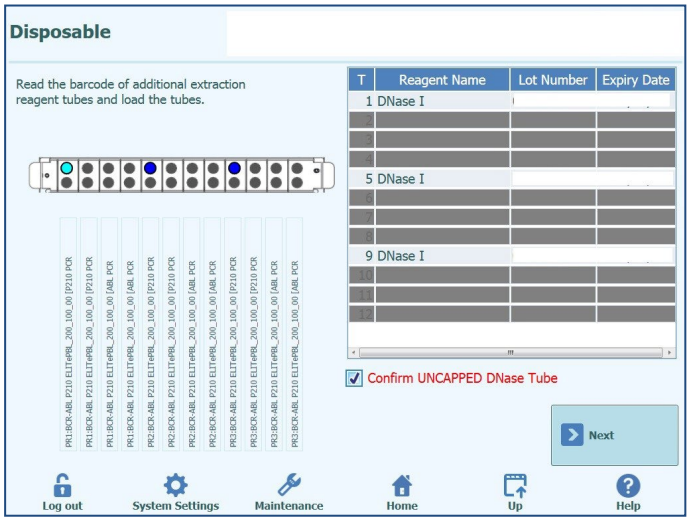


Figure 10: The “Disposable” screen is used to confirm loading of DNase I in Elution Tube Rack

13. Place the DNase I, into the DNase I tube adapter, indicated in position 4 (cfr. Page 10, Figure 1).
14. Press the “Next” button.

The “Disposable” screen for elution tube loading with Elution Tube Rack appears (Figure 10)

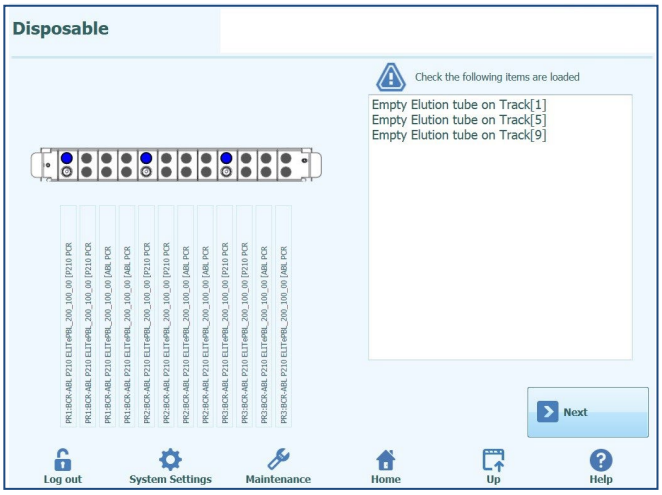


Figure 11: The “Disposable” screen is used to confirm loading of Elution Tube Rack with elution tube

15. Place the amount of elution tubes, indicated in position 4 (cfr. page 10, Figure 1).
16. Press the “Next” button.

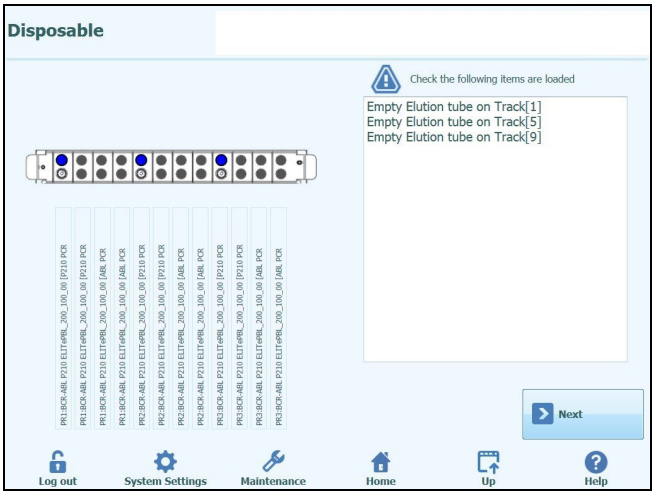


Figure 12

The “Disposable” screen for tip rack loading appears (Figure 13).

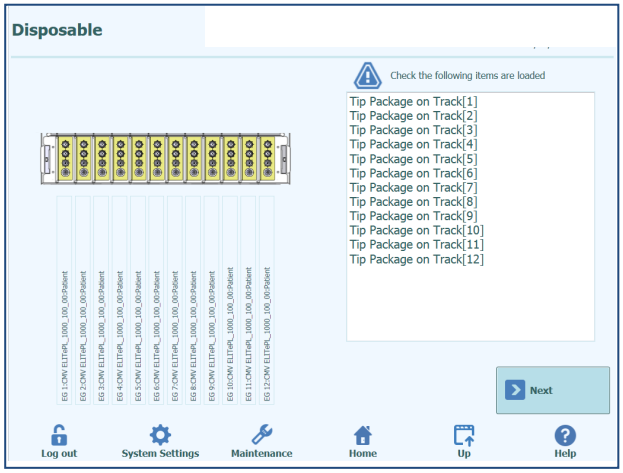


Figure 13: The “Disposable” screen is used to confirm loading tips racks

17. Place the amount of Tip cassettes indicated in position 3 (cfr. page 10, Figure 1).

Ensure that the Tip (1) and the piercer (3) are placed as shown in the picture below (Figure 12).

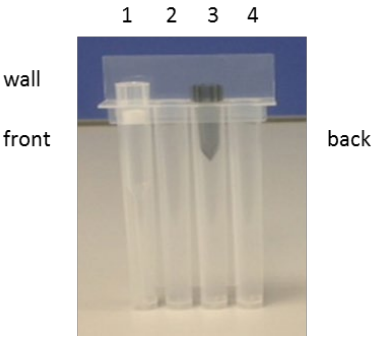


Figure 14: Tips disposition on Tip Cassette

18. Press the “Next” button.

The “Disposable” screen for extraction tube rack loading appears (Figure 15).

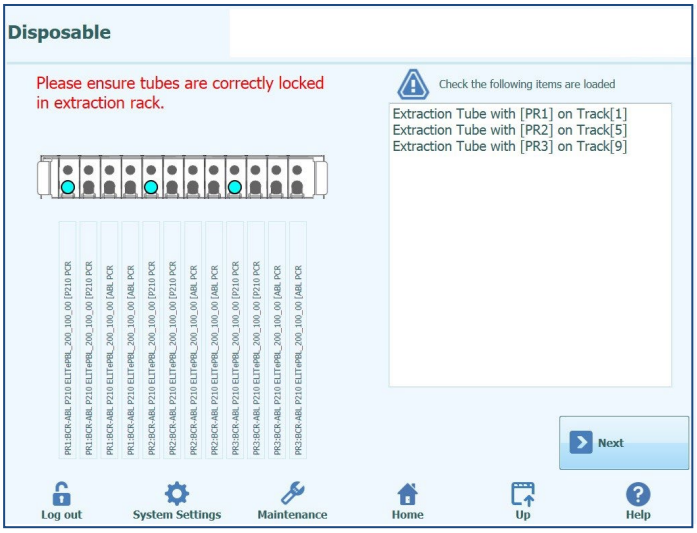


Figure 15: The “Disposable” screen is used to confirm loading extraction tube racks

19. Place the amount of extraction tubes indicated in position 2 (cfr. page 10, Figure 1).
20. Press the “Next” button.

Note: 200 µL of the sample must be present in the "Extraction Tube".

The “Disposable” screen for sample rack loading appears (Figure 16).

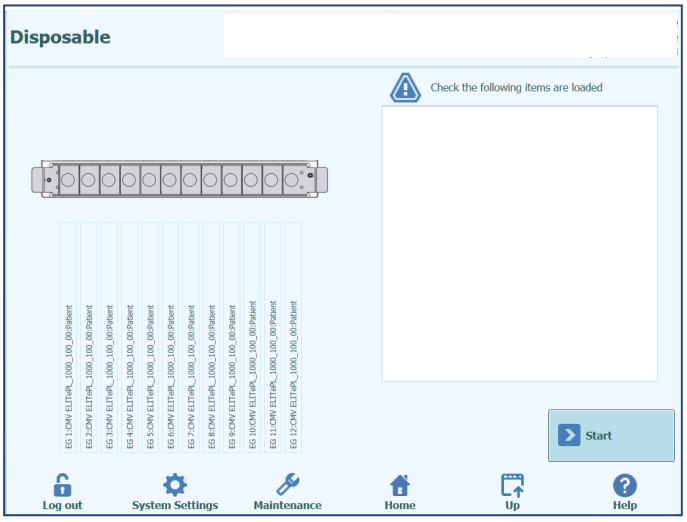


Figure 16: The “Disposable” screen is used to confirm loading of sample racks.

21. Press the “Start” button to start the run.

The following message is shown (Figure 17).

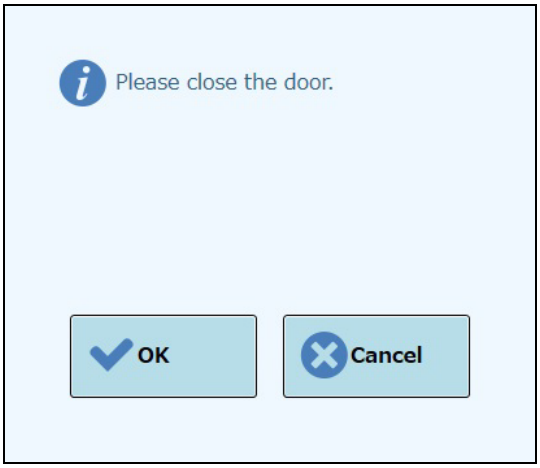


Figure 17: Instrument close door request message

22. Close the front door and press the “OK” button on the popup message.

The “During Run” screen appears (Figure 18). The run process can be followed on this screen.

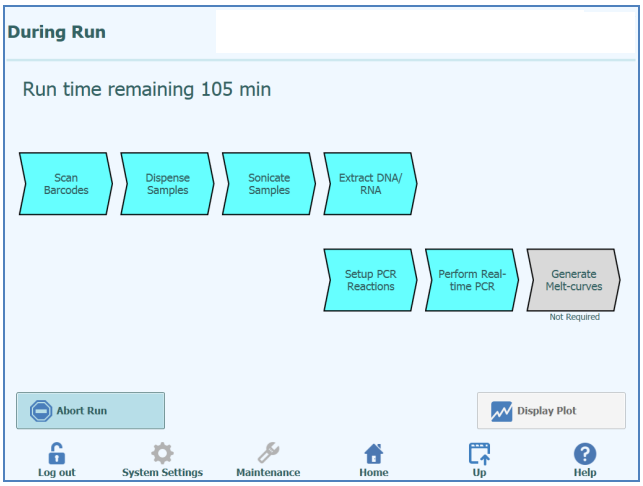


Figure 18: During run screen

End of Assay:

If an “Extraction plus PCR” protocol was selected, the “End of Run” screen is shown. The “OK” button becomes active when the instrument front door may be opened (Figure 19).

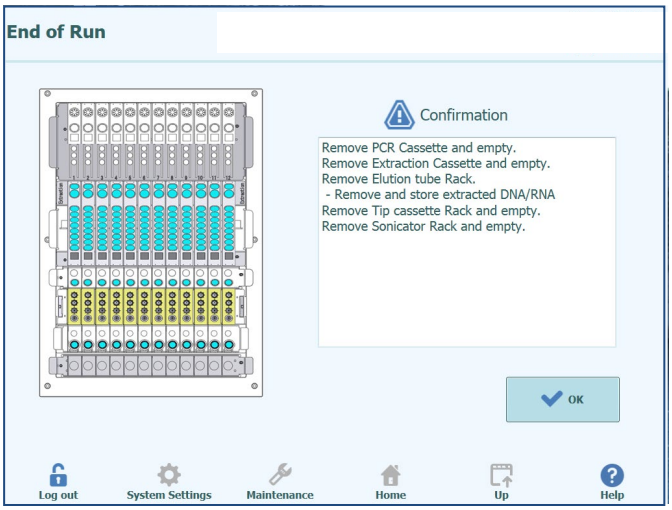


Figure 19: The End of Run screen

23. Open the front door.

Instructions to unload, store or discard samples, materials and reagents are listed in the “End of Run” screen.

24. Carry out the actions listed immediately.

25. To confirm all actions have been completed, press “OK”.

The extracted RNA may be stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Freeze/Thawing cycles of extracted RNA must be limited to 5 times in order to avoid titre loss.

As with other diagnostic equipment, all waste products (liquids, tips, tubes and cartridges) should be treated as potentially dangerous bio-hazardous waste and discarded accordingly.

Shutdown of System:

26. On the Home screen, select “End of Day”. The following screen is shown (Figure 20).

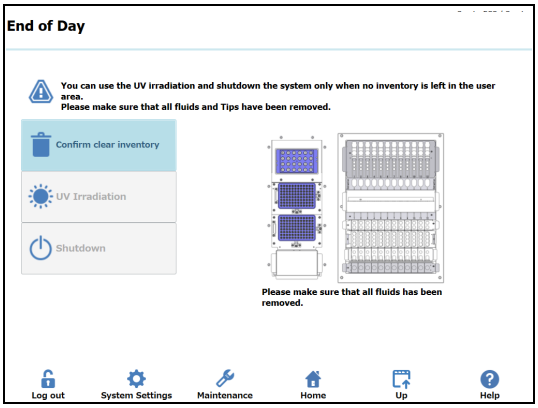


Figure 20: End of Day screen

27. Verify that the user area has been unloaded.

28. Press “Confirm clear inventory” button. The elimination of the reagents is saved in the system that will then allow shutdown to be executed.

Daily maintenance (UV decontamination):

The **«ELITe InGenius»** instrument 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 any run is started. The suggested decontamination time is about 30 min.

1. To start UV decontamination, on the home screen of the **«ELITe InGenius»** instrument, select “End of Day” and then press “UV Irradiation”.

Following message is displayed (Figure 21):

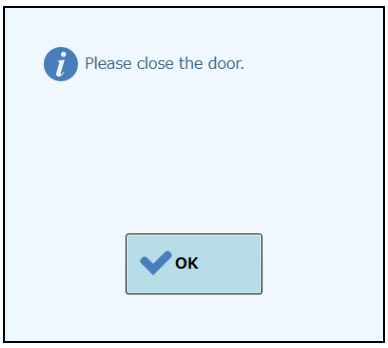


Figure 21: The Close door request message

2. Close the front door and press “OK”.

A message is displayed to allow the choice of automatic shutdown after irradiation (Figure 22).

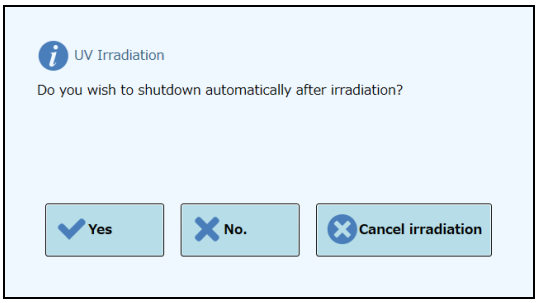


Figure 22: Choice of automatic shutdown after irradiation message

3. Select the desired option. Irradiation will be started.

As irradiation is performed, a status screen will be displayed showing the progress of the process.

ELITE BEGENIUS PROCEDURE

Refer to the «ELITe BeGenius» operator’s manual.

1. Prepare the sample as indicated in the Procedure of the preparation of the sample.
2. Switch on the «ELITe BeGenius» instrument using the power switch located on the right side of the instrument.

The «**ELITe BeGenius**» instrument software will be automatically loaded after the system has booted up. Please keep the door of the instrument system closed during system initialization.

Instrument set-up

After logging in by "Open" or "Closed" modality (IVD certified), the main screen "Home" appears.

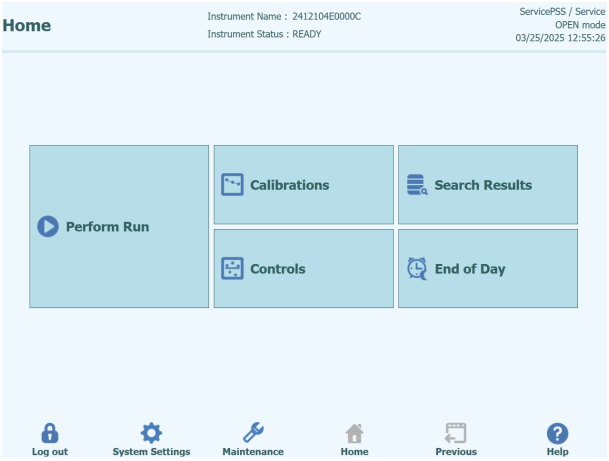


Figure 23**: ELITe BeGenius Home Screen**

3. Click on “Perform Run” button.
4. Select functions from the “Perform Run” screen.
5. It is possible to perform a session for “Extraction Only” or “Extraction and PCR”.

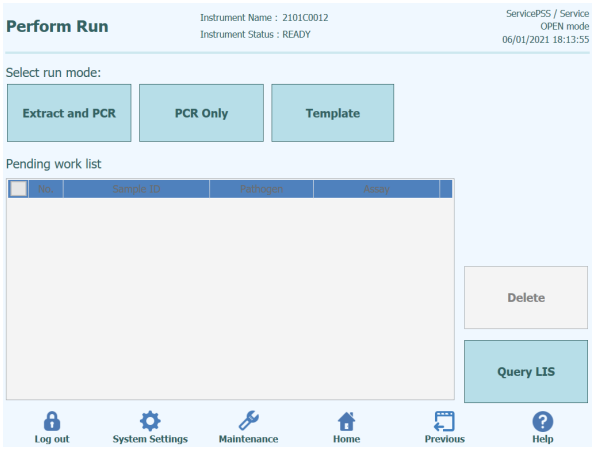


Figure 24: Run mode Selection Screen.

Minimum volume of samples in primary tubes

The procedure of the ELITe BeGenius System is optimized for the isolation of DNA and RNA from 200 µL samples. However, depending on sample tube type, a minimum sample volume is needed to prevent pipetting errors.

Note: If the ELITe BeGenius System detects an insufficient sample volume, it skips the sample and makes a note in the Result Report.

Volume of samples in the Extraction tubes and in the 2mL Sarstedt tube

All sample types can be directly loaded into the system using the extraction tube («ELITe InGenius SP 200 Consumable Set», ELITechGroup S.p.A., code INT032CS) or, when “Fast Lane” Mode is selected on the GUI, by using for all the twelve-extraction position the Sarstedt 2 mL tube (Sarstedt #72.694.006).

The volume required in “Fast Lane” Mode must be exactly 200 µL. If the available sample volume is lower than required, the sample volume may be adjusted by adding saline or phosphate buffered saline (PBS).

In the “Fast Lane” Mode the software allows to skip the single aspiration of the sample from the primary tube to the Extraction tube. The 12-noozle directly transfers lysis buffer from extraction cartridge to 2 mL Sarstedt tube, mixes and aspirates all the amount of liquid for each tube and moves to the cartridge.

If the “Fast Lane” is selected on the GUI, all tubes into lane 4 (or 5) must be 2 mL Sarstedt tubes ONLY.

If 2 mL Sarstedt tube is used and the “Fast Lane” mode is not selected, 40 µL of dead volume is required.

Tube Type	Minimum volume of sample
2 mL Sarstedt Tube in “Fast Lane” Mode	200 µL
2 mL Sarstedt Tube (no “Fast Lane” Mode)	240 µL

4. The L5 Sample Rack Insertion screen is displayed.

Figure 25: Run Setup for Rack L5 .

Note: with ELITe InGenius SP RNA Cartridges,the Input Volume of samples can be only 200 µL.

5. Insert the L5 Sample Rack with the 2 mL Sarstedt Tubes containing the Sample for the first extraction. If a barcode is attached to the Sample Tube, place it so that the barcode can be seen green indicator is turning on.
6. Gently insert the Sample Rack L5 in the Cooler Unit.
7. When a barcode on a Sample Tube is scanned successfully, the scanned Sample ID is displayed and the "Status" field changes to "Read".
8. The “2 mL Tube” field MUST be flicked.

Figure 26: Rack barcode scan results

NOTE Icons displayed on Sample Rack image

L5 icon	Display on Status field	State of installation
	Read	Sample ID scanned by a traceability barcode reader
	Entered manually	Sample ID entered by a user with an on-screen keyboard
	Empty	Tube is not installed
	No Barcode	Tube is installed but the barcode cannot be read
	Duplicate	Duplicate Sample ID
	Mismatch	Different Sample ID was captured by a traceability barcode reader after the user entered Sample ID with an on-screen keyboard

9. If you place a Sample Tube without the Sample ID barcode attached and insert the Sample Rack, "No Barcode" will be displayed in the "Status" column.

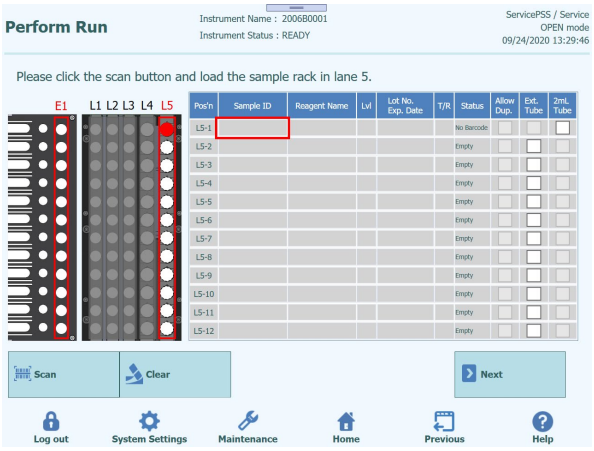


Figure 27: Rack barcode not read

10. Click the "Sample ID" field to display the on-screen keyboard. Enter the Sample ID.

The "Status" column will change to "Entered manually"

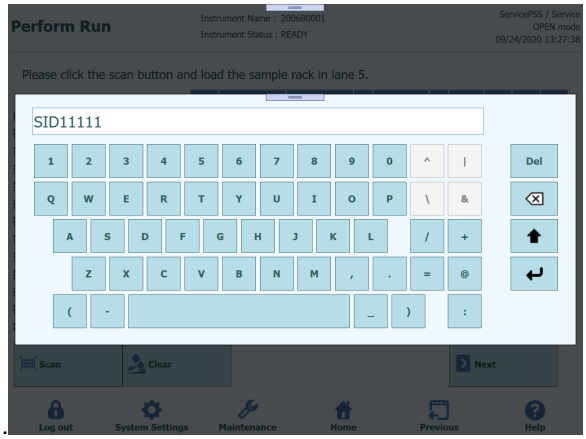


Figure 28: enter ID display

Figure 29: ID entered manually

11. Click “Next” and the Display of the L5 Assay setting window is showed. Select the liquid volume “200µL” to be used in the first extraction (Extraction Input Volume) and the liquid volume of nucleic acid extraction to be produced (Extracted Eluate Volume).

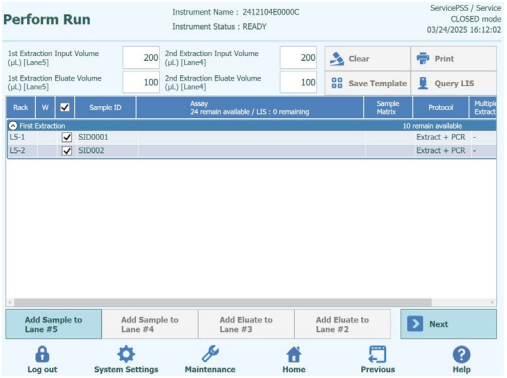


Figure 30: L5 Assay setting window

12. Click the Assay field of to choose the correct Assay Protocol.

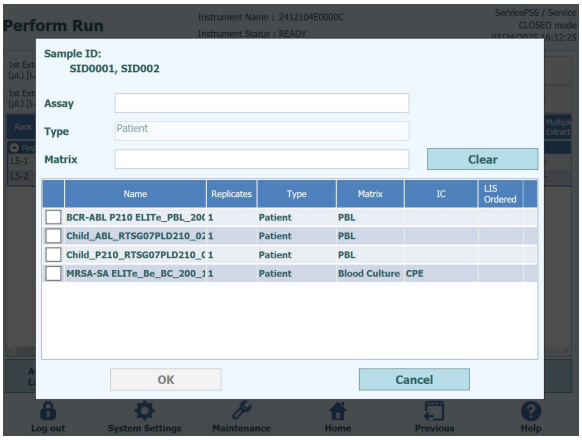


Figure 31: Assay Selection Window

13. Check the Assay to be executed.
14. Click the Next button.

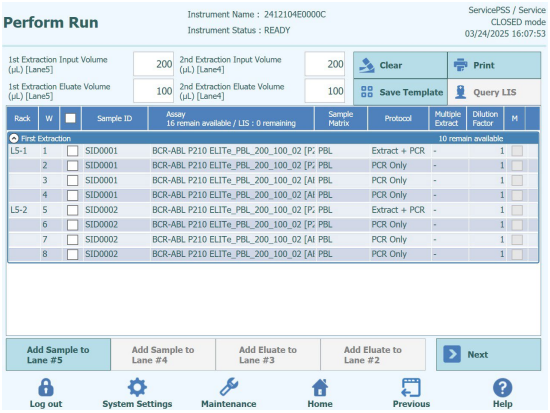


Figure 32: L5 Assay Protocol selected.

15. Repeat the steps 1 to 5 if others sample have to be extracted and loaded on the L4 Sample Rack.Click “Next” until the Display of the printout screen of Data Matrix Code for L3 Eluate Tube is showed (for the second extraction setting please refer to «ELITe BeGenius» operator’s manual). A Data Matrix Code to be attached to the 0.5mL Eluate Tube which contains the nucleic acid extraction produced in the first extraction is displayed.

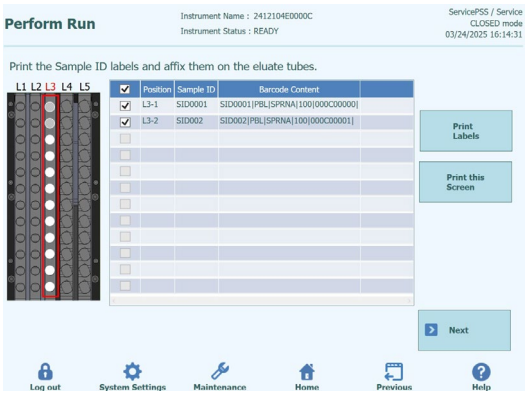


Figure 33: Screen for the Printout of Data Matrix Code for L3 Eluate Tube

16. Check the Position to print and prepare an empty 0.5mL Tube.

17. Click "Print Labels" to print out the Data Matrix Code for the checked Position.

18. Paste the printed Data Matrix Code on an empty 0.5mL Tube.

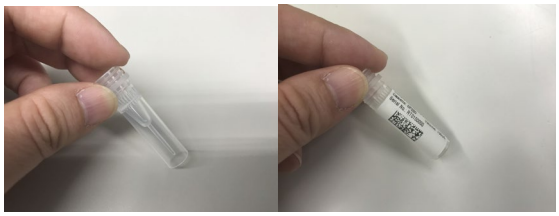


Figure 34: example of Data Matrix.

19. Take the L3 Reagent Rack and Set up an empty 0.5mL Eluate Tube with Data Matrix Code attached according to the installation image on the Position where the "Status" column of the ejected Reagent Rack is displayed as "Reserved".

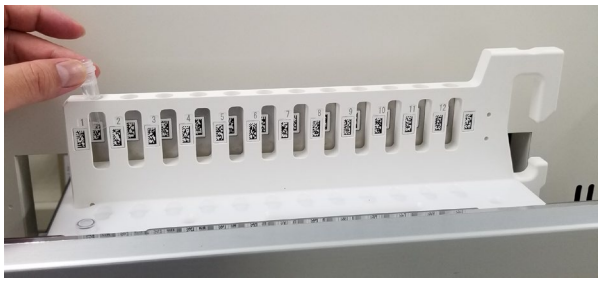


Figure 35: L3 Reagent Rack with the empty Elution Tubes.

20. Gently insert the Reagent Rack with Eluate Tube installed into the L3 of the Cooler Unit.

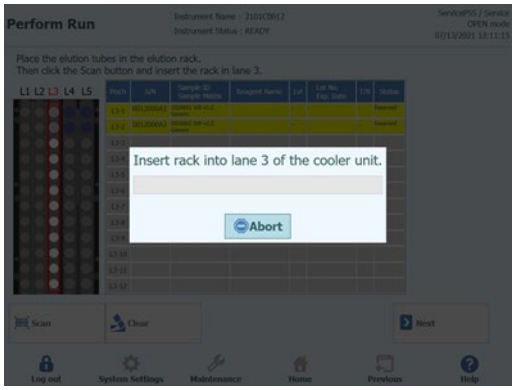


Figure 36

21. When the Data Matrix Code on the Eluate Tube is successfully read, the "Status" field will change to "Read".

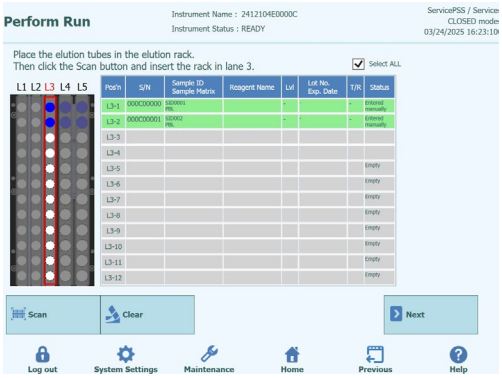


Figure 37: L3 Reagent Rack correctly loaded.

22. Click "Next" to display the L2 Reagent Rack insertion screen.

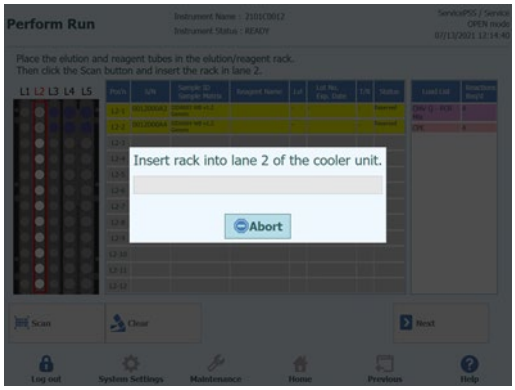


Figure 38

23. Take the L2 Reagent Rack and Set up requested 0.5mL reagent tube in an empty Position.
24. Gently insert the Reagent Rack with Eluate Tube installed into the L2 of the Cooler Unit.

When the Data Matrix Code on the reagent Tube is successfully read, the "Status" field changes to "Read".

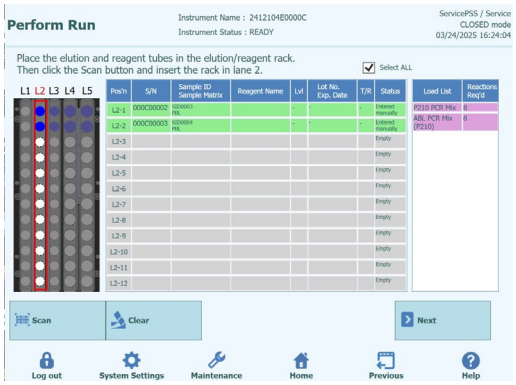


Figure 39: L2 Reagent Rack with empty Elution Tubes and the reagents

NOTE: is possible to load the reagent on the same rack with 05. mL empty elution tubes or is possible to load the reagent on the L1 Reagent Rack.

25. Click "Next".

Assay setting window will appear. Check if the correct Assay Protocol are set.

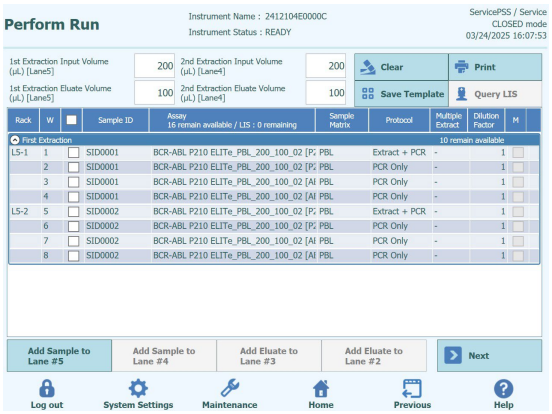


Figure 40: Assay Selected

26. Click next

The L1 Reagent Rack Insertion screen appear

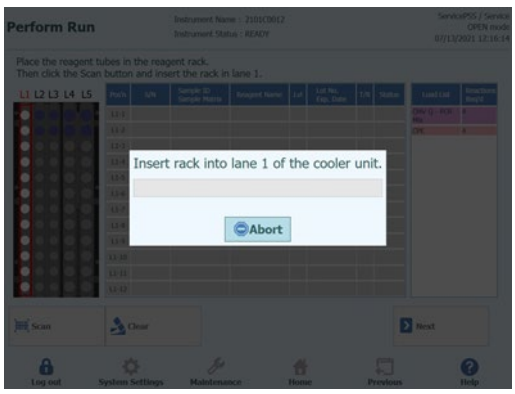


Figure 41

27. Take the L1 Reagent Rack and Set up requested PCR reagent tubes in an empty Position.
28. Gently insert the Reagent Rack with Reagent Tube installed into the L1 of the Cooler Unit.
29. When the Data Matrix Code on the reagent Tube is successfully read, the "Status" field changes to "Read".

Note: For products composed of Mix+RT enzyme, the number of reactions per tube readable by QR code refers to the mix tube not yet complete (without RT addition).

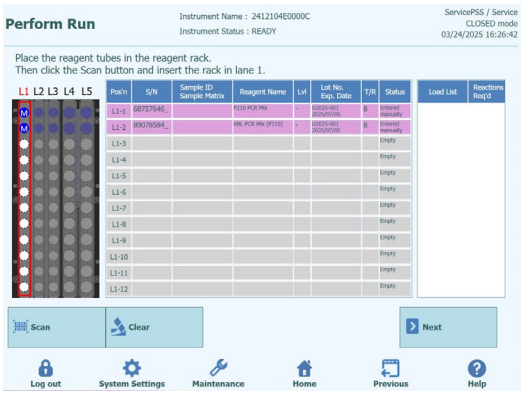


Figure 42

30. Once the required PCR reagents have been placed and all in the Load List have been cleared, click "Next".
31. Install Single Tips and make sure they are the same as the remaining number of Single Tips that are currently filled in the instrument.

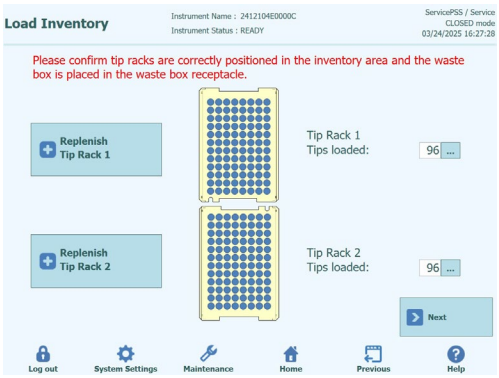


Figure 43: The “Load / Unload Inventory” screen confirms tip rack placement

32. Install PCR Reaction cassettes showed in installation image of the PCR Reaction cassette required for Run.

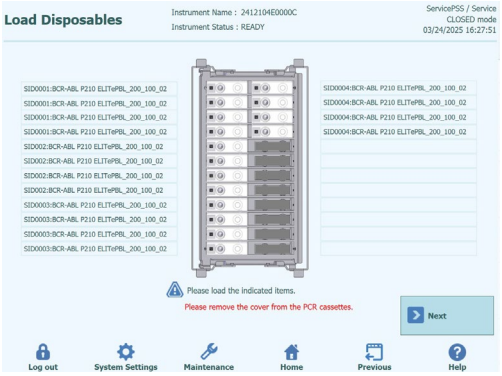


Figure 44: PCR Reaction cassette screen.

33. Click Next

The Load Disposable screen appear. t

Follow the instruction on the GUI for the positioning of the DNase I

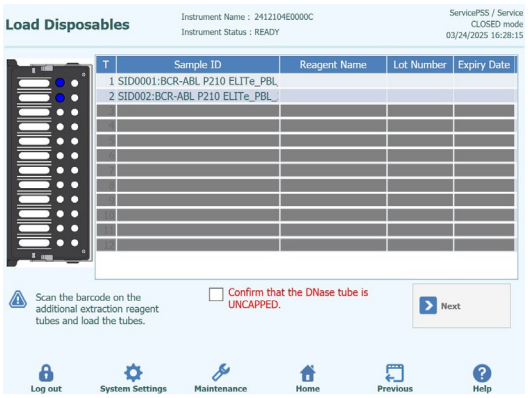


Figure 45:DNase I position in the Extraction Rack.

NOTE: In the “Reagent Name field indicate “DNase I”Flick the “Confirm that the DNase tube is UNCAPPED” field as showed in the Fig. 46 below.

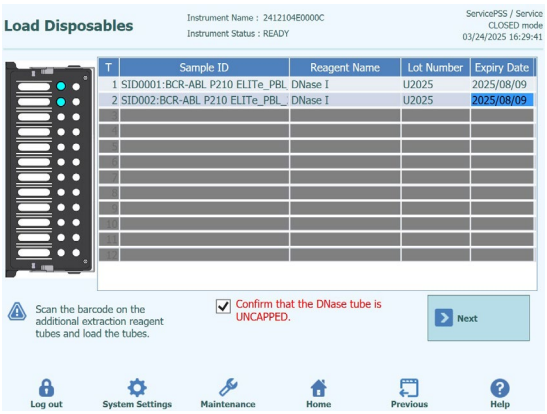


Figure 46: “Confirm that the DNase tube is UNCAPPED” flicked.

NOTE: if all the information about the DNase I are correctly inserted, its graphic visualization will turn from dark blue blue to light blue.

34. Click Next.

The Load of the Disposable set continue with the place of the ELITe InGenius SP RNA nucleic acid extraction cartridge and the Tip Cassette.

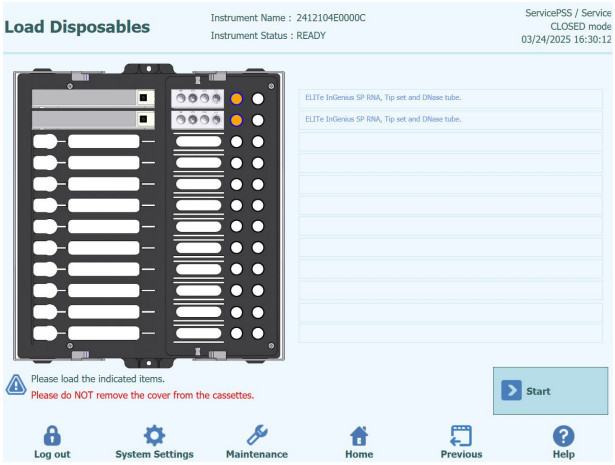


Figure 47

35. Close the door and click "Start" button.

The End of Run Screen provides instructions on unloading, storing or discarding the samples, materials and reagents. Please carry out these actions immediately.

36. Dispose consumables according to the instrument image in which the consumables are placed.

(Note) Red circles are samples with a risk of infection and should be disposed with caution.

Figure 48: End of Run screen.

37. After disposing of the consumables, click "OK" to display Home screen.
38. Click "End of Day" on Home window

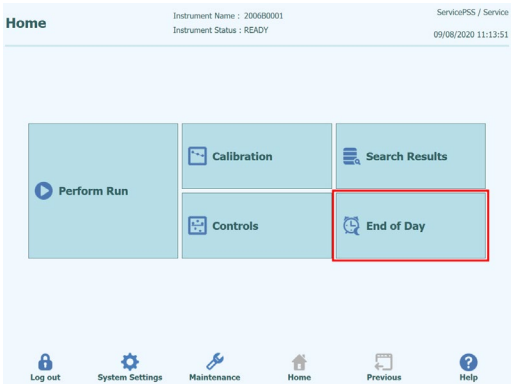


Figure 49

39. Click "Confirm inventory has been cleared".

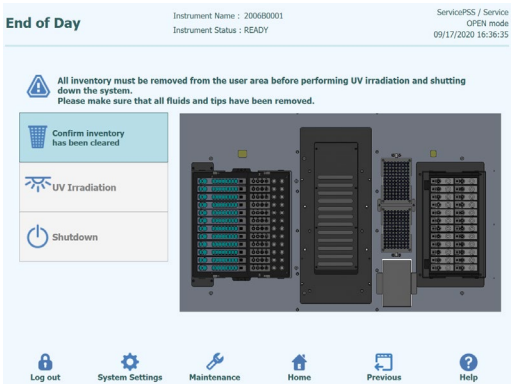


Figure 50

40. Click "UV Irradiation". The front door will be locked.

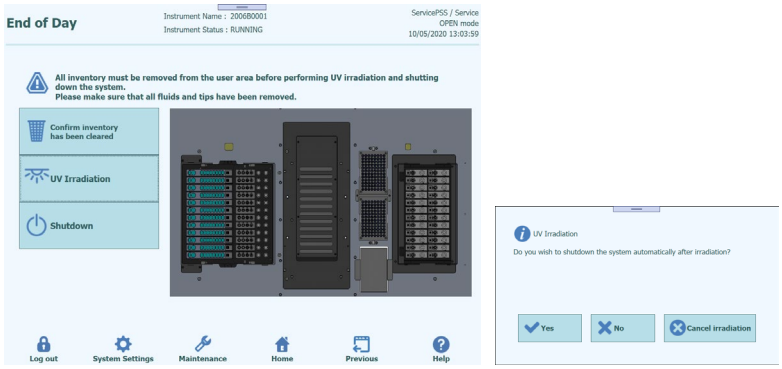


Figure 51

41. Select "Yes" to shut down the system after the UV irradiation is complete.

When "No" is selected, the system is not shut down after the UV irradiation is complete.
Warning message appears to confirm the UV lamp is ON. Click „Yes“ or „No“ to confirm or not the switching of the UV lamp.

42. After the system shuts down (after the display gets dark), turn off the power switch on the right side of the instrument.

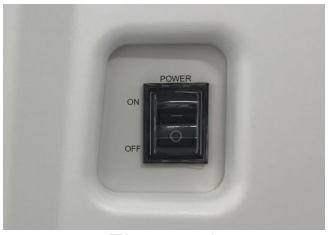


Figure 52

(Note) The power must be turned off manually.

PROCEDURE LIMITATIONS

Only use the following clinical samples with this product: lympho-monocyte suspensions and leukocyte suspensions isolated from peripheral blood collected in EDTA or sodium citrate. The kit validation is limited to the matrices mentioned in the intended use, other matrices lead to loss of compliance with Regulation IVDR (EU) 2017/746 for the respective process. No guarantee is issued with differing sample type or change in the procedure.

This product is in compliance with the Regulation IVDR (EU) 2017/746 for *in-vitro* medical devices. In-vitro diagnostic use of the product in countries where the Regulation IVDR (EU) 2017/746 is not recognized may be subjected to the fulfilment of registration procedures according to local competent authorities.

The user is responsible for validating the performance of the product if used with assays different from those validated by ELITechGroup S.p.A. as reported in the instructions for use. ELITechGroup S.p.A. does not provide validation of performance characteristics of the product regarding these applications.

The product may be used in a clinical laboratory if the laboratory diagnostic system has been validated as per EN ISO 15189 in European countries or equivalents in other countries.

Do not use whole blood samples collected in heparin with this product. Heparin inhibits DNA polymerase enzymes (such as thermostable DNA polymerases) and leads to invalid or incorrect results in subsequent steps of the analysis performed on the extracted nucleic acids.

Any inhibition phenomena from drugs that may be present in the starting sample may be evaluated in the extraction product depending upon how the extraction product is used.

The results obtained with this product are subject to the correct identification, collection, transport, storage and preparation of samples. To avoid incorrect results, it is necessary to take particular care during these activities and to carefully follow the instructions provided.

This product must be handled by qualified personnel and trained in the processing of potentially infective biological samples and dangerous chemical preparations in order to prevent accidents with potentially serious consequences for the user or other people.

This product requires the use of work clothes and work areas that are suitable for the processing of potentially infective biological samples and dangerous chemical preparations to prevent accidents with potentially serious consequences for the user or other people.

This product must be handled by qualified personnel and trained in molecular biology techniques, such as extraction, amplification and detection of nucleic acids, to avoid incorrect results with potentially serious consequences for the patient in subsequent steps of the analysis performed on the extracted nucleic acids.

This product must be handled in separate areas for extraction / preparation of amplification reactions and for amplification / detection of amplification products to avoid false positive results with potentially serious consequences for the patient in subsequent steps of the analyses performed on the extracted nucleic acids.

This product requires the use of special clothing and instruments for extraction, preparation of amplification reactions and for amplification / detection of amplification products to avoid false positive results with potentially serious consequences for the patient in subsequent steps of the analysis performed on the extracted nucleic acids.

TROUBLESHOOTING

Problem	Probable Cause	Comments and Suggestions
Low yield of extraction or RNA purity	Sample status	Verify that the sample storage condition is appropriate as reported in the sample and controls section. Use only fresh sample or sample stored under appropriate conditions. Extraction yield can vary from fresh or frozen sample.
	Reagent status	Verify that the extraction reagent cartridge storage condition is appropriate. Do not freeze the reagents and avoid storage locations subject to vibration.
	Solid items residues	Sample extracts with solid residues may cause tip obstruction, and the mixing process may not function properly. The sample should be a homogeneous solution for smooth handling by the 1000 µL pipet. Do not use solids in samples to be extracted.
	Issues with automation system	Refer to the error code displayed in the instrument operator's manual.
Contaminated extracts	Contamination with DNA or RNA	Clean carefully all instrument components and surfaces after use, using an agent capable of eliminating DNA and RNA.
RNA is degraded	Sample concentration too high	If a high concentrated sample has been used, the RNase cannot be inactivated. Dilute sample before loading.
	Elution storage	Do not store eluate at RT for long time. Tighten cap of elution tube as soon as possible, and keep samples at -20 °C.
	External RNAse contamination	After use, clean all parts on the instrument surface carefully by using RNase removal agents.

SYMBOLS

REF	Catalogue Number
	Temperature limits
LOT	Batch code
	Use by (last day of month)
IVD	*In vitro* diagnostic medical device
CE	Fulfilling the requirements of the Regulation IVDR (EU) 2017/746 for *in vitro* diagnostic medical device
UDI	Unique Device Identification
	Contains sufficient for "N" tests
	Do not reuse
	Consult instruction for use
CONT	Contents
	Keep away from sunlight
	Manufacturer
	Country of manufacture
	Health Hazard
	Danger
	Flammable
	Corrosive

NOTICE TO THE USERS

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and /or the patient is established.

To inform ELITechGroup S. p. A., manufacturer of this device, please use the following mail address: egspa.vigilance@elitechgroup.com.

NOTICE TO PURCHASER: LIMITED LICENSE

ELITe InGenius® technology is covered by patents and requests for patents.

This limited license allows the person or entity to whom the product has been provided to use the product and data generated with the use of the product, only for human diagnostics. Neither ELITechGroup S.p.A. nor its licensors grant other explicit or implied licenses for other purposes.