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NOTICE of CHANGE dated 01/12/2022

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITe InGenius® SP 200»
Ref. INT032SP200

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

- *Update with indication of the sample volume required for the 2 mL tubes and description of the 'Fast Lane' mode.*

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 200

Reagents for Nucleic Acid Extraction

REF INT032SP200 IVD +10 °C +30 °C

UDI 03661540900020

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INTENDED USE

The **«ELITe InGenius® SP 200»** is a cartridge ready to use containing reagents for extraction and purification of nucleic acids (NA) for single test.

«ELITe InGenius SP 200» (ELITechGroup S.p.A., code INT032SP200) is used in association with the **«ELITe InGenius®»** (ELITechGroup S.p.A., code INT030) and «**ELITe BeGenius®**» (ELITechGroup S.p.A., code INT040) instruments and constitutes, together with ELITechGroup Real Time PCR assays, the **ELITe InGenius and BeGenius** Systems, a fully automated molecular diagnostics system performing extraction, purification, amplification, detection and results interpretation.

The NA isolation protocol is based on magnetic beads and designed for automated preparation of highly pure genomic DNA (human, bacterial ,viral, fungal and parasitic) and viral genomic RNA from the following human clinical samples: whole blood collected in EDTA or citrate, serum, plasma collected in EDTA or citrate, urine, cerebrospinal fluid (CSF), amniotic fluid, cavitary fluid, respiratory samples (Bronchoalveolar Lavage / Broncho aspirate, Sputum and nasopharyngeal aspirate), respiratory swab (nasal swab, throat swab), buccal swab, saliva, cervical-vaginal swab, mucocutaneous lesions swab, rectal swab, stool, blood culture, biopsies and gastric aspirates.

«ELITe InGenius SP 200» does not provide diagnostics results by itself. To obtain diagnostic results, this product must be used with a NA amplification assay and **ELITe InGenius** and **ELITe BeGenius** instruments. The **«ELITe InGenius»** and **«ELITe BeGenius»** instruments are intended to perform Real Time PCR after NA 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 200»** is the reagent set for automated DNA and RNA extraction and purification from fresh or frozen cellular and non-cellular fluid samples in association with the **«ELITe InGenius»** and **«ELITe BeGenius»**. The reagent set has been optimized for the isolation of nucleic acids from 200 µL samples. The resulting nucleic acid extracted is then available for Real Time PCR application with **«ELITe InGenius»** and **«ELITe BeGenius»**.

The NA isolation process is based on the Magtration® Technology, an automated extraction technology based on magnetic beads.

The sample is lysed with a lysis solution and proteinase K, Carrier RNA and an Internal Control template.

After removal of proteins and other biological substances, the NA adsorb on to magnetic beads covered with a hydrophilic surface.

The unabsorbed materials are removed by magnetic bead separation followed by several washing steps. Finally, purified NA is eluted in distilled water, as shown in Figure A below.

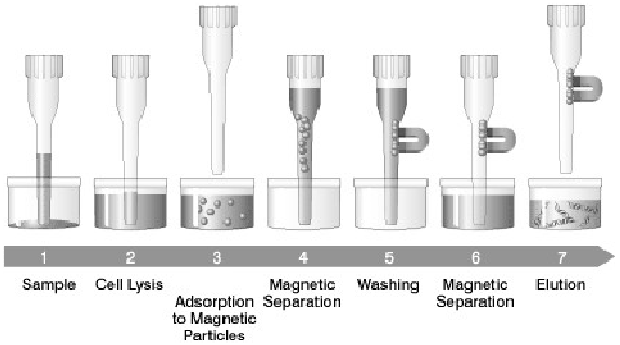

Figure A: Extraction Workflow

The **«ELITe InGenius»** and **«ELITe BeGenius»** automatically perform sample dispensing from primary tubes. The NA 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 use of a unique barcode for each sample avoids unwanted transpositions. Barcode accepted are described in the Operator's manual.

The resulting highly purified nucleic acids are eluted with distilled water. The extraction process on 12 samples takes approximately 30 minutes.

The purified nucleic acids are ready to use for downstream assays based on 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. 4 runs x 12 samples).

Note: The minimum number of samples to be processed per run with the **«ELITe InGenius»** and **«ELITe BeGenius»** is 1, the maximum number is 12.

MATERIALS PROVIDED

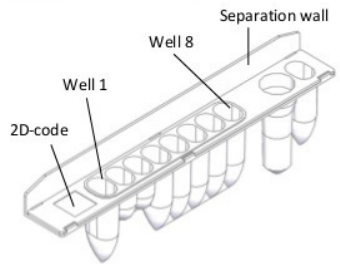

Figure B: Nucleic Acid Extraction Cartridge

The kit contains 48 unitary prefilled Nucleic Acid extraction cartridges.

Each Nucleic acid extraction cartridge contains:

Well No.	Reagent Name	Quantity	Hazard Codes
1	Lysis solution	400 µL	H302, H315, H319, H335, H400, H410
2	PK solution	80 µL	-
3	Carrier solution	80 µL	-
4	Magnetic beads	200 µL	-
5	Binding buffer	1000 µL	H225, H319, H335, H361, H370, H372, H373
6	Wash buffer 1	1200 µL	
7	Wash buffer 2	700 µL	
8	Distilled water	1200 µL	-
9	Empty	-	-
10	Empty	-	-

Note: The two empty wells are used during the extraction process for sample heat treatment.

Material Storage

The **«ELITe InGenius SP 200»** 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 200»** for applications as described in the manual.

In accordance with the EGSpA certified Quality Management System, the **«ELITe InGenius SP 200»** has been tested against established acceptance criteria to ensure consistent product quality.

ELITe InGenius® SP 200
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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 (12,000 - 14,000 RPM).
- Bench centrifuge (3,000 RPM).

Sample tubes for samples are not provided. To run samples on the **ELITe InGenius System**, the user should use the primary tubes listed below. For other samples types, the user should use one of the secondary tubes listed below.

Sample Tubes for ELITe InGenius System
Primary tubes
BD 3.0 mL Vacutainer, 13 x 75mm (e.g. BD #367856)
BD 4.0 mL Vacutainer, 13 x 75mm (e.g. BD #368861)
BD 6.0 mL Vacutainer, 13 x 100mm (e.g. BD #367864)
eNAT™ collection and storage system, 12 x 80 mm (Copan Italia SpA #606CS01R)
Secondary tubes
Sarstedt 5 mL tube, 13 x 75mm (Sarstedt #55.475.030)
Extraction tubes (ELITechGroup S.p.A., code INT032CS)
Sonication tubes (ELITechGroup S.p.A., code INT032SON)

Sample tubes for samples are not provided. To run samples on the **ELITe BeGenius System**, the user should use the primary tubes listed below. For other samples types, the user should use one of the secondary tubes listed below.

Sample Tubes for ELITe BeGenius System
Primary tubes
BD 3.0 mL Vacutainer, 13 x 75mm (e.g. BD #367856)
BD 4.0 mL Vacutainer, 13 x 75mm (e.g. BD #368861)
BD 6.0 mL Vacutainer, 13 x 100mm (e.g. BD #367864)
BD 10.0 mL Vacutainer, 16 x 100mm (e.g. BD #366643)
COPAN UTM 12 x 80 mm (e.g, Copan Italia SpA #360C)
COPAN UTM 16 x 100 mm (e.g. Copan Italia SpA #306C)
Secondary tubes
Sarstedt 2 mL tube, (Sarstedt #72.694.006)
Extraction tubes (ELITechGroup S.p.A., code 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
Filter tips 300 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	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., code INT030) or the **«ELITe BeGenius»** instrument (ELITechGroup S.p.A., code INT040), and with the **«ELITe InGenius® SP 200 Consumables Set»** (ELITechGroup S.p.A., code INT032CS) and the «**ELITe InGenius® Sonication tubes**» (ELITechGroup S.p.A., code INT032SON).

The consumables necessary to carry out the extraction procedure are included in the «**ELITe InGenius SP 200 Consumable Set**». The consumable set can be ordered separately using the code ELITechGroup S.p.A., code INT032CS. 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 cassettes	4 x 12	Cassette containing a piercing tip and a pipette tip used during the extraction procedure
Elution tubes	50	0.5 mL tube and cap used to collect the extracted Nucleic Acid (NA)

The consumables necessary to carry out the sonication procedure are included in the «**ELITe InGenius® Sonication tubes**». The sonication tubes and caps can be ordered separately using the code ELITechGroup S.p.A., code INT032SON. The components are listed below:

Component	Quantity	Description
Sonication tube	192	Disposable tube to be placed in the sonication position. It can also be used as secondary tube for loading samples
Sonication tube cap	192	Cap used to seal sonication tubes during sonication

Extraction and Inhibition Internal Control is not included in this kit. When this extraction kit is used in association with an amplification ELITe MGB kit by ELITechGroup S.p.A., for the Extraction and Inhibition Internal Control, please refer to the amplification ELITe MGB kit IFU.

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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 exclusively used 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. 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

The following components of the **«ELITe InGenius SP 200»** 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 Hexadecyl trimethylammonium chloride and Guanidinium chloride

Danger

H302: Harmful if swallowed.
H315: Causes skin irritation.
H319: Causes serious eye irritation
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.

P264:	Wash the hands thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P273:	Avoid release to the environment.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312:	IF SWALLOWED: Call a POISON CENTER or a doctor if you feel unwell.
P302+P352:	IF ON SKIN: Wash with plenty of water.
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.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P321:	Specific treatment.
P330:	Rinse mouth.
P332+P313:	If skin irritation occurs: Get medical advice/attention.
P337+P313:	If eye irritation persists get medical advice/attention.
P362:	Take off contaminated clothing.
P391:	Collect spillage.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.
P405:	Store locked up.
P501:	Dispose of contents/container according to national regulation.

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

Danger

H225:	Highly flammable liquid and vapour.
H319:	Causes serious eye irritation.
H335:	May cause respiratory irritation.
H361:	Suspected of damaging fertility or the unborn child.
H370:	Causes damage to organs.
H372:	Causes damage to organs through prolonged or repeated exposure.
H373:	May cause damage to organs through prolonged or repeated exposure.
P201:	Obtain special instructions before use.
P202:	Do not handle until all safety precautions have been read and understood.
P210:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233:	Keep container tightly closed.
P240:	Ground/bond container and receiving equipment.
P241:	Use explosion-proof electrical/ventilating/lighting equipment.
P242:	Use only non-sparking tools.
P243:	Take precautionary measures against static discharge.
P260:	Do not breathe dust/fumes/gas/mist/vapours/spray.
P261:	Avoid breathing dust/fume/ gas/mist/vapours/spray.
P264:	Wash the hands thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353:	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
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.
P308+P311:	If exposed or concerned: Call a POISON CENTER or a doctor.
P308+P313:	If exposed: Call a POISON CENTER or a doctor.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P314:	Get medical advice/attention if you feel unwell.
P321:	Specific treatment.
P337+P313:	If eye irritation persists: Get medical advice/ attention.
P370+P378:	In case of fire: use carbon dioxide, foam, dry chemical and water fog to extinguish.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.

P403+P235:	Store in a well-ventilated place. Keep cool.
P405:	Store locked up.
P501:	Dispose of contents/container according to national regulation.

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

No other component of the **«ELITe InGenius SP 200»** 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 Systems

In the case of an instrument error message, please refer to instrument Operator's Manual (ELITechGroup S.p.A., code INT030 or INT040).

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.

The "ELITe InGenius SP 200" product has been validated in association with various molecular diagnostic assays by ELITechGroup S.p.A. and the following biological samples:

- Whole blood collected in EDTA or citrate
- Serum
- Plasma collected in EDTA
- Urine
- Cephalorachidian fluid (CSF)
- Amniotic fluid
- Cavitary Fluids
- Respiratory Samples (Bronchoalveolar lavage / bronchoaspirate, sputum and nasopharyngeal aspirate)
- Respiratory swabs (nasal and pharyngeal)
- Buccal swabs
- Saliva
- Cervico-vaginal swabs
- Swabs of skin and mucocutaneous lesions
- Rectal swabs
- Feces
- Blood cultures
- Biopsies
- Gastric aspirates

For information relating to the collection, transport, storage and pre-treatment of individual biological samples, refer to the user manuals of the individual ELITechGroup S.p.A. products

As general examples, we provide some suggestions of possible pre-treatments and storage methods for the different biological samples.

Different primary tubes (see "Materials required but not provided", page 3) and anticoagulants (EDTA, citrate, but not heparin) can be used to collect the samples to be used with the **«ELITe InGenius SP 200»**.

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

Whole blood collected in EDTA or citrate

Whole blood samples (peripheral and from bone marrow) for nucleic acid extraction must be collected in EDTA or citrate according to laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of three days, otherwise they must be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Whole blood samples do not require pre-treatment and may be directly extracted.

Serum

After collection and centrifugation, according to laboratory guidelines, serum for nucleic acid extraction must be transported and stored at +2 / +8 °C for a maximum of 4 hours. For long term storage, we recommend freezing samples at -20 °C (up to 30 days storage) or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Serum samples do not require pre-treatment and may be directly extracted.

Plasma collected in EDTA or citrate

The plasma samples for nucleic acids extraction must be collected in EDTA according to laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of three days, otherwise they must be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Plasma samples do not require pre-treatment and may be directly extracted.

Urine

Urine samples for nucleic acid extraction must be collected in preservative-free containers according to laboratory guidelines, transported and stored at room temperature (+18 / + 25 °C) for a maximum of four hours, otherwise they must be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Note: Freezing of urine samples often causes the formation of precipitates: thaw urine samples carefully, dissolving all possible precipitates.

Urine samples do not require pre-treatment and may be directly extracted.

Cerebrospinal fluid (CSF)

CSF samples for nucleic acid extraction must be collected according to laboratory guidelines, avoiding contamination from the patient's blood, transported and stored at +2 / +8 °C for a maximum of 4 hours otherwise they must be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Cerebrospinal fluid samples do not require pre-treatment and may be directly extracted.

Amniotic fluid

The amniotic fluid samples for nucleic acid extraction must be collected according to the laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of four hours, otherwise they must be frozen and stored at -20°C for a maximum of thirty days or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Amniotic fluid samples do not require pre-treatment and may be directly extracted.

Cavitary fluids

The cavitary fluid samples for nucleic acid extraction for *Mycobacterium tuberculosis* diagnosis must be collected and identified according to mycobacteriology laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of two days. Samples must be concentrated and decontaminated with sodium hydroxide solution (Mycobacteriology Laboratory Manual, Global Laboratory Initiative). The concentrated and decontaminated sample must be then inactivated at 95 °C for 30 minutes. The concentrated and decontaminated cavitary fluid samples can be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

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Respiratory samples (Bronchoalveolar Lavage (BAL) / Broncho aspirate (BA), Sputum and nasopharyngeal aspirate)

The BAL samples for nucleic acids extraction must be collected according to laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of one week, otherwise they must be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C up to one year, according to laboratory practice. Avoid multiple freeze-thaw cycles of the sample.

The BAL samples do not require pre-treatment and may be directly extracted.

The Sputum and BA samples for nucleic acids extraction must be collected according to laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of one week. Mucous samples must be liquefied according to laboratory guidelines. The samples can be frozen and stored at -20 °C for a maximum of thirty days or at -70 °C up to one year, according to laboratory practice. Avoid multiple freeze-thaw cycles of the sample.

The Respiratory samples for nucleic acid extraction of *Mycobacterium tuberculosis* must be collected and identified according to mycobacteriology laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of two days. Samples must be liquefied with a solution of N-Acetil L-Cysteine and decontaminated with sodium hydroxide solution (Mycobacteriology Laboratory Manual, Global Laboratory Initiative). The liquefied and decontaminated sample must be then inactivated at 95°C for 30 minutes. The liquefied and decontaminated samples can be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

The Respiratory samples of nasopharyngeal aspirate for nucleic acids extraction must be collected according to laboratory guidelines, transported and stored at room temperature (+18 / +25 °C) for a maximum of two days or at +2 / +8 °C for a maximum of seven days, otherwise they must be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

The Respiratory samples of nasopharyngeal aspirate do not require pre-treatment and may be directly extracted.

Respiratory swab (throat and nasal swab)

The throat and nasal swab samples for nucleic acids extraction must be collected in preservative-free containers according to laboratory guidelines, transported and stored at room temperature (+18 / +25 °C) for a maximum of one day, otherwise they must be transported and stored at +2 / +8 °C for a maximum of seven days, or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Respiratory swab samples do not require pre-treatment and may be directly extracted.

Buccal swab

The buccal swab samples for nucleic acid extraction should be collected with the collection and transport systems «eSwab Collection Kit» (Copan Italia SpA), identified according to laboratory guidelines, and transported and stored at room temperature (+18 / + 25 °C) for a maximum of five days, otherwise at +2 / +8 °C for up to seven days, otherwise they must be frozen and stored at -20 °C for a maximum of six months or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Buccal swab samples do not require pre-treatment and may be directly extracted.

Saliva

The saliva samples for nucleic acid extraction must be collected in a sterile tube according to laboratory guidelines, transported and stored at room temperature (+18 / +25 °C) for a maximum of two day or at +2 / +8 °C for a maximum of three days, otherwise they must be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Saliva samples do not require pre-treatment and may be directly extracted.

Cervical-Vaginal swab

The cervical-vaginal swab samples for nucleic acid extraction must be collected in eSWAB® kit (Copan Italia SpA) and identified according to laboratory guidelines, transported and stored at room temperature (+18 / +25 °C) for a maximum of two days or at +2 / +8 °C for a maximum of two days. The cervical-vaginal swab samples can be frozen and stored at -20 °C for a maximum of two months or at -70 °C until two years. Avoid multiple freeze-thaw cycles of the sample.

Cervical-vaginal swab samples do not require pre-treatment and may be directly extracted.

Cutaneous and mucocutaneous lesion swab samples

The cutaneous and mucocutaneous lesion swab samples for DNA extraction must be collected and stored in UTM, M4, M4RT, M5 or M6 viral transport media and identified according to laboratory guidelines. The specimens must be transported and stored in a refrigerator (+2 / +8 °C) for a maximum of 7 days or at -70 °C for a maximum of 3 months.

Split the samples into aliquots before freezing, in order to prevent repeated cycles of freezing and thawing.

Store purified nucleic acids at +2 / +8 °C if they will be used on the same day they were extracted or at -20 °C for long term storage.

Samples provided in an ELITe InGenius compatible primary tube (12×80 mm or 13x100 screw cap tube with internal conical shape, Copan Italia S.p.A., or similar) with a sample volume of at least 2.2 mL can be placed directly in the ELITe InGenius primary sample rack. Samples provided in a tube that is not compatible with the ELITe InGenius or that has a sample volume lower than 2.2 mL require a 200 µL aliquot to be transferred into a extraction tube placed in the ELITe InGenius Sonication/Extraction tube rack. Refer to the ELITe InGenius Operator's Manual (SCH mINT030) for more information.

Rectal swab

The rectal swab samples for nucleic acid extraction must be collected in FecalSwab™ (Copan Italia SpA) and identified according to laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of three days. Before the analysis with this product 0.5 mL of sample in FecalSwab™ medium has to be transferred in a fresh eNAT™ tube with 2.0 mL of medium (Copan Italia SpA), mixed by vortexing. The samples diluted in eNAT™ medium can be stored at +2 / +8 °C for a maximum of 4 weeks or frozen and stored at -20 °C for a maximum of six months or at -70 °C for longer periods. After addition of 0.5 mL of sample in FecalSwab™ medium, the eNAT™ tube can be directly loaded in the system as a primary tube.

The rectal swabs for nucleic acid extraction must be collected in eSwab® (Copan Italia SpA) and identified according to laboratory guidelines, transported and stored at room temperature (+18 / +25 °C) for a maximum of 24 hours or transported and stored at +2 / +8 °C for a maximum of 48 hours. Before analysis with this product 0.25 mL of sample in eSwab® medium has to be transferred in a fresh eNAT® tube with 2.0 mL of medium, mixed by vortexing. The samples diluted in eNAT® medium can be frozen and stored at -20 °C for a maximum of six months or at -70 °C for longer periods. After addition of 0.25 mL of sample in eSwab® medium, the eNAT® tube can be directly loaded in the system as a primary tube.

Rectal swab samples do not require pre-treatment and may be directly extracted.

Stool

The stool samples, intended for nucleic acid extraction, should be collected following standard stool collection and handling procedures and identified according to laboratory guidelines. Raw stool should be sealed in a sterile screw-cap container that can be adequately sealed to prevent accidental discharge of the contents and must be transported following all applicable regulations for the transport of etiologic agents. Store samples refrigerated (+2 / +8 °C) for up to 48 hours before processing. If stool clarification cannot be performed within 48 hours of collection, store samples at -70 °C. Avoid multiple freeze-thaw cycles of the sample.

Stool samples for nucleic acid extraction of *C. difficile* require the following pre-treatment: prepare two labeled 1.5 mL tubes for each raw stool and dispense 0.8 mL of S.T.A.R. buffer into one tube. Vortex the raw stool, and then use a pipettor with an aerosol resistant tip to transfer approximately 200 µL (use a wide bore tip or plastic spatula as necessary for thick stool samples) of the raw stool into the 1.5 mL tube containing the S.T.A.R. buffer. Cap the tube securely, and then vortex the tube to homogenize mixture (20-30 sec). Centrifuge the homogenized solution at 13.000×g (RCF) for 1 minute to clarify the sample. Carefully transfer 200 µL of the clarified stool supernatant into a Extraction tube provided with **«ELITe InGenius SP 200 Consumable Set»**, being careful not to disturb the pelleted fecal material. Store the clarified stool in at +2 / +8 °C for up to 7 days before proceeding with the extraction.

Stool samples for nucleic acid extraction of Norovirus, Rotavirus, Astrovirus, Adenovirus and Hepatitis E virus require the following pre-treatment: vortex the raw stool, transfer about 3 mL stool in the 50 mL conical tube (corresponding to fill the conical bottom), add 5 mL of molecular biology grade water, vortex until the sample is homogeneous, transfer 100 µL of water-treated stool sample to 900 µL of molecular biology grade water into the 1.5 mL tube, vortex until the sample is homogeneous, centrifuge at 11000 rpm for 1 minute. Carefully transfer 200 µL of the stool supernatant into a Extraction tube provided with **«ELITe InGenius SP 200 Consumable Set»**, being careful not to disturb the pelleted fecal material.

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Blood culture

The blood culture samples for nucleic acid extraction must be collected and identified according to laboratory guidelines. The samples must be transported and stored at room temperature for a maximum of 24 hours. Before the analysis with this product dilute the sample 1:1000 in molecular biology grade water (at least 10 µL of samples into 10 mL of water), mix by vortexing and transfer 0.2 mL of the diluted samples in a Extraction tube provided with **«ELITe InGenius SP 200 Consumable Set»**.

Biopsies

The biopsy samples for nucleic acid extraction of *Mycobacterium tuberculosis* must be collected and identified according to mycobacteriology laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of two days. Break down the samples according to laboratory procedures and decontaminate them with a sodium hydroxide solution (Mycobacteriology Laboratory Manual, Global Laboratory Initiative). The decontaminated sample must be then inactivated at 95 °C for 30 minutes. The decontaminated biopsy samples can be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze / thaw cycles of the sample.

Gastric aspirates

The gastric aspirate samples for nucleic acid extraction of *Mycobacterium tuberculosis* must be collected and identified according to mycobacteriology laboratory guidelines, transported and stored at +2 / +8 °C for a maximum of two days. Samples must be liquefied with a solution of N-Acetil L-Cysteine and decontaminated with sodium hydroxide solution (Mycobacteriology Laboratory Manual, Global Laboratory Initiative). The liquefied and decontaminated sample must be then inactivated at 95 °C for 30 minutes. The liquefied and decontaminated gastric aspirate samples can be frozen and stored at -20 °C for a maximum of one month or at -70 °C for longer periods. Avoid multiple freeze-thaw cycles of the sample.

Interfering substances

Whole blood samples and plasma 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 DNA and 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 DNA and 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.

ELITE INGENIUS PROCEDURE

Read the «**ELITe InGenius**» operator's manual carefully.

PREPARATION OF SAMPLES

Note: Samples must be transferable by pipette; ensure there are no clots or other solid materials. If primary tubes are used and completely filled, please mix the sample to ensure a homogenous solution is formed before loading onto the instrument.

Minimum volume of samples in primary tubes

The procedure of the **ELITe InGenius 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. The minimum volume of samples required are shown in the table below.

Tube Type	Minimum volume of sample
13x75 U-bottom tube: BD 3.0 mL - BD 4.0 mL Vacutainer, Sarstedt 5 mL tube (secondary tube)	2.2 mL
eNAT™, 12 x 80 mm, Copan Italia SpA	2.2 mL
13x100mm U-bottom tube: BD 6.0 mL Vacutainer	4.2 mL

Note: If the **ELITe InGenius System** detects a low sample volume, it skips the sample and makes a note in the Result Report.

Volume of samples in the Extraction tubes and Sonication tubes

All sample types can be directly loaded into the system using the extraction and sonication tube (**«ELITe InGenius SP 200 Consumable Set»**, ELITechGroup S.p.A., code INT032CS and «**ELITe InGenius® Sonication tubes**», ELITechGroup S.p.A., code INT032SON).

The volume required when using extraction tubes is 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).

DESCRIPTION OF THE EXTRACTION PROCEDURE

Extraction with the **«ELITe InGenius SP 200»** reagent cartridge is performed automatically by the **ELITe InGenius 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. Prepare each sample as indicated by the GUI:

Consumption for one clinical sample with sonication is as follows:

- ELITe InGenius SP 200 cartridge 1 pc
- Tip Cassette 1 pc
- Sonication tube 1 pc
- Sonication cap 1 pc
- Elution tube 1 pc

Consumption for one clinical sample without sonication is as follows:

- ELITe InGenius SP 200 cartridge 1 pc
- Tip Cassette 1 pc
- Extraction tube 1 pc
- Elution tube 1 pc

5. Close the instrument front cover.
6. Push Start button to start the nucleic acid extraction process.
7. After process completion, open the front cover by following prompts on the system screen.
   Extracted NA will be used directly in PCR reaction if a full “Extraction plus PCR” method was selected.

If “Extraction plus PCR” was not selected, the extracted NA may also be stored in the 0.5 mL elution tube. After the run, tighten the screw cap and store the sample for future use.

ELITe InGenius® SP 200
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General overview of the ELITe InGenius 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.

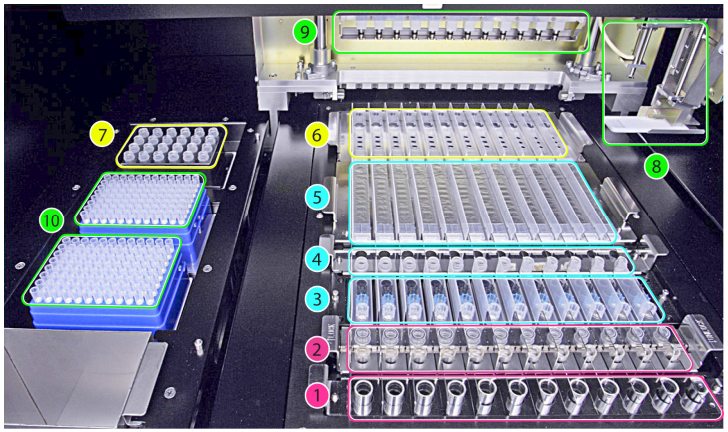

Figure 1: The **«ELITe InGenius»** loading area

Figure 1 shows: Primary tube rack position (**1**), Sonication/Extraction tube and cap rack position (**2**), Tip rack position (**3**), Elution tube rack position (Extra Tube) (**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.

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).

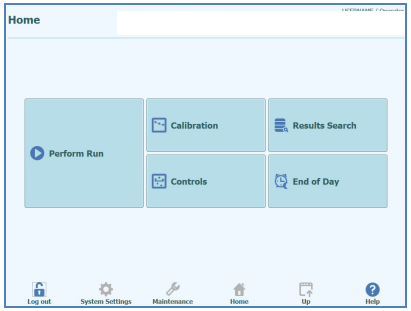

Figure 2: «ELITe InGenius» Home screen

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

The Perform Run screen appears (Figure 3).

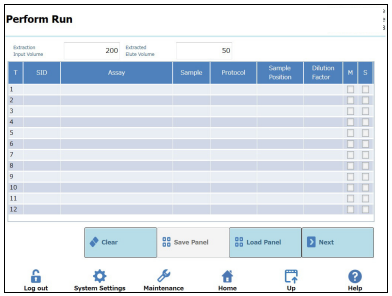

Figure 3: “Perform Run” screen

"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 have to be specified. The picture below shows an example of three assays assigned to a single SID (Figure 4).

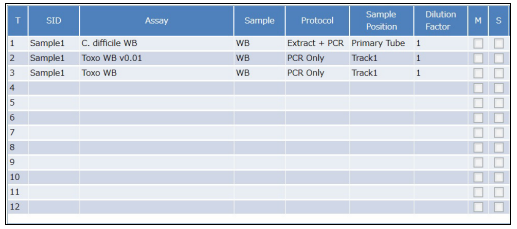

Figure 4: Example of Sample ID and Assay specification

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
5. Select “Sample Position” to identify the position from which the sample will be collected: “Primary tube” or “Extractionn tube” (used as secondary tube) position.

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.

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

The “Load / Unload Inventory” screen appears (Figure 5).

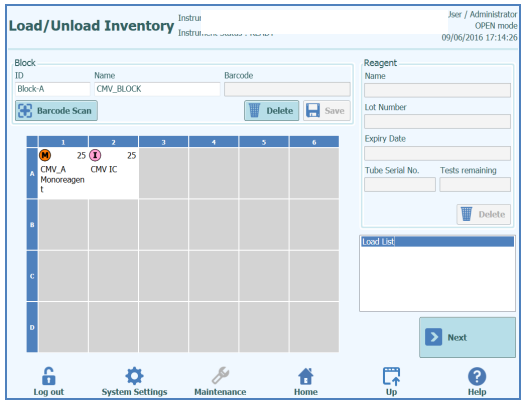

Figure 5: “Load / Unload Inventory” screen

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

7. To confirm that sufficient reagents for the number of tests selected are placed in the inventory manager position 7 (cfr. page 11, 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 6).

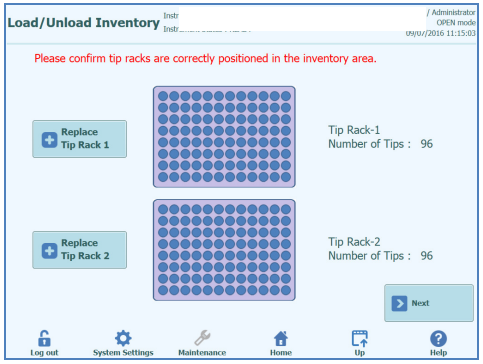

Figure 6: The “Load / Unload Inventory” screen confirms tip rack placement

8. Place sufficient Tips racks in position 10 (cfr. page 11, Figure 1).
9. 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 7).

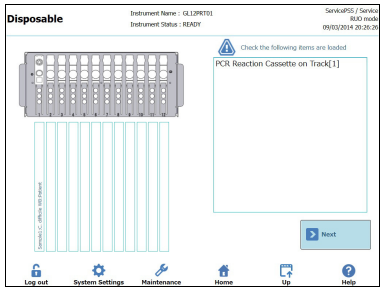

Figure 7: The “Disposable” screen is used to confirm loading PCR racks

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

10. Place the PCR cassettes indicated in position 6 (cfr. page 11, Figure 1).
11. 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).

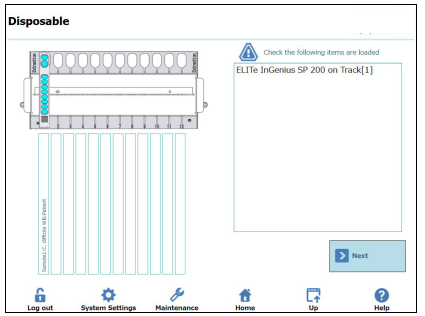

Figure 8: The “Disposable” screen is used to confirm Extraction Rack loading

12. Place the Extraction cartridge cassette(s) indicated in position 5 (cfr. Page 11, Figure 1).
13. 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 elution tube loading with Extra Tube Rack appears (Figure 9).

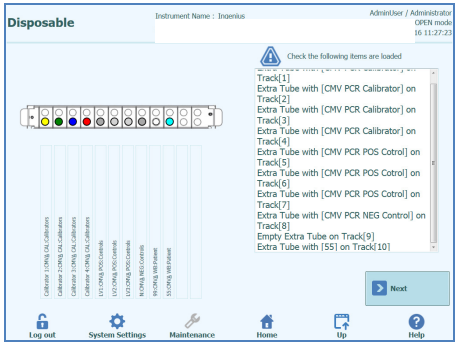

Figure 9: The “Disposable” screen is used to confirm loading of Extra Tube Rack with elution tube

14. Place the amount of elution tubes Extra Tube, indicated in position 4 (cfr. page 11, Figure 1).
15. Press the “Next” button.

The “Disposable” screen for tip rack loading appears (Figure 10).

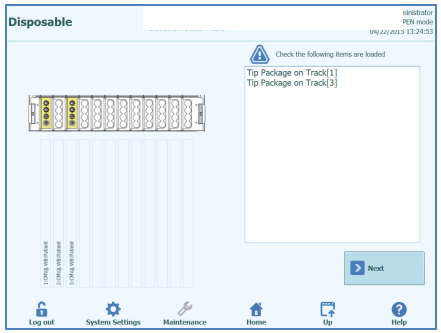

Figure 10: The “Disposable” screen is used to confirm loading tips racks

16. Place the amount of Tip cassettes indicated in position 3 (cfr. page 11, Figure 1).

Ensure that the Tip (1) and the piercer (3) are placed as shown in the picture below (Figure 11).

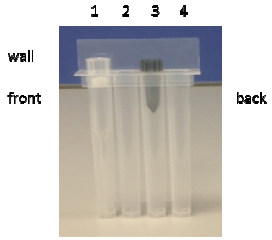

Figure 11: Tips disposition on Tip Cassette

17. Press the “Next” button.

The “Disposable” screen for sonication/extraction tube rack loading appears (Figure 12).

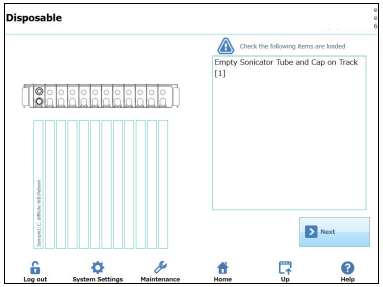

Figure 12: The “Disposable” screen is used to confirm loading sonication/extraction tube racks

18. Place the amount of extraction tubes indicated in position 2 (cfr. page 11, Figure 1).
19. Press the “Next” button.

Note: When "Extraction Tube" (as secondary tube) was selected as the position of the sample in the "Perform Run" screen, 200 µL of the sample must be present in the "extraction Tube".

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

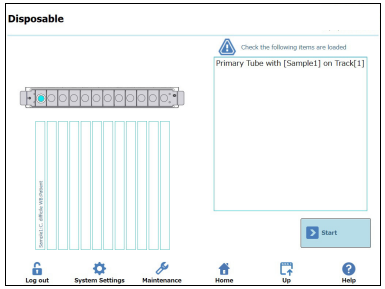

Figure 13: The “Disposable” screen is used to confirm loading of sample racks.

20. When "Primary Tube" has been selected as sample position in the “Perform Run” screen, place the Primary Tubes indicated in position 1 (cfr. page 11, Figure 1).
21. Press the “Start” button to start the run.

Note: If a "extraction Tube" was selected as a position of the sample in the "Perform Run", is not required to loading the primary tube.

The following message is shown (Figure 14).

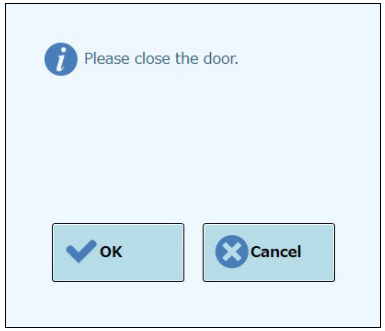

Figure 14: Instrument close door request message

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

The “During Run” screen appears (Figure 15). The run process can be followed on this screen.

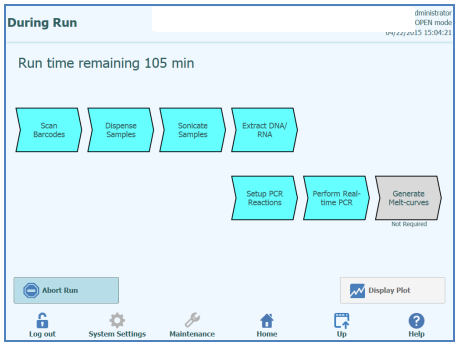

Figure 15: During run screen

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 16).

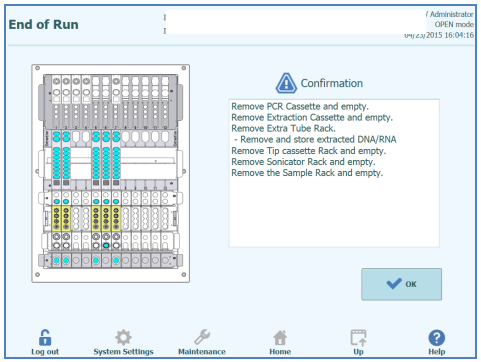

Figure 16: The End of Run screen

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. Close the sample tubes using caps and store them as described in “Sample and Controls”.
25. To confirm all actions have been completed, press “OK”.

The extracted DNA or 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 DNA or 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 17).

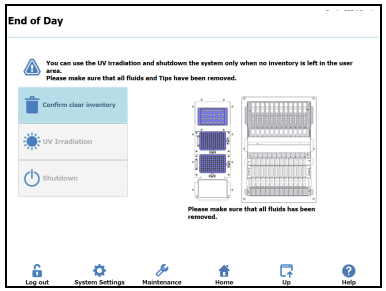

Figure 17: End of Day screen

27. Verify that the user area has been unloaded.
28. Press “Confirm clear inventory” button. This confirmation 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 18):

Figure 18: 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 19).

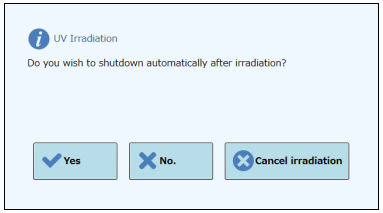

Figure 19: Choice of automatic shutdown after irradiation message

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

Read the «**ELITe BeGenius**» operator's manual carefully.

PREPARATION OF SAMPLES

Note: Samples must be transferable by pipette; ensure there are no clots or other solid materials. If primary tubes are used and completely filled, please mix the sample to ensure a homogenous solution is formed before loading onto the instrument.

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. The minimum volume of samples required are shown in the table below.

Tube Type	Minimum volume of sample
2 mL Sarstedt Tube	200 µL
13x75 mm U-bottom tube (e.g. BD 3.0 mL, BD 4.0 mL Vacutainer)	700 µL
12x80 mm conical-bottom tube (e.g. COPAN UTM 1 mL, COPAN eNAT™ 2 mL)	500 µL
13x100 mm U-bottom tube (e.g. BD 6.0 mL Vacutainer)	800 µL
16x100 mm U-bottom tube (e.g. BD 10.0 mL Vacutainer, COPAN UTM 3 mL)	900 µL

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 used in "Fast Lane" Mode

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 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.

ELITe InGenius® SP 200
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REF INT032SP200

DESCRIPTION OF THE EXTRACTION PROCEDURE

The following description is referred to an "Extraction Only" procedure starting from a primary tube. For the procedure starting from different primary and/or secondary tube please refer to the «**ELITe BeGenius**» operator's manual.

Extraction with the **«ELITe InGenius SP 200»** reagent cartridge is performed automatically by the **ELITe BeGenius System**. The procedure includes the following steps:

1. Choose the Protocol you wish to run:

- **Extract + PCR**
  Full sample-to-answer process.
- **Extract Only**
  The sample will be processed to extract DNA but processing will not proceed to PCR step, so no diagnostic result will be output.

2. Click "Extract and PCR" for both options.

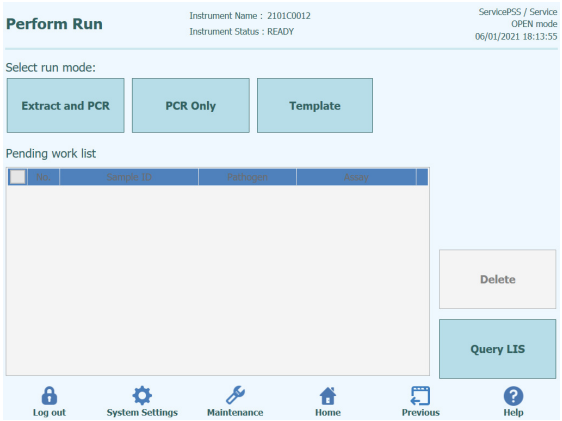


Figure 2 : Protocol Selection.

L5 Sample Rack Insertion screen is displayed.

Figure 21 : Run Setup Rack Insertion

3. Take the L5 Sample Rack and place a Tube containing 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.

NOTE Wipe off any water droplets on the Sample Rack. Otherwise the traceability barcode reader may fail to scan a barcode on the Rack.

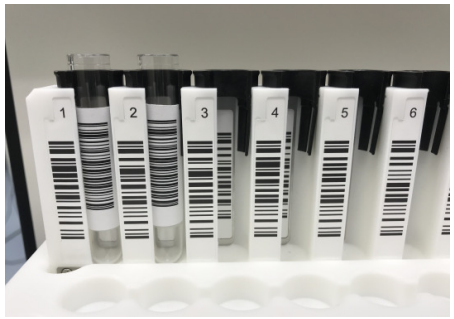


Figure 22 : Rack barcode

4. Gently insert the Sample Rack with Sample installed on the L5 of the Cooler Unit.

When a barcode on a Sample Tube is scanned successfully, the scanned Sample ID is displayed and the "Status" field changes to "Read".

Figure 23 : 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

5. 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.

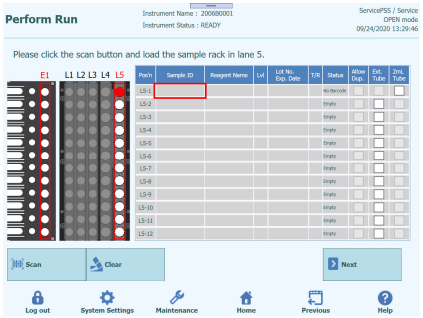


Figure 24 : Rack barcode not read

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

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

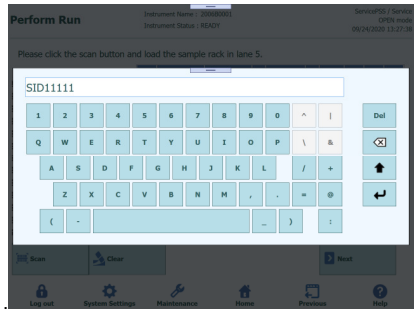
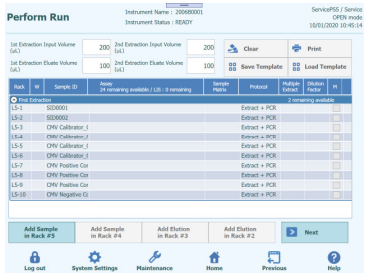


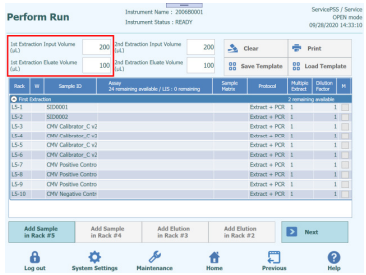
Figure 25 : enter ID display

Figure 26: ID entered manually

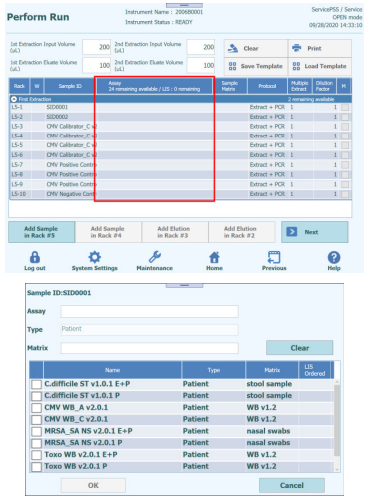
7. Click “Next” and the Display L5 Assay setting window is showed.



8. 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).

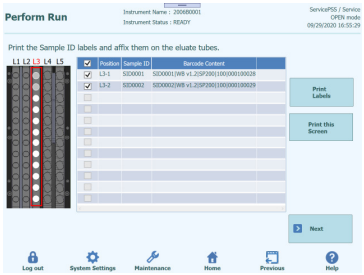


9. Click the Assay field of each Position to display the Assay selection screen.

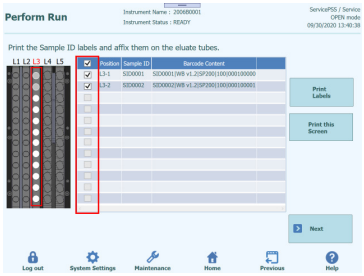


10. Check the Assay to be executed and click the OK button.

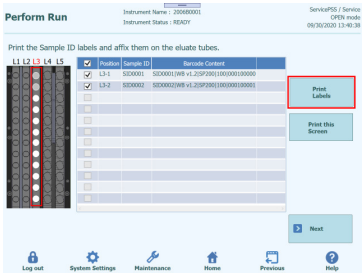
11. Click “Next” until the Display of the printout screen of Data Matrix Code for L3 Eluate Tube is showed (for the second extraction setting please refer to «ELITe BeGenius» operator’s manual). A Data Matrix Code to be attached to the 0.5mL Eluate Tube which contains the nucleic acid extraction produced in the first extraction is displayed.



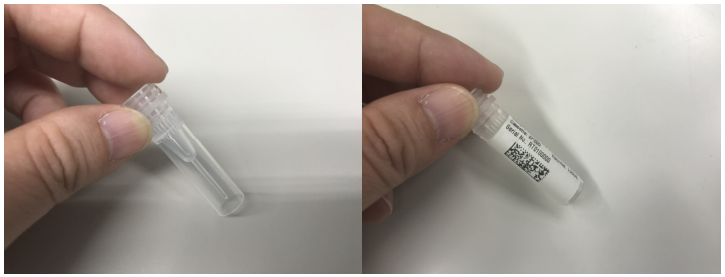
12. Check the Position to print and prepare an empty 0.5mL Tube.



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

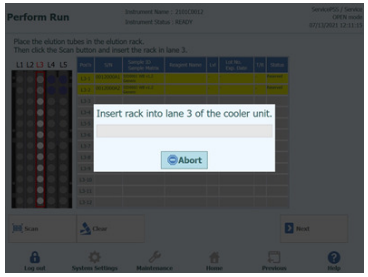


14. Paste the printed Data Matrix Code on an empty 0.5mL Tube.



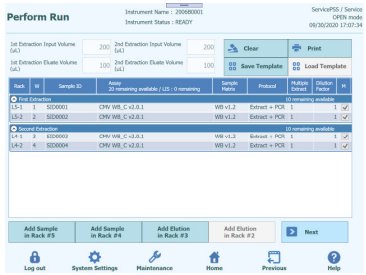
15. Take the L3 Reagent Rack and Set up an empty 0.5mL Eluate Tube with Data Matrix Code attached according to the installation image on the Position where the "Status" column of the ejected Reagent Rack is displayed as "Reserved".

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

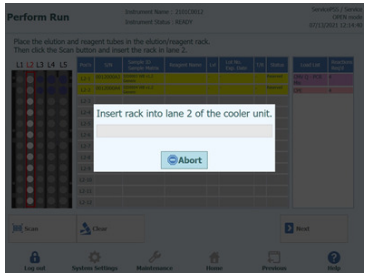


17. When the Data Matrix Code on the Eluate Tube is successfully read, the "Status" field will change to "Read".

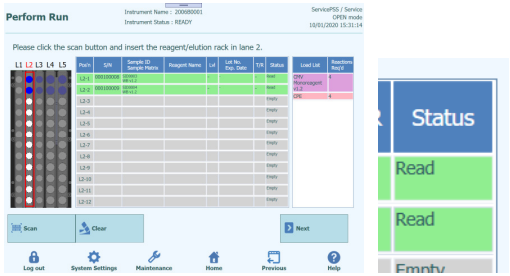
18. After completing the L3 Reagent Rack setting, click "Next". Assay setting window will appear.



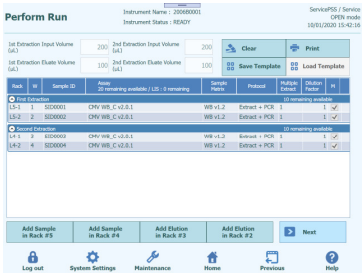
19. If there is no additional Eluate Tube or PCR Only Calibration/Control, click "Next" to display the L2 Reagent Rack insertion screen.



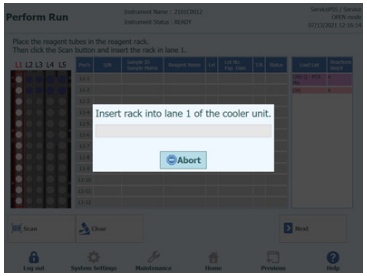
20. Take the L2 Reagent Rack and Set up requested 0.5mL reagent tube in an empty Position.
21. Gently insert the Reagent Rack with Eluate Tube installed into the L2 of the Cooler Unit.
22. When the Data Matrix Code on the reagent Tube is successfully read, the "Status" field changes to "Read".



23. After completing the L3 Reagent Rack setting, click "Next". Assay setting window will appear.

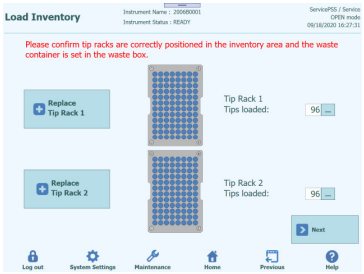


24. Click "Next" to display L1 Reagent Rack Insertion screen.



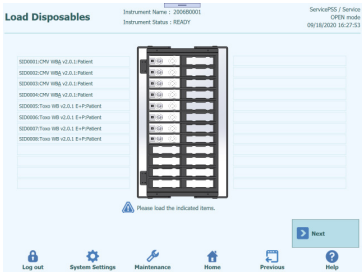
25. Take the L1 Reagent Rack and Set up requested PCR reagent tubes in an empty Position.
26. Gently insert the Reagent Rack with Reagent Tube installed into the L1 of the Cooler Unit.
27. When the Data Matrix Code on the reagent Tube is successfully read, the "Status" field changes to "Read".
28. Once the required PCR reagents have been placed and all in the Load List have been cleared, click "Next".

29. Install Single Tips and make sure it is the same as the remaining number of Single Tips that are currently filled in the instrument.



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

.

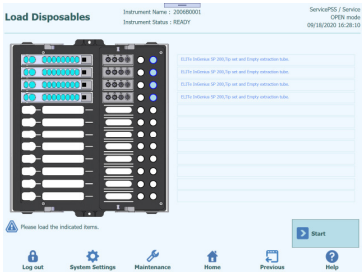


31. Place the PCR Reaction cassette on the PCR Rack according to the installation image and install the PCR Rack on the instrument stage.

(Note) Make sure that the PCR Rack is not floating.

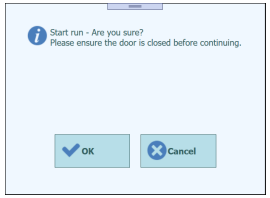
(Note) Make sure that the PCR Rack is correctly closed: a broad white line and the PCR cassette number position are not visible when the anti-lift grid is closed, as displayed in the following images.


32. Click "Next" after installing the PCR Rack
33. Install consumables for the extraction as displayed in the image

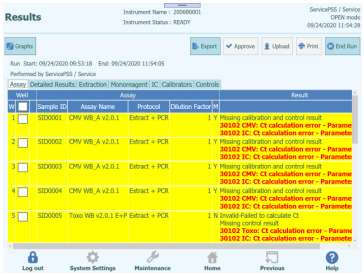


34. Take out Extraction Rack from the instrument stage, place the nucleic acid extraction cartridge, the Tip-set, and empty Extraction Tube according to the placement image, and then install the Extraction Rack into the instrument stage.
35. Close the door and click "Start".

Click "OK" on the execution confirmation screen to start the extraction.



36. When the Run finishes, Results screen appears.

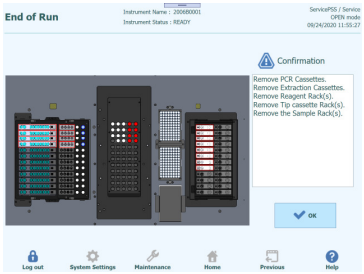


37. Click "End of Run".

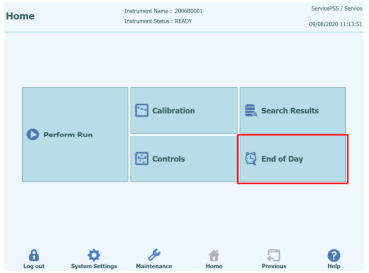
The End of Run Screen provides instructions on unloading, storing or discarding the samples, materials and reagents. Please carry out these actions immediately.

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

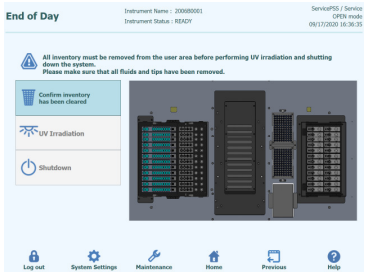
(Note) Red circles are samples with a risk of infection and should be disposed with caution.



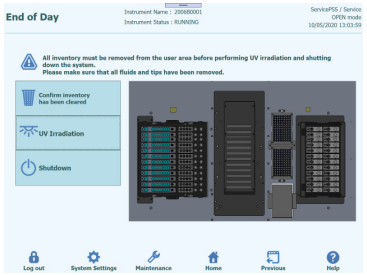
39. After disposing of the consumables, click "OK" to display Home screen.
40. Click "End of Day" on Home window

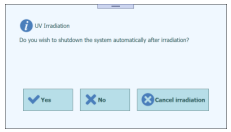


41. Click "Confirm inventory has been cleared".



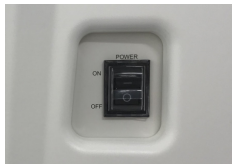
42. Click "UV Irradiation". The front door will be locked.





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.

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



(Note) The power must be turned off manually.

PROCEDURE LIMITATIONS

Only use the following clinical samples with this product: human whole blood collected in EDTA or citric acid, human serum, plasma collected in EDTA or citric acid, urine, cerebrospinal fluid (CSF), amniotic fluid, cavitary fluids, respiratory samples (Bronchoalveolar Lavage/Broncho aspirate, Sputum and nasopharyngeal aspirate), respiratory swab (nasal swab, throat swab), buccal swab, saliva, cervical-vaginal swab, mucocutaneous lesions swab, rectal swab, stool, blood culture, biopsies and gastric aspirates .

The kit validation is limited to the matrices mentioned in the intended use, other matrices leads 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 to validate 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 and plasma 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 personnel competent 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 persons.

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 persons.

This product must be handled by personnel qualified competent 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 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.

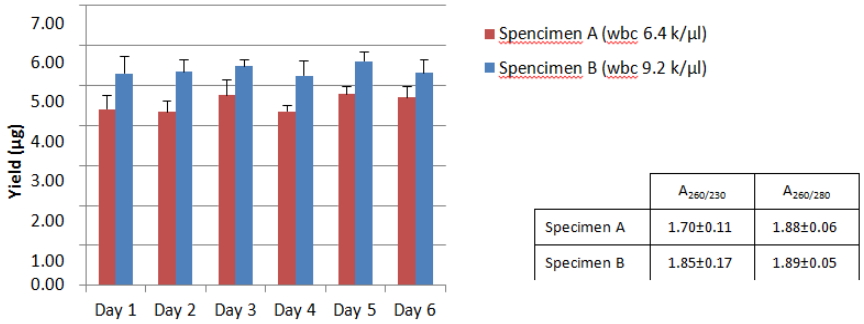
PERFORMANCE CHARACTERISTICS

Yield and quality of genomic DNA from Blood

The amount of purified DNA by the **«ELITe InGenius SP 200»** from whole blood depends on the leucocyte content, as well as the sample source, transport, storage and age.

The kit provides reagents for the purification of pure genomic DNA from 200 µL whole blood with an ABS_{260} / ABS_{280} ratio ≥ 1.6 - 1.9. The concentration depends on the health status of the blood donor and the elution volume used, as shown in the following Figure (Figure 20).

Genomic DNA was extracted from human EDTA-2Na (specimen A) or ACD (specimen B) whole blood samples using **«ELITe InGenius SP 200»** for a total of 6 days (6 replicates by each run). The white blood cell (WBC) numbers of specimen A and B were 6.4 and 9.2 10^3 cells/µl (k/µL) respectively. The concentrations and purities of the extracts were measured using a ND-1000 spectrometer (NanoDrop). After 6 runs, there were no significant variations between the genomic DNA from whole blood sample.



	$A_{260/230}$	$A_{260/280}$
Specimen A	1.70±0.11	1.88±0.06
Specimen B	1.85±0.17	1.89±0.05

Figure 24: The yield, A260/280, and A260/230.

ELITe InGenius® SP 200
Reagents for Nucleic Acid Extraction
REF INT032SP200

TROUBLESHOOTING

Problem	Probable Cause	Comments and Suggestions
Low yield of extraction or NA 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 an homogeneous solution for smooth handling by the 200 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 an high concentrated sample has 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 RNAase 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
	Acute aquatic toxicity

ELITe InGenius® SP 200
Reagents for Nucleic Acid Extraction

REF **INT032SP200**

NOTICE TO PURCHASER: LIMITED LICENSE

ELITe InGenius® and ELITe BeGenius® 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 dits licensors grant other explicit or implied licenses for other purposes.