

ELITE InGenius



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ELITE InGenius® SP 200 Consumable Set

Consumables for Nucleic Acid Extraction

REF INT032CS



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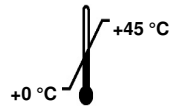


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INTENDED USE

The **ELITE InGenius® SP 200 Consumable Set** (Catalog number INT032CS) provides consumables to be used with **ELITE InGenius® SP 200** (Catalog number INT032SP200) extraction cartridge for nucleic acid extraction from biological samples, in association with the **ELITE InGenius®** instrument (Catalog number INT030-K). **ELITE InGenius** system, is a fully automated molecular diagnostics system performing extraction, purification, amplification and detection.

DESCRIPTION

The **ELITE InGenius SP 200 Consumable Set** product provides consumables to be used with the product **ELITE InGenius SP 200**.

The product provides plastic consumables for **48 extractions** (4 runs x 12 samples).

MATERIALS PROVIDED

Each package contains the following:

Component	Quantity	Description
Extraction tubes	48	Disposable tube to be placed in the extraction position. It can also be used as a 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)

Handling and Storage

Powder free glove in nitril or similar material must be worn when handling the components in the **ELITE InGenius SP 200 Consumable Set**.

The **ELITE InGenius SP 200 Consumable Set** should be stored at room temperature (+0 / +45 °C).

Refer to the product label for the expiration date.

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

Avoid exposure to UV light and direct sunlight.

Material Quality Controls

ELITechGroup S.p.A. (EGSpA) guarantees the performance characteristics of the **ELITE InGenius SP 200 Consumable Set** for applications as described in the operator's manual.

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

OTHER PRODUCTS REQUIRED

This product must be used in association with the product **ELITE InGenius SP 200** and the **ELITE InGenius** instrument.

WARNING 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.

Inspect components for damage upon receipt. If damage has occurred, immediately contact ELITechGroup Molecular Diagnostics Customer Support.

For United States customer/technical support:

Telephone: 1.800.453.2725

E-mail: mdx@elitechgroup.comWebsite: www.elitechgroup.com

The 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 contaminated gloves.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in 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 provided product instructions 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 components.

Only use the reagents provided in the product and those recommended by the manufacturer.

Do not use reagents from different batches.

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 free of DNase, RNase, DNA and RNA.

PROCEDURE

The complete procedure involves nucleic acid extraction and purification from fresh or previously frozen cellular and non-cellular fluid samples in association with the **ELITE InGenius**.

Note: Complete procedures are detailed in the **ELITE InGenius** Operator Manual. For instructions on starting the instrument and stepping through the loading process in preparation to perform extraction, refer to the operator manual.

SYMBOLS



Catalog Number



Temperature limits



Batch code



Use by (last day of month)



in vitro diagnostic medical device



Fulfills requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device.



Do not reuse



Contains sufficient for "N" tests



Consult instruction for use



Contents



Keep away from sunlight



Manufacturer

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