

ELITE InGenius



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ELITE InGenius® PCR cassette

Consumables for use with Real Time PCR

REF INT035PCR

INTENDED USE

The product **ELITE InGenius® PCR Cassette** (catalog number INT035PCR) provides consumables to be used in association with the **ELITE InGenius®** instrument (catalog number INT030-K) for Real Time PCR reactions. **ELITE InGenius** system, is a fully automated molecular diagnostics system performing extraction, purification, amplification and detection.

DESCRIPTION

The **ELITE InGenius PCR Cassette** provides consumables to be used in association with PCR reagents to perform PCR on the **ELITE InGenius** instrument (catalog number INT030-K).

Each **ELITE InGenius PCR Cassette** is comprised of 1) a PCR vessel and 2) a cap. The cap is used by the instrument to seal the tube immediately before performing PCR.

To avoid contamination each cassette is individually covered on top.

A package of **ELITE InGenius PCR Cassette** provides consumables for 192 Real Time PCR reactions.

MATERIALS PROVIDED

Each package of **ELITE InGenius PCR Cassette** contains:

Component	Quantity	Description
PCR cassette	4 x 48	Sealed PCR vessels and caps.

Handling and Storage

Powder free glove in nitril or similar material must be worn when handling the components in the **ELITE InGenius PCR Cassette**.

The **ELITE InGenius PCR Cassette** 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 or direct sunlight.

Material Quality Controls

ELITechGroup S.p.A. (EGSpA) guarantees the performance characteristics of the **ELITE InGenius PCR Cassette** for applications as described in the instrument's operator manual.

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

OTHER PRODUCTS REQUIRED

This product must be used in association with ELITechGroup PCR reagents IVD and assays on the **ELITE InGenius** instrument.

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IVD

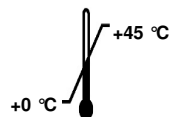


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WARNING AND PRECAUTIONS

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 for PCR 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.com

Website: 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 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 reagents recommended by the manufacturer.

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 under a laminar airflow hood. 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.

Warnings and precautions specific to components

GHS Hazard and Precautions are not applicable to this product.

PROCEDURE

Remove the PCR rack from the ELITE InGenius instrument and place the PCR rack on a stable workbench to perform the following steps:

1. Carefully place the **ELITE InGenius PCR Cassette** in the PCR rack, making sure that it is fastened.
2. Remove the seal just before loading the rack.
3. Load the rack on the **ELITE InGenius** instrument following the instruction on the instrument screen when prompted.
4. After completion of the PCR, discard the cassette without removing the PCR cap to avoid the risk of contamination.

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

SYMBOLS

REF

Catalog Number



Temperature limits

LOT

Batch code



Use by (last day of month)

IVD

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 instructions for use

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Keep away from sunlight



Manufacturer