



AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS
USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

CONTROL IN HAIR FOR DELTA- 9-THC

Code GC53019

OBJECTIVE



These controls in hair matrix are used for internal quality control, and serve to monitor the accuracy and precision of the analytical procedures dedicated to the quantitative determination of the analytes contained therein.

STORAGE AND STABILITY

After opening the vial, withdrawn the necessary volume, closing it with the reagent used and keep a -20 °C. Stable 6 months. Do not use it after the expiration date. Reagent S – Blank hair and Reagent A - Dilution Solution may be stored at ambient temperature.

PRECAUTIONS

These controls in human matrix should be treated with care and treated as potentially infectious.

LOT		

PACKAGING AVAILABLE:

- GC53019 CONTROLS IN HAIR FOR DELTA-9-THC

PACK 1 x 2000 mg/ 1 x 0,5 ml/ 1 x 10ml

LOT		

Preparation of the Chemical Standards:

Prepare 2 glass tubes, called A and B and dilute the Chemical Standard (**Reagent F**) with **Reagent A – Diluting Solution** as reported in tab. below:

Tubes	Reagent F - Chemical Standard Sol.	Reagent A – Diluting Sol.
A	10 µl	9990 µl
B	10 µl	990 µl

Close the tubes – Vortex for 1 minute

Prepare 2 glass tubes of 10 ml called L1-L2.

Add at each tube (L1-L2) the standard chemical just prepared (A and B) referring to the table below:

Control 1	Control 2
150 µl of A	100 µl of B

Evaporate to dryness with the aid of a stream of helium or nitrogen (in this step the temperature must be < 40 °C).

Add to each tube of the calibrators 50 mg of **Reagent S – Blank Hair** (supplied in kit).

At this point Controls are ready and the concentrations to will be:

Analyte	Control 1		Control 2	
	MEDIUM VALUE	RANGE	MEDIUM VALUE	RANGE
Delta-9-THC				

* The procedures for production and validation / quality control of every batch shall be performed using the chromatographic method LC / MS / MS validated according to international guidelines of the Food and Drug Administration (FDA-May 2001) and the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained during the validation phase of batch processing for level four bottles in duplicate.

This product fulfills all the requirements of Directive 98/79/EC of 27/10/1998 on in vitro diagnostic medical devices (IVD). The declaration of conformity is available upon request.



FOR IN VITRO DIAGNOSTIC USE ONLY



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