



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

CALIBRATOR IN HAIR FOR DELTA- 9-THC

Code GC53016
TO USE WITH THE KIT CODE GC53010

OBJECTIVE



The calibrators in hair are used to calibrate the HPLC system for the quantitative measurement of analytes contained therein. Each analyte has a concentration that allows the construction of a calibration curve of six points.

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After opening the vial, withdrawn the necessary volume, closing it with the reagent used and keep a -20 °C. Stable 6 months.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 F – Blank hair** and **Reagent A - Dilution Solution** may be stored at ambient temperature.

PRECAUTIONS

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

LOT		



PACKAGING AVAILABLE:

- GC53016 CALIBRATOR IN HAIR FOR DELTA-9-THC
PACK 1 x 2000 mg/ 1 x 0,3 ml/ 1 x 10 ml

CONCENTRATIONS

CODE

GC53016

LOT		

Preparation of the Calibrators on 5 levels:

Prepare 3 glass tubes, called A; B; C and dilute the Chemical Standard (**Reagent G**) with **Reagent A – Diluting Solution** as reported in tab. below:

Tubes	Reagent G - Chemical Standard Sol.	Reagent A – Diluting Sol.
A	10 µl	9990 µl
B	10 µl	990 µl
C	20 µl	180 µl

Close the tubes – Vortex for 1 minute

Prepare 5 glass tubes of 10 ml called C0-C1-C2-C3-C4.

Add at each tube (C0-C1-C2-C3-C4) the standard chemical just prepared referring to the table below:

Calibrator C0	Calibrator C1	Calibrator C2	Calibrator C3	Calibrator C4
100 µl of Reagent A – Diluting Sol.	100 µl of A	200 µl of A	200 µl of B	100 µl of C

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 F – Blank Hair** (supplied in kit).

At this point Calibrators of 5 points are ready and the concentrations to be used for the calibration curve will be:

Analyte	Calibrator C0	Calibrator C1	Calibrator C2	Calibrator C3	Calibrator C4
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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