



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

CALIBRATOR IN HAIR FOR DRUGS OF ABUSE

(Morphine, Codeine, 6-MAM, Amphetamine, Metamphetamine, MDA, MDE, MDMA, Methadone, EDDP, MBDB, Cocaine, Cocaethylene, Ecgonine methyl-ester, Buprenorphine, Norbuprenorphine, BEG)

Code GC49016 TO USE WITH THE KIT CODE GC49010

OBJECTIVE



These calibrators in hair are used to calibrate the chromatographic system in quantitative determination of analytes in them. For each analyte is possible to construct a calibration curve on 6 points.

STORAGE AND STABILITY

Once you open the vial, withdrawn the volume needed, recap and stored at -20 ° C. Stable 6 months. Do not use after the expiration date. Reagent S – Blank Hair and Reagent A - Diluting Solution can be stored at room temperature

PRECAUTIONS

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



LOT		

PACKAGING AVAILABLE:

- GC49016 CALIBRATOR IN HAIR FOR DRUGS OF ABUSE
PACKAGING 1 x 2000 mg/ 1 x 3 x 0,3 ml/ 1 x 20 ml

N° 003

09/2024

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PREPARATION of CHEMICAL STANDARDS

Prepare 3 glass tubes, call them 1 A; 1 B; 1 C and dilute each Chemical Standard (T1-T2-T3) with **Reagent A – Diluting Solution** as reported in tab. below:

Tubes	Reagent T1 – Chemical Std. Solution 1	Reagent T2 – Chemical Std. Solution 2	Reagent T3 – Chemical Std. Solution 3	Reagent A – Diluting Sol.
1 A	10 µl	//	//	990 µl
1 B	//	10 µl	//	990 µl
1 C	//	//	10 µl	990 µl

Close the tubes – Vortex for 1 minute

ENRICHMENT OF HAIR:

Prepare 6 tubes of 10 ml glass denominated C0, C1, C2, C3, C4, C5.

Add to each tube (C0, C1, C2, C3, C4, C5) chemical standards freshly prepared (1A, 1B, 1C) and the Reagents T1-T2-T3, referring to the table below:

C0	C1	C2	C3	C4	C5
50 µl <u>Reagent A</u>	10 µl 1 A	20 µl 1 A	100 µl 1 A	5 µl T1	10 µl T1
50 µl <u>Reagent A</u>	10 µl 1 B	20 µl 1 B	100 µl 1 B	5 µl T2	10 µl T2
50 µl <u>Reagent A</u>	10 µl 1 C	20 µl 1 C	100 µl 1 C	5 µl T3	10 µl T3

Bring each calibrator dry freshly prepared with the aid of a helium or nitrogen stream (in this step Working temperature must be < 40° C).

Add to each tube of the calibrators C0-C1-C2-C3-C4-C5 just brought to dryness, 50 mg of **Reagent S – Blank Hair**.

At this point, the calibrators on six points are ready and concentrations to use for calibration curve are:

Analyte	Calibrator C0	Calibrator C1	Calibrator C2	Calibrator C3	Calibrator C4	Calibrator C5
Morphine, Codeine, 6-MAM, Beg, Amphetamine, Methamphetamine, MDA, MDE, MDMA, Methadone, EDDP, MBDB						
Cocaine						
Cocaethylene, Ecgonine Methyl Estere						
Buprenorphine						
Norbuprenorphine						
Beg						

* 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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