



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

### CONTROL 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 GC49019

#### OBJECTIVE



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

#### STORAGE AND STABILITY

Once you open the vial, withdrawn the volume needed, reseal it with the reagent used and stored at -20 ° C. Stable 6 months.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 controls in human matrix should be treated with care and treated as potentially infectious.

LOT		

#### PACKAGING AVAILABLE:

- GC49019 CONTROL IN HAIR FOR DRUGS OF ABUSE  
PACKAGING 1 x 2000 mg/ 1 x 3 x 0,5 ml/ 1 x 30 ml

LOT		

**PREPARATION of CHEMICAL STANDARDS**

Prepare 6 glass tubes, call them 2 A; 2 B; 2 C; 3 A; 3 B; 3 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.
2 A	15 µl	//	//	985 µl
2 B	//	15 µl	//	985 µl
2 C	//	//	15 µl	985 µl
3 A	25 µl	//	//	225 µl
3 B	//	25 µl	//	225 µl
3 C	//	//	25 µl	225 µl

**Close the tubes – Vortex for 1 minute**

**ENRICHMENT OF HAIR:**

Prepare 2 tubes of 10 ml glass denominated L1 and L2.

Add to each tube (L1-L2) chemical standards freshly prepared (2A, 2B, 2C, 3A, 3B, 3C), referring to the table below:

Control 1	Control 2
10 µl of 2 A	75 µl of 3 A
10 µl of 2 B	75 µl of 3 B
10 µl of 2 C	75 µl of 3 C

Evaporate to dryness the solvent with the aid of a light stream of helium or nitrogen paying attention to remain in the hair / fur on the bottom of the tube. Alternatively remove with a clean forceps with Acetone (not supplied in the kit), the hair / fur from the tube and place on paper towels until completely dry. In this last case the blotter paper should be changed for each sample.

Add to each tube of the checks L1-L2 just brought to dryness, 50 mg of **Reagent S – Blank Hair**.

At this point, the controls on two points are ready and the concentrations to be used are:

<b>Analyte</b>	<b>Control 1</b>	
	<b>MEDIUM VALUE</b>	<b>RANGE</b>
<b>Morphine, Codeine, 6-MAM, Beg, Amphetamine, Methamphetamine, MDA, MDE, MDMA, Methadone, EDDP, MBDB</b>		
<b>Cocaine</b>		
<b>Cocaethylene, Ecgonine Methyl Estere</b>		
<b>Buprenorphine</b>		
<b>Norbuprenorphine</b>		
<b>Beg</b>		

Analyte	Control 2	
	MEDIUM VALUE	RANGE
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.**

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**FOR IN VITRO DIAGNOSTIC USE ONLY**



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