



# Toxicology Line

Drugs of abuse, medicaments and  
alcohol marker (Ethyl glucuronide) in hair.

[comedical.biz](http://comedical.biz)

 **Comedical®**



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# ABOUT **US**

Over the past 20 years, Comedical has expanded its interests into Clinical and Forensic Toxicology.

Comedical developed analytical solutions in LC-MS/MS and Immunometric Test for the detection of medicaments, drugs of abuse and psychoactive substances in biological matrices.

Comedical is present in three continents: Europe, Africa and South America.

VMA-T Reagent, M3 Reagent and TricoCheck Controls are Comedical's solutions for fast and easy analysis of the keratin matrix.

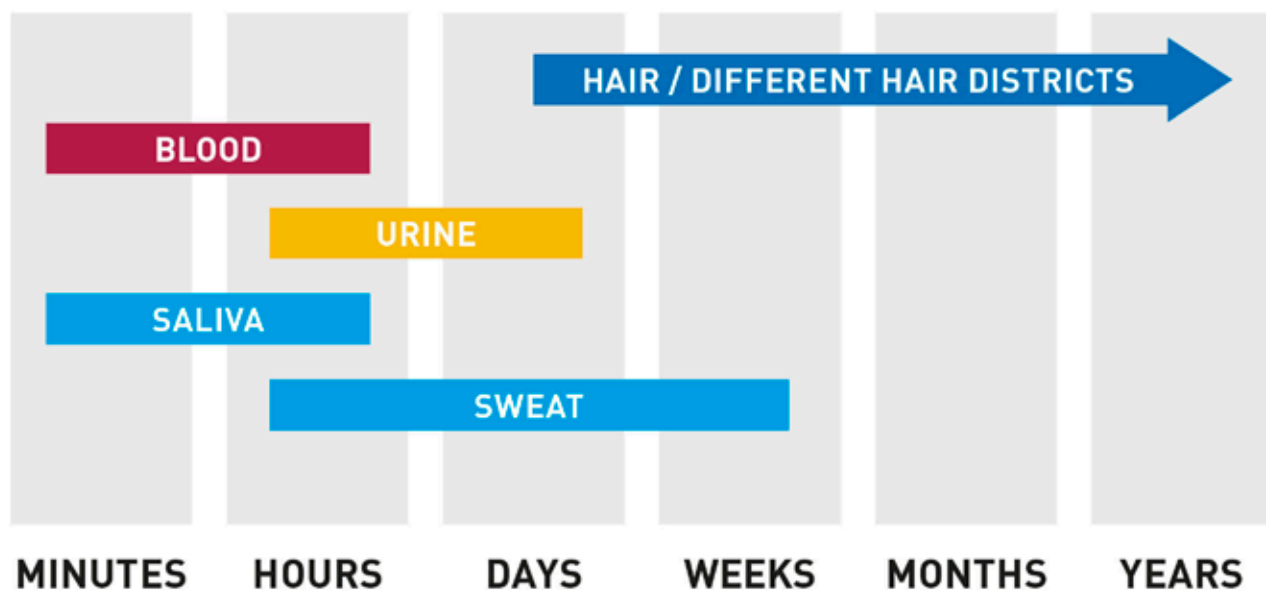
VMA-T and M3 Reagents are able to extract and stabilize all medicaments and drugs of abuse from the keratin matrix at once.

Comedical's TricoCheck Controls, made from real keratin matrix, have been shown to retain substances like real hair during the incubation process. It is the only product on the market to have this characteristic.

All Comedical products are CE-IVD certified.



# WHY **ANALYZE** HAIR?



In blood/serum or saliva, the recent use of illicit substances is assessed in a time window of several minutes/hours.

In urine, the recent consumption of illicit substances is assessed in a time window of a few days.

The keratin matrix (hair, nails), on the other hand, enables the assessment of prior use/abuse of illicit substances in a time window of months/year.

A segment of interest can also be analyzed, considering that growth is about 1 cm per month on average (0.8 - 1.2 cm per month).

Hair allows us to investigate long-term substance abuse.

Hair matrix cut-offs are in accordance with the SoHT (Society of Hair Testing) consensus. (<https://www.soht.org/consensus>).



# **VMA Line<sup>®</sup>**

**Products for immunoassay screening test**



# HAIR SCREENING INTRODUCTION

Comedical's VMA-T Reagent was developed in 2003 for the extraction of drugs of abuse and medicaments from the keratin matrix. VMA-T converts parent drugs into metabolites. Thus, the extract can be analyzed with a standard biochemistry analyzer and urine enzyme immunoassay reagents.



## CAL VMA-T Calibrators

Calibration kits composed of 5 levels ready to use.



## VMA-T Reagent

Able to solubilize and stabilize both acidic and alkaline molecules present in the hair.

Converts some parent drugs present in the hair into metabolites.



## TricoCheck Controls

Real keratin matrix, fortified with medicaments and drugs of abuse. It undergoes the same pre-treatment as the real sample.



## SLV VMA-T Washing Solution

Washing solution for decontamination of keratin samples.

# HAIR SCREENING EXTRACTION

## Quick and easy hair sample preparation



Collect the  
keratin  
matrix  
sample



Weigh 33 mg  
in test tube  
for digestion



Add 1 mL of **SLV  
VMA-T** solution.  
Gently shake for  
10/20 seconds.  
Discard solution



Add 0,4 mL of  
**VMA-T** Reagent.  
Digest for 1 h  
at 100° C



Cool down  
and put the  
supernatant into  
the cups



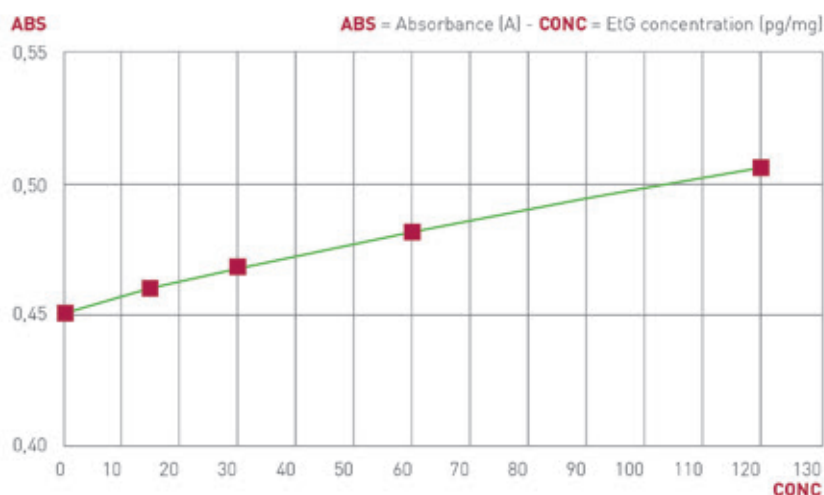
Read the  
semi-  
quantitative  
result

## Classes of Drugs of Abuse and Medicaments

Amphetamines	MDMA	Cocaine
Cannabinoids	Opioids	Buprenorphine
Ketamine	Benzodiazepines	Nicotine
Methadone	Oxycodone	Tramadol

And for the first time in screening **Ethyl glucuronide (EtG)**, a direct metabolite of ethyl alcohol.

Levels	Concentration (pg/mg)
Cal. Lev. 1	0
Cal. Lev. 2	15
Cal. Lev. 3	30
Cal. Lev. 4	60
Cal. Lev. 5	120





# HAIR SCREENING IMMUNOASSAY REAGENT

The urine enzyme immunoassay reagents certified by Comedical for hair analysis are listed below. For Ethyl glucuronide, the ARK™ Ethyl glucuronide Assay with Comedical's COMpacta biochemistry analyzer must be used.

**The urinary enzyme immunoassay reagents for drugs of abuse that can be used for hair screening are:**

- Thermo Scientific™ DRI™
- Siemens EMIT® II
- Immulysis Urine HEIA™
- ARK™ Ethyl glucuronide Assay



**COMpacta**<sup>TM</sup>270  
Biochemical Analyzer

# HAIR SCREENING

## SCIENTIFIC REFERENCES\*

### Main scientific articles involving the use of the VMA-T Reagent

R. de la Torre, E. Civit, F. Svaizer, A. Lotti, M. Gottardi, M. Miozzo, **High throughput analysis of drugs of abuse in hair by combining purposely designed sample extraction compatible with immunometric methods used for drug testing in urine**, Forensic Sci. Int. 196 (2010) 18-21.

F. Svaizer, A. Lotti, M. Gottardi, M.P. Miozzo, **Buprenorphine detection in hair samples by immunometric screening test: preliminary experience**, Forensic Sci. Int. 196 (2010) 118-120. doi: 10.1016/j.forsciint.2009.12.047. Epub 2010 Jan 18.

C. Moore, **Oral fluid and hair in workplace drug testing programs: new technology for immunoassays**, Drug Test Anal, 3 (2011) 166-168. doi: 10.1002/dta.140. Epub 2010 Jun 15.

2010



2010



2011



2014



2012



S. Pichini, M. Gottardi, E. Marchei, F. Svaizer, García Algar, R. Pacifici, **Rapid extraction, identification and quantification of drugs of abuse in hair by immunoassay and ultra-performance liquid chromatography tandem mass spectrometry**, Clin. Chem. Lab. Med. 52 (2014) 679-686. doi: 10.1515/cclm-2013-0784.

M.R. Baumgartner, R. Guglielmello, M. Fanger, T. Kraemer, **Analysis of drugs of abuse in hair: evaluation of the immunochemical method VMA-T vs. LC-MS/MS or GC-MS**, Forensic Sci. Int. 215 (2012) 56-59. doi: 10.1016/j.forsciint.2011.08.025.

\* Information entered in April 2024

# M3 Line®

**Products and confirmatory techniques  
for ELISA screening**



# CONFIRMATORY HAIR ANALYSIS INTRODUCTION

Comedical's M3 Reagent is designed for LC-MS/MS analysis and is able to extract and stabilize all substances of abuse and medicaments from hair. The extraction process is unique for all substances, including EtG and THC-COOH.



## CAL M3 Calibrators

Calibration kits composed of 5 levels ready to use. Calibrators are added to the hair blank and the mix of deuterated internal standards (IDS1/IDS2), and follow the preparation of controls and samples.



## M3 Reagent

Able to solubilize and stabilize both acidic and alkaline molecules included in the hair.



## TricoCheck Controls

Real keratin matrix, fortified with medicaments and drugs of abuse. It undergoes the same pre-treatment as the real sample.

# CONFIRMATORY HAIR ANALYSIS EXTRACTION

## Quick and easy hair sample preparation



Collect the  
keratin  
matrix  
sample



Weigh 25 mg  
in test tube  
for digestion



Add 0.005 mL of  
deuterated mix



Add 0,5 mL of  
**M3 Reagent**.  
Digest for 1 h  
at 100° C



Cool down  
and put the  
supernatant into  
the autosampler  
vial



Read the  
quantitative  
result

## Substances present in the calibrators and controls of the M3 line

### ESI+

Amphetamine	Methamphetamine	MDA
MBDB	MDMA	MDEA
Alprazolam	Bromazepam	Diazepam
Etizolam	Lorazepam	Nordiazepam
Oxazepam	Temazepam	Zolpidem
CBD	CBN	THC
Cocaine	Norcocaine	Benzoyllecgonine
Cocaethylene	Ecgonine methyl ester	Buprenorphine
Norbuprenorphine	Codeine	Dihydrocodeine
Fentanyl	Methadone	EDDP
Morphine	6-MAM	Tramadol
Ketamine	Norketamine	Oxycodone

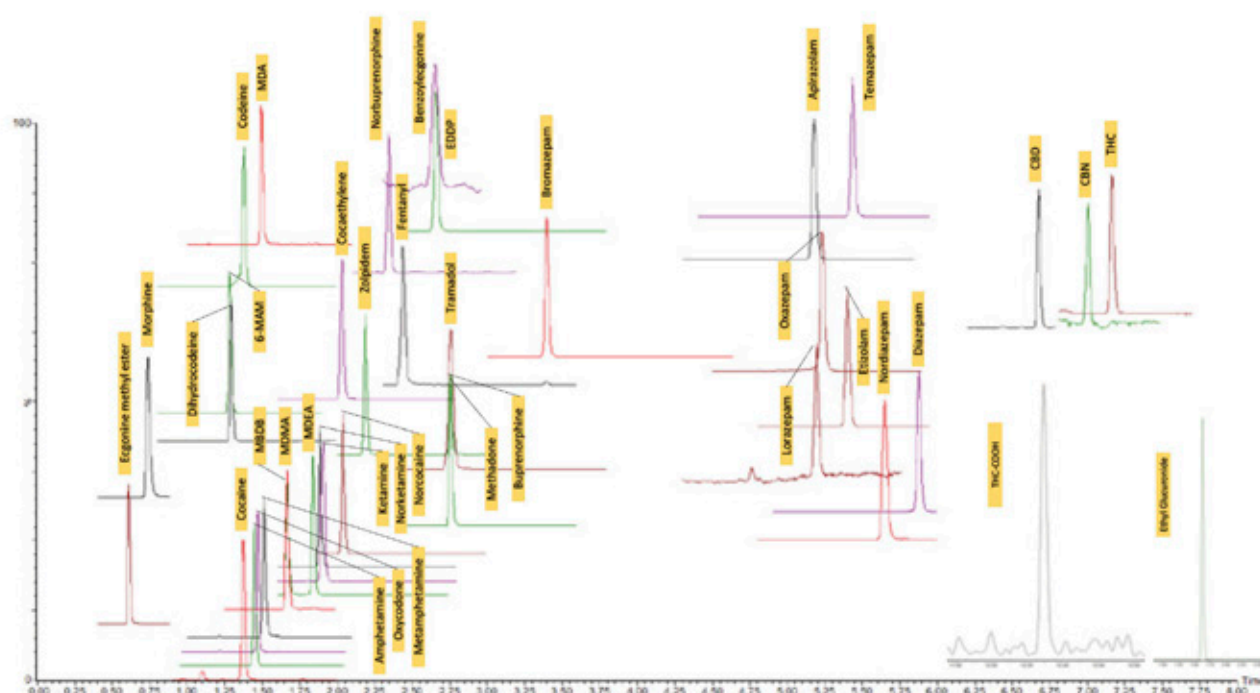
### ESI-

Ethyl glucuronide	THC-COOH
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# CONFIRMATORY HAIR ANALYSIS LC-MS/MS

**Example of a chromatogram obtained with UPLC Acquity I Class coupled with Waters XEVO TQ-S Micro mass spectrometry**



Comedical's Confirmatory analytical methods in M3 are all validated on the Waters TQS Micro and Waters XS mass spectrometers.

Comedical can supply the chromatographic column and mobile phase formulations (following the acceptance of an NDA) and remotely set up the instrumental method in Waters systems.





# CONFIRMATORY HAIR ANALYSIS

## SCIENTIFIC REFERENCES\*

### Main scientific articles involving the use of the M3 Reagent

F.P. Busardò, J. Carlier, R. Giorgetti, A. Tagliabracci, R. Pacifici, M. Gottardi, S. Pichini, **Ultra-High-Performance Liquid Chromatography-Tandem Mass Spectrometry Assay for Quantifying Fentanyl and 22 Analogs and Metabolites in Whole Blood, Urine, and Hair**, Front. Chem. 7 (2019) 184. doi: 10.3389/fchem.2019.00184. eCollection 2019.

G. Mannocchi, A. Di Trana, A. Tini, S. Zaami, M. Gottardi, S. Pichini, F.P. Busardò, **Development of fast UHPLC-MS/MS screening method for 87 NPS and 32 other drugs of abuse in hair and nails: application to real cases**, Anal. Bioanal. Chem. 412 (2020) 5125-5145. doi: 10.1007/s00216-020-02462-6. Epub 2020 Feb 15.

F.K. Nzekoue, M. Agostini, M. Verboni, C. Renzoni, L. Alfieri, S. Barocci, M. Ricciutelli, G. Caprioli, S. Lucarini, **A comprehensive UHPLC-MS/MS screening method for the analysis of 98 New Psychoactive Substances and related compounds in human hair**, J Pharm Biomed Anal. 205 (2021) doi: 10.1016/j.jpba.2021.114310.

2019



2020



2021



2023



2023



C. Calvetti, A. Salomone, A. Verzeletti, F. Di Nardo, P.M.G. Begni, S. Vezzoli, **Are the NPS commonly used? An extensive investigation in Northern Italy based on hair analysis**, J Anal Toxicol, 00 (2023) 1-6. doi: 10.1093/jat/bkad040. Online ahead of print.

E. Groff, M. Lucchiari, G. Stocchero, F. Donini, G.M. Marchio, F. Ingenito, L. Bertoldi, L. Pecoraro, E. Bertol, D. Favretto, A. Anesi, **Comparison of two methods for the extraction of ethylglucuronide from hair**, Drug Test Anal. (2023) doi: 10.1002/dta.3516. Online ahead of print.

\* Information entered in April 2024



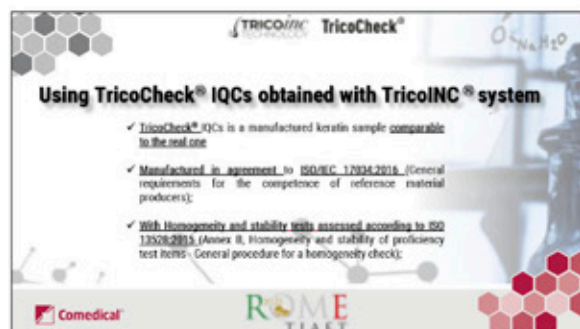
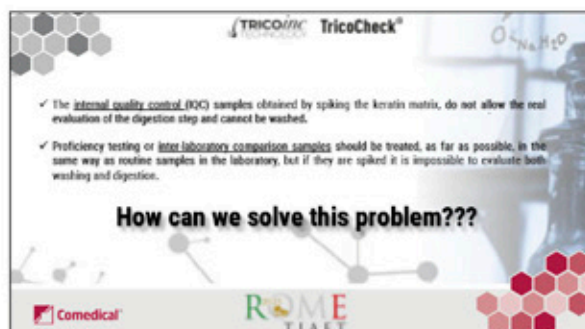
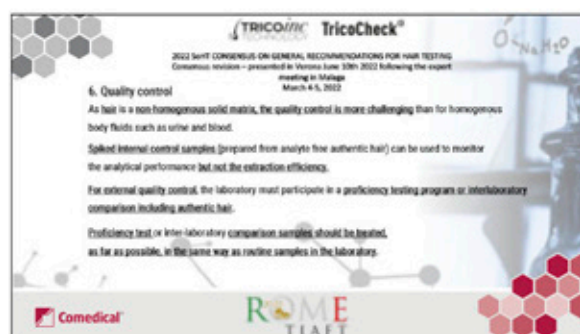
# TricoCheck<sup>®</sup>

**Controls for screening and confirmatory hair tests**

# INTERNAL QUALITY CONTROLS INTRODUCTION

Comedical's Internal Quality Controls (IQC) include CTRL H2O multiCONTROL, CTRL EtG CONTROL, CTRL Neg multiCONTROL, and screening controls, all of which are in real keratin matrix fortified with medicaments, drugs of abuse, or EtG. At TIAFT's 60th International Congress of Forensic Toxicology, held in Rome from August 27th to August 31st, 2023, Comedical demonstrated that TricoCheck behaves like real hair in extraction. The presentation is as follows:

## INTERNAL QUALITY CONTROLS TIAFT 2023





# INTERNAL QUALITY CONTROLS TIAFT 2023

**TricoCheck®**

Some publications including the use of TricoCheck® samples.

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**Screening Immunassays:**

- CTRL-T AMF: Amphetamines, MDMA
- CTRL-T NEG: Blank sample;
- CTRL-T POS: Cocaine, Opiates, Methadone and ECOP;
- CTRL-T THC: Cannabinoids
- CTRL-T BUP: Buprenorphine
- CTRL-T BDZ: Benzodiazepines
- CTRL-KTZ: Ketamine, Tramadol, Zolpidem, Oxycodone

**Confirmation in LC-MS/MS:**

- CTRL-H 20 multiCONTROL: 30 pharmaceuticals and drugs of abuse in the same sample.
- CTRL-NEG multiCONTROL: Blank sample
- CTRL-ENG low
- CTRL-ENG high

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**CTRL-H 20:**

- ✓ Amphetamine
- ✓ Methamphetamine
- ✓ MDMA
- ✓ MDA
- ✓ MDA
- ✓ Alprazolam
- ✓ Bromazepam
- ✓ Diazepam
- ✓ Etizolam
- ✓ Lorazepam
- ✓ Naloxonium
- ✓ Oxazepam
- ✓ Tetrahydropall
- ✓ Zolpidem

**✓ Cocaine**

**✓ Benzoylcocaine**

**✓ Cocacetylone**

**✓ Ecgonine methyl ester**

**✓ Codeine**

**✓ Dihydrocodeine**

**✓ Fentanyl**

**✓ Buprenorphine**

**✓ Naluprenorphine**

**✓ Methadone**

**✓ ECOP**

**✓ Morphine**

**✓ 6-o-MAM**

**✓ Tramadol**

**✓ Ketamine**

**✓ Norketamine**

**✓ CIN - Canebinol**

**✓ THC (Δ9 Tetrahydrocannabinol)**

**✓ THC COOH (11 Nor-9 carboxy THC)**

**CTRL-ENG CONTROL:**

- ✓ ENG 20 pg/mg
- ✓ ENG 40 pg/mg

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**TricoCheck®**

**TricoINC® technology is also used to produce PT and customized IQC**

- ✓ Comedical has been used this technology to produce the External Quality Control Samples or New Psychotropic Substances (NPS), carried out by the Italian Early Warning System (Sistema Nazionale di Allerta Precoce, SNAP).
- ✓ Comedical provides External Quality Control (EQC) samples in hair matrix, for some PT organizers internationally.
- ✓ Comedical also offers customized Quality Controls, in real keratinic matrix, fortified with pharmaceuticals, drugs of abuse and ENG.

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**TricoCheck®**

**NPS - LABVEQ**

**SNAP**

- ✓ NPS standard distribution to laboratory network.
- ✓ Participation to a quality control program (VEQ) for the determination of NPS in hair and oral fluid
- ✓ Sharing of analytical methods for the identification of NPS in biological matrices

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**TricoCheck®**

**Aims and Objectives**

**How do we know that the TricoCheck IQCs are comparable to real samples?**

- ✓ To compare the behaviour of the TricoChecks with that of the real samples on the hair digestion;
- ✓ To demonstrate that TricoChecks can be washed in the what suggested by SoH1, with an analyte loss comparable to that of real samples.

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**TricoCheck®**

Fifteen TricoCheck® samples and 5 real specimens collected from drug users were selected. All the hair samples contained Cocaine, b-acetylmorphine, Tetrahydrocannabinol (THC) at different concentrations.

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**TricoCheck®**

2023 Self-Consensus on General Recommendations for Hair Testing  
Consensus revision - presented in Verona June 20th 2022 following the expert meeting in Milano March 4-5, 2022

**3. Washing of the hair samples**

Washing of hair samples prior to analysis has two main purposes:

Firstly, to remove hair care products, sweat, sebum or surface material (e.g., skin cells, head lice, body fluids, etc.) that may interfere with the analysis or that may reduce extraction recovery.

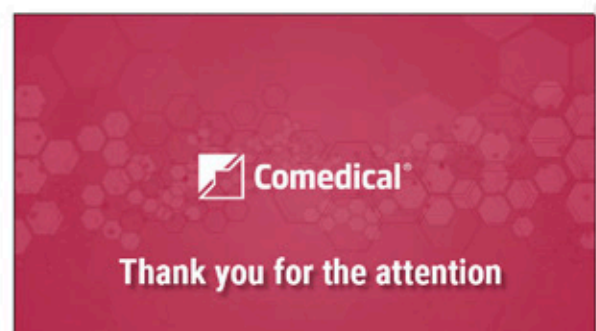
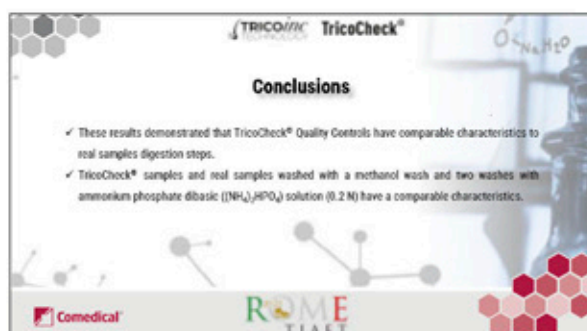
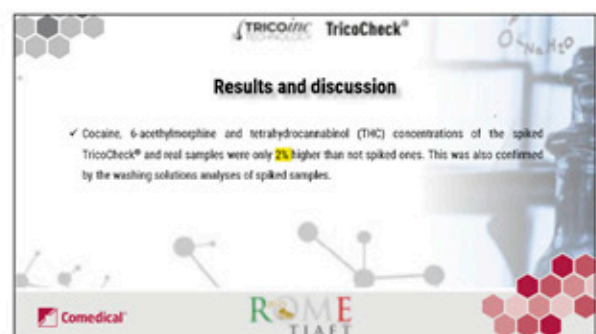
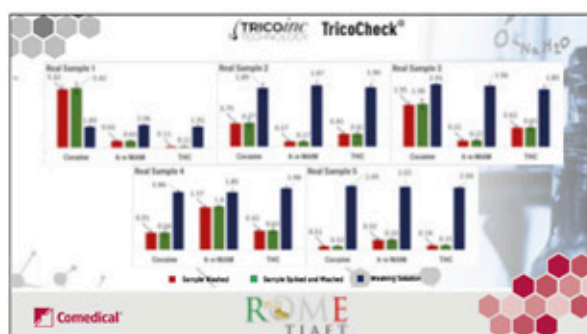
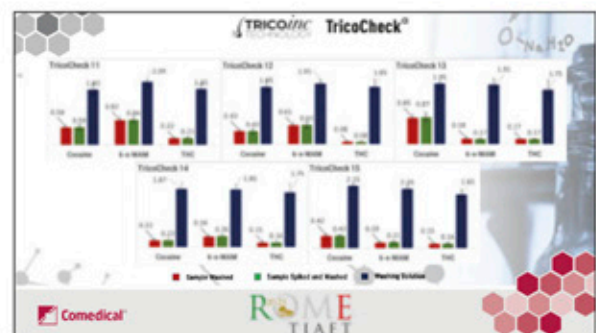
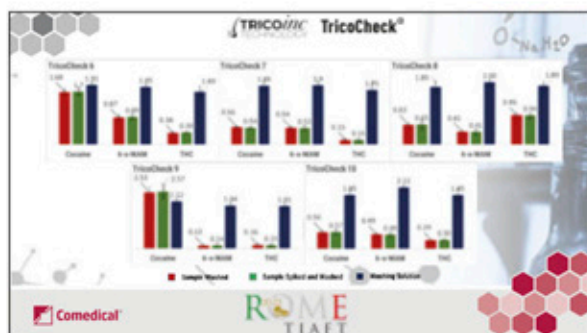
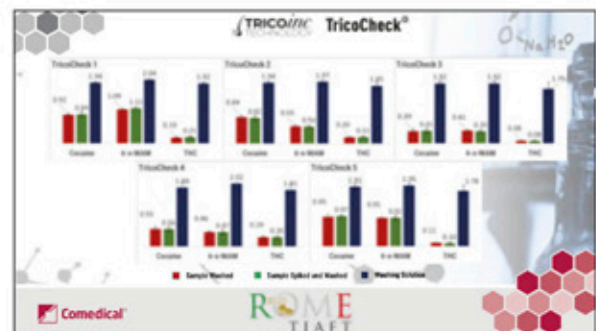
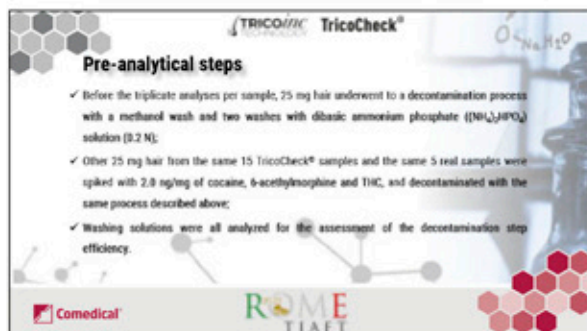
Secondly, to remove potential external contamination of aerobiotics from the environment.

- Organic solvents and/or aqueous solutions can be used. Any wash protocol will require validation by the laboratory to assess its efficacy.
- The washings may be stored for additional analysis.

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# INTERNAL QUALITY CONTROLS TIAFT 2023





# INTERNAL QUALITY CONTROLS CUSTOMIZED PRODUCTS

## EQA External Quality Control

- » Comedical also offers customized External Quality Assessment (EQA), in real keratinic matrix, fortified with medications, drugs of abuse and EtG.
- » The TricoINC technology used by Comedical to artificially incorporate the keratin matrix is also used for IQC, for the evaluation of the external quality of New Psychotropic Substances (NPS), carried out by the Italian Early Warning System (SNAP).
- » The TricoINC system allows you to obtain a keratin sample that closely resembles the real one. This enables you to test the efficiency of the hair digestion method. Spiked hair sample does not permit the real evaluation of the incubation step.
- » Comedical's EQA are manufactured in compliance with ISO/IEC 17034:2016 (General requirements for the competence of reference material producers).
- » The homogeneity and stability of Comedical's EQA are assessed according to ISO 13528:2015 (Annex B, Homogeneity and stability of proficiency test items - General procedure for a homogeneity check).

## New sample preparation tools

### Hydrolysis Tube

**REF 703 0005**

Length 65 mm;  
ø16 mm.



Scale 1:1

### Accessory for weighing hair samples

**REF 705 0000**

Hold-up for glass  
tubes ø 16 mm.



# CLIENTS AND COLLABORATIONS

## WITH PUBLIC BODIES AND PRIVATE COMPANIES\*

### Comedical products are used by

The **VMA-T Line** is used in **24 centres** in **Italy**, including **Local Health Authorities** (ASL, USL, ULSS, ASP), **Hospital Laboratories**, **Forensic Toxicology Laboratories** at **Forensic Medicine**.

The **M3 Line** is used in **21 centres** in **Italy**, including **Local Health Authorities** (ASL, USL, ULSS, ASP), **Hospital Laboratories**, **Forensic Toxicology Laboratories** at **Forensic Medicine**.

The **TricoCheck Quality Controls** are used in **34 centres**, including **Local Health Authorities** (ASL, USL, ULSS, ASP), **Hospital Laboratories**, **Forensic Toxicology Laboratories** at **Forensic Medicine** and **Company**.

### Comedical cooperates with

- » **National Centre on Addiction and Doping**, Istituto Superiore di Sanità (ISS), Rome (Italy)
- » **Unit of Forensic Toxicology**, Section of Legal Medicine, Department of Excellence SBSP, Università Politecnica delle Marche, Ancona (Italy)
- » **LGC Standard Ltd**, Queens Road, Teddington, Middlesex (United Kingdom)
- » **Waters Corporation**, Milford, Massachusetts (United States)

\* Information entered in April 2024







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