

ACETATES IN URINE BY GC/MS-HEADSPACE

REF GC30010

ACRYLONITRILE, BUTYLACETATE, HEPTANE, ETHYL ACETATE, ISOBUTYLACETATE,
TETRAHYDROFURAN

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



INSTRUCTIONS FOR USE

IVD

For *in vitro* diagnostic use

CE

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INTENDED USE

In vitro diagnostic medical device for the detection and the quantitative analysis of acrylonitrile, butylacetate, heptane, ethylacetate, isobutylacetate, tetrahydrofuran in urine as aid in the diagnosis of occupational diseases. Manual method for professional use.

KIT CONTENT FOR 100 TESTS

CONTENT	DESCRIPTION	PACKAGING	WARNING
Reagent A	Matrix Modifier Solution	2 x 500 ml	Store at T ranging between +15 and +25 °C
Reagent B	Test Solution	1 x 10 ml	Store at T ranging between -25 and -15 °C
Reagent C	Internal Standard Solution	1 x 5 ml	Store at T ranging between -25 and -15 °C
Multiparametric Calibrator		5 x 2 x 10 ml	(packed separately – Code GC30016 -see data sheet)

ACCESSORIES AND CONSUMABLES AVAILABLE SEPARATELY

CODE	DESCRIPTION	PACKAGING
GC30016	Calibrator for Acetates in urine	5 x 2 x 10 ml
GC30019	Control for Acetates in urine – Levels 1 and 2	2 x 10 x 10 ml
SCP8944	VF-5ms (30 m x 0,25 mm – 0,25 µm) Analytical Column [or similars]	1 Pc
STH99993188	KIT 20ml Clear Square Crimp HeadSpace 75.5x22.5mm Round Bottom+20mm Cap	1 x 100 Pcs

S50404669	New Easy Grip Manual Crimper for 20 mm	1 Pc
S50404671	New Easy Grip Manual Decapper for 20 mm Crimper Top vials	1 Pc

INSTRUMENTS

DESCRIPTION	WARNING
GC/MS Instrument - headspace	Required
Operational Computer	Required
Autosampler	Required

MATRIX - COLLECTION AND STORAGE PROCEDURE

MATRIX	PROCEDURE
Urine	At the end of the work shift, collect 10 ml of urine in a hermetically sealed glass tube (aluminum ferrules and Teflon caps). Transfer of the sample into the container should be done as soon as possible. The sample is stable for about 7 days at 2-8 °C.

BIOLOGICAL LIMIT VALUES (BLVs)

ANALYTES	VALUE (mg/l)
Acrylonitrile	n.a.
Butylacetate	n.a.
Heptane	n.a.
Ethylacetate	n.a.
Isobutylacetate	n.a.
Tetrahydrofuran	n.a.

PREANALYTICAL PROCEDURE

Inject 1 ml of **Reagent B** into GC/MS-headspace as per instrumental specifications to identify retention times of different analytes.

ANALYTICAL PROCEDURE

STEP	DESCRIPTION
ANALYTICAL PROCEDURE	Dispense in headspace vial of 20 ml: • 1 ml of urine • 9 ml of Reagent A • 50 µl of Reagent C
Injection	Inject 1 ml of the vapor phase into the GC system or into instruments with equivalent parameters.

COMBIPAL AUTOSAMPLER SETTING FOR HEADSPACE

PARAMETERS	SETTING
Incubation Temperature	60 °C
Incubation time	2 min
Syringe Temperature	70 °C

For pneumatic autosamplers set equivalent parameters.

MASSA DETECTOR SETTING

MS acquisition in SCAN (range 33-150)

ANALYTES	RT (min)
Acrylonitrile	1.3
Butylacetate	5.2
Heptane	2.4
Ethylacetate	1.7
Benzene Fluoride (IS)	2.2
Isobutylacetate	3.9
Tetrahydrofuran	1.8

PROGRAMMED THERMAL SETTING

TEMPERATURE PROGRAM

TEMPERATURE	TIME
40°C	5 min
Increase of 50°C/min	Up to 240°C

TEMPERATURES AND OPERATING FLOWS

PARAMETERS	SETTINGS
Injector	T=250°C
Split ratio	1:10
Transferline	T=250°C
Helium flow	See temperature program

ANALYTES AND INTERNAL STANDARD (IS) USED FOR CALIBRATION

ANALYTES	INTERNAL STANDARD USED FOR CALIBRATION
Acrylonitrile	BENZENE FLUORIDE
Butylacetate	BENZENE FLUORIDE
Heptane	BENZENE FLUORIDE
Ethylacetate	BENZENE FLUORIDE
Isobutylacetate	BENZENE FLUORIDE
Tetrahydrofuran	BENZENE FLUORIDE

TECHNICAL FEATURES - PART I

ABBREVIATIONS	MEANING
C LLOQ	Concentration at low limit of quantification
C1	Low concentration
C2	Medium concentration
C3	High concentration

ANALYTES	CONCENTRATIONS USED TO CALCULATE REPRODUCIBILITY AND ACCURACY (mg/l)			
	C LLOQ	C1	C2	C3
Acrylonitrile	1	5	15	25
Butylacetate	1	5	15	25
Heptane	1	5	15	25
Ethylacetate	1	5	15	25
Isobutylacetate	1	5	15	25
Tetrahydrofuran	1	5	15	25

ANALYTES	ACCURACY INTRA SERIE (RELATIVE ERROR %)			
	CLLOQ (%)	C1 (%)	C2 (%)	C3 (%)
Acrylonitrile	1,83	5,33	5,40	3,28
Butylacetate	3,16	4,85	4,92	3,55
Heptane	8,46	5,10	5,38	3,44
Ethylacetate	11,65	8,04	6,48	3,01
Isobutylacetate	8,63	8,65	6,35	3,84
Tetrahydrofuran	8,74	8,42	5,02	5,53

ANALYTES	ACCURACY INTER SERIE (RELATIVE ERROR %)			
	CLLOQ (%)	C1 (%)	C2 (%)	C3 (%)
Acrylonitrile	15,58	8,41	7,14	4,02
Butylacetate	5,31	7,41	7,42	7,21
Heptane	14,56	7,09	9,60	6,68
Ethylacetate	15,36	11,57	8,51	6,39
Isobutylacetate	9,74	9,71	7,74	5,08
Tetrahydrofuran	14,59	9,62	8,84	7,59

TECHNICAL FEATURES - PART II

ANALYTES	REPRODUCIBILITY INTRA SERIE (COEFFICIENT OF VARIATION %)			
	CLLOQ (%)	C1 (%)	C2 (%)	C3 (%)
Acrylonitrile	1,71	2,37	3,18	3,88
Butylacetate	2,61	2,28	2,63	4,30
Heptane	3,52	1,47	3,09	3,22
Ethylacetate	6,15	4,99	4,48	2,59
Isobutylacetate	4,31	3,08	3,18	4,26
Tetrahydrofuran	1,13	2,27	5,57	3,22

ANALYTES	REPRODUCIBILITY INTER SERIE (COEFFICIENT OF VARIATION %)			
	CLLOQ (%)	C1 (%)	C2 (%)	C3 (%)
Acrylonitrile	11,78	5,10	9,37	4,92
Butylacetate	9,04	5,69	9,08	5,35
Heptane	4,06	2,48	5,61	3,53
Ethylacetate	8,89	10,06	7,44	7,13
Isobutylacetate	9,55	5,72	9,91	4,95
Tetrahydrofuran	8,75	3,61	8,37	7,60

TECHNICAL FEATURES - PART III

ANALYTES	LLOD (mg/l)	LINEARITY (mg/l)	COEFFICIENT OF CORRELATION R2 + STD DEV
Acrylonitrile	0,33	1 - 300	0,9972 ± 0,0009
Butylacetate	0,33	1 - 300	0,9973 ± 0,0011
Heptane	0,33	1 - 300	0,9961 ± 0,0013
Ethylacetate	0,33	1 - 300	0,9969 ± 0,0006
Isobutylacetate	0,33	1 - 300	0,9958 ± 0,0013
Tetrahydrofuran	0,33	1 - 300	0,9970 ± 0,0012

ANALYTES	RECOVERY (%)	MATRIX EFFECT (%)	CARRY OVER (%)	LOT VARIABILITY (%)
Acrylonitrile	93,9	n.d.	0,01	10,7
Butylacetate	101,5	n.d.	0,01	10,0
Heptane	95,5	n.d.	0,01	7,4
Ethylacetate	95,3	n.d.	0,01	9,0
Isobutylacetate	97,0	n.d.	0,01	12,7
Tetrahydrofuran	94,3	n.d.	0,01	10,0

REFERENCE CHROMATOGRAMS

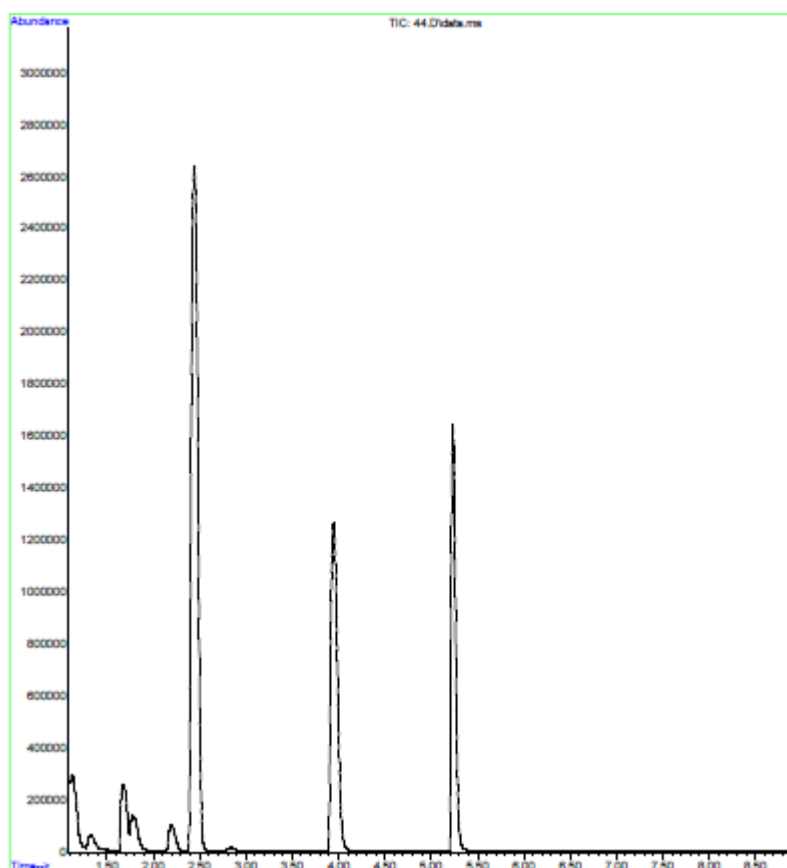


Fig. 1 Calibrator for Acetates in urine

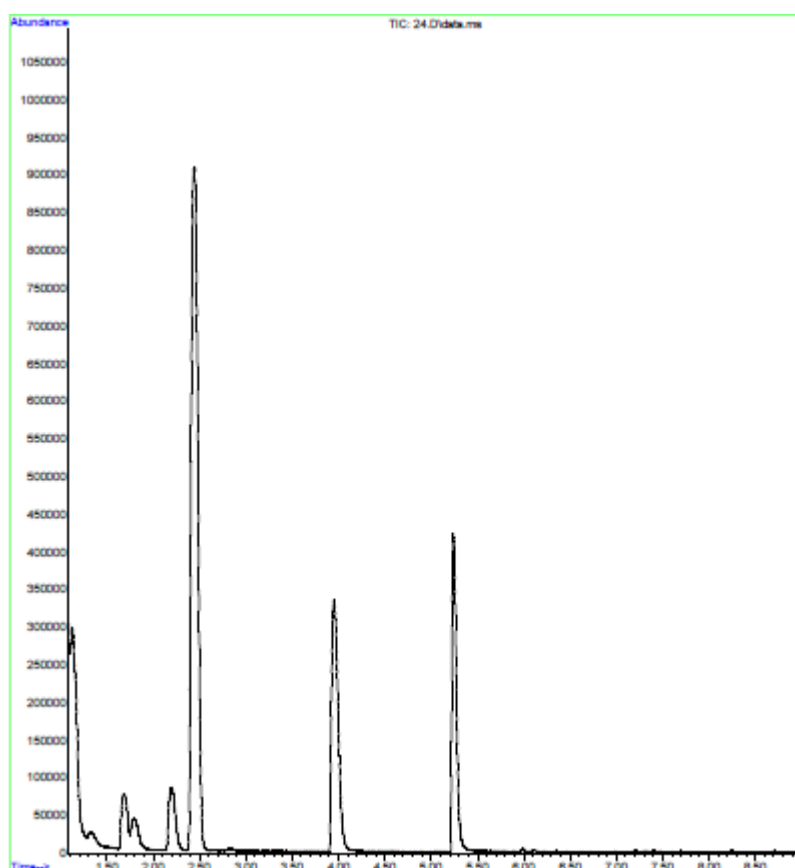


Fig. 2 Control for Acetates in urine

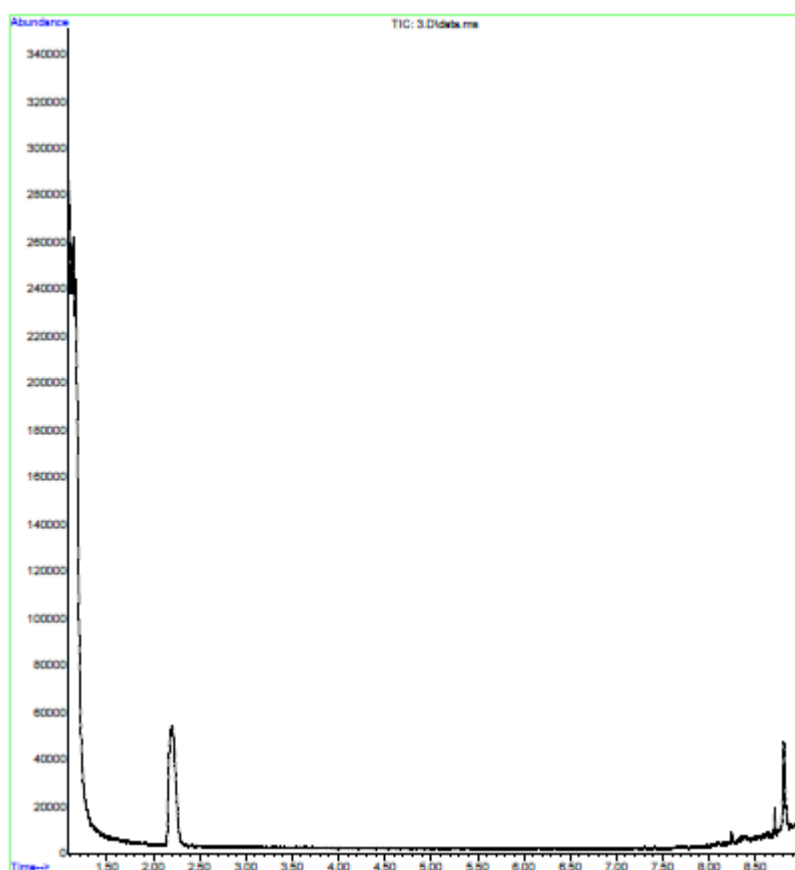


Fig.3 Real sample: Acetates in urine

GENERAL WARNINGS

1. STORAGE AND SHELF LIFE

All the components are ready-to-use. Stable for 3 years at 15-25°C except Reagent B (Test Solution) and Reagent C (Internal Standard Solution) that must be stored at a T ranging between -25°C and -15°C.

REAGENT	COMPOSITION	CONCENTRATIONS (mg/l)
Reagent B	Acrylonitrile Butylacetate Benzene fluoride (IS) Heptane Ethylacetate Isobutylacetate Tetrahydrofuran	2

2. NEW COLUMN TREATMENT

Install the new VF-5ms (30 m x 0,25 mm – 0,25 µm) Analytical Column.

Cut ends with appropriate column cutter. Purge column with flow rate of 1 ml/min at 240°C for 8 hours (mount column on injector side only).

3. INJECTION NEEDLE WASHING

Under flow of Nitrogen.

ABBREVIATIONS

ABBREVIATIONS	MEANING
es. 5 x 1 x 1 ml	N° of levels x N° of vials x volume
DEV STD	Deviazione standard
LLOD	Low limit of detection
Pc/pcs	Piece/pieces
rpm	revolutions per minute
RT	Retention Time
n.a.	Not available
n.d.	Not detectable
IS	Internal Standard

BIBLIOGRAPHY

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2. Amandine Erb, *et al.* Simultaneous determination of aromatic and chlorinated compounds in urine of exposed workers by dynamic headspace and gas chromatography coupled to mass spectrometry (dHS-GC-MS), *Journal of Chromatography B* 1125 (2019) 121724
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4. SW-846 Test Method 8260D: Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS), EPA, United States Environmental Protection Agency
5. Han-Na Song, *et al.* Simultaneous determination of volatile organic compounds (VOCs) with a wide range of polarities in urine by headspace solid-phase microextraction (HS-SPME) coupled to gas chromatography-mass spectrometry, doi: 10.1002/rcm.7827
6. Hans Gu"nther Wahl, *et al.* Analysis of volatile organic compounds in human urine by headspace gas chromatography–mass spectrometry with a multipurpose sampler, *Journal of Chromatography A*, 847 (1999) 117–125

REFERENCE STANDARDS

Quality Assurance System compliant with regulations:

UNI CEI EN ISO 13485:2016,
UNI EN ISO 9001:2015

Any modification made to the Medical Device unless authorized by Eureka S.r.l. - Lab Division makes this declaration invalid.

We declare that the devices comply with the following **Technical Standards**:

UNI CEI EN ISO 14971:2012
UNI CEI EN ISO 15223-1:2017
UNI EN ISO 18113-2:2012

We declare that the device is sold in a non-sterile package.

IVD SYMBOLS

NUMBER	SYMBOL	DESCRIPTION
1		Manufacturer
2		Product Model Number / Designation or Part Number
3		Caution, consult accompanying documents
4		Product Lot Number
5		Use By (Expiry)
6		Consult Operating Instructions
7		Date of manufacture
8		Temperature limitation
9		For <i>in vitro</i> diagnostic use
10		European Union conformity
11		Packaging