VMA, HVA, 5-HIAA LC-MS/MS Analysis Kit
in Human Urine Samples

BIOGENIC AMINES

Good NEWS:
You don't have to deal with the problems of ECD anymore !

Robust, sensitive and quantitative analysis of VMA, HVA, 5-HIAA
NOW AVAILABLE
in 15 minutes

Suitable for any
LC-MS/MS System

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

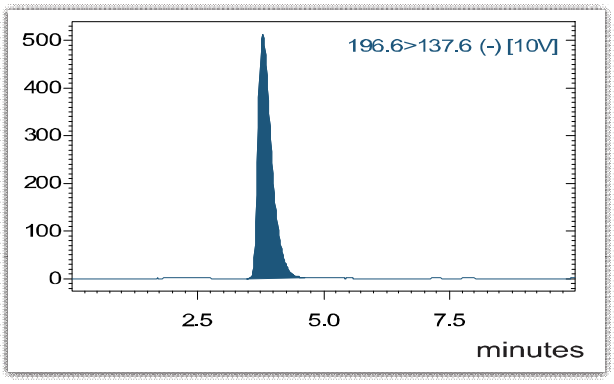
Properties of the analysis kit

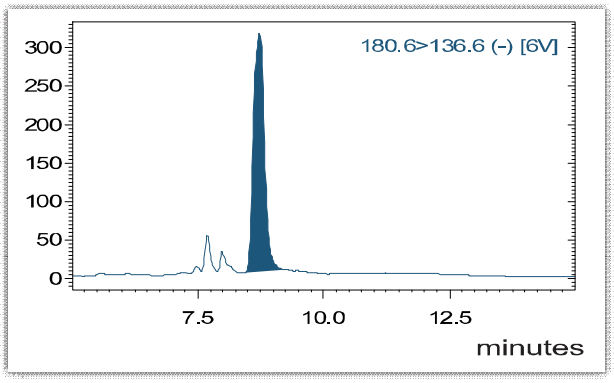
- **15 minutes analysis time**
- **Sensitive separation with Zivak® VMA HPLC column**
- **Deuterated internal standards**
- **No derivatisation, evaporation or SPE process**
- **Approximately 1000 analysis with one column**

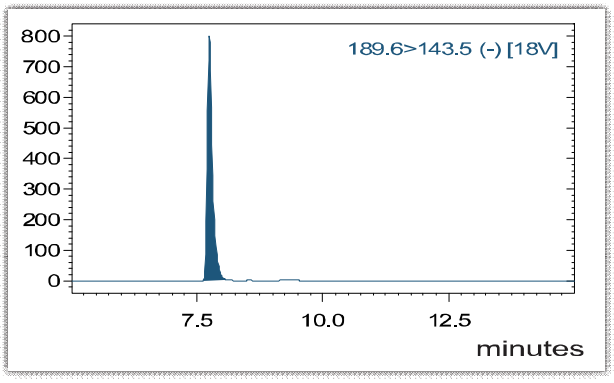
VMA, HVA, 5-HIAA LC-MS/MS Analysis Kit
in Human Urine Samples

Sample Chromatograms and Validation Results

Sample chromatograms are for urine control level 2 of Zivak® VMA LC-MS/MS Analysis Kit







VMA		
LOD	(µmol/L)	0.3
LOQ	(µmol/L)	0.9
Accuracy	(%)	97.5
Precision Intra-Assay	(%CV)	2.9
Precision Inter-Assay	(%CV)	4.3
Linearity	(R^2)	0.9990

HVA		
LOD	(µmol/L)	0.2
LOQ	(µmol/L)	0.6
Accuracy	(%)	98.7
Precision Intra-Assay	(%CV)	2.3
Precision Inter-Assay	(%CV)	3.5
Linearity	(R^2)	0.9992

5-HIAA		
LOD	(µmol/L)	0.2
LOQ	(µmol/L)	0.6
Accuracy	(%)	96.3
Precision Intra-Assay	(%CV)	3.3
Precision Inter-Assay	(%CV)	4.9
Linearity	(R^2)	0.9989

The test results have been validated with an AB Sciex API 4000 LC-MS/MS instrument in Nov. 2014.

Psychoactive Drugs LC-MS/MS Analysis Kit
in Human Urine Samples

DRUG MONITORING

Reliable, sensitive and quantitative detection of **most common drugs** in 12 minutes

Suitable for any **LC-MS/MS System**

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

Properties of the analysis kit

- Also *available* with Zivak® Multitasker Full Automated Sample Preparation AND Injection System
- 12 minutes analysis time
- Sensitive separation with Zivak® Psychoactive Drugs HPLC column
- Deuterated internal standards
- Approximately 1000 analysis with one column
- No evaporation, derivatisation or SPE process

Psychoactive Drugs LC-MS/MS Analysis Kit

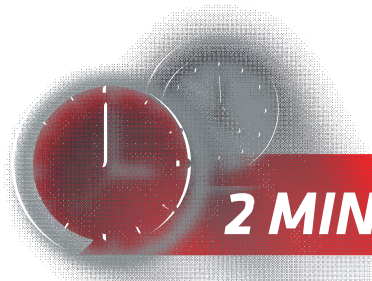
in Human Urine Samples

Validation Results

No	Analyte	LOD (µmol/L)	LOQ (µmol/L)	Accuracy (%)	Precision Intra-Assay (%CV)	Precision Inter-Assay (%CV)	Linearity (R^2)
1	Amphetamine	0.27	0.90	99.24	2.6	2.9	0.9994
2	Methamphetamine	0.31	1.02	100.9	4.8	5.3	0.9998
3	MDA	0.08	0.26	95.32	2.6	2.9	0.9976
4	MDMA	0.12	0.39	98.54	2.9	3.3	0.9991
5	MDEA	0.07	0.23	98.74	3.4	3.7	0.9998
6	Diazepam	0.10	0.33	95.86	2.4	2.6	0.9999
7	Morphine	0.08	0.26	100.5	6.7	6.9	0.9999
8	Codeine	0.31	1.02	92.10	4.4	4.7	0.9969
9	Cocaine	0.09	0.30	96.84	2.8	3.1	0.9989
10	Alprazolam	0.09	0.30	96.96	2.8	3.2	0.9996
11	Delta-9-THC	0.50	1.65	98.82	4.1	4.5	0.9998
12	Clonazepam	0.16	0.53	97.42	2.9	3.3	0.9998
13	Flunitrazepam	0.13	0.43	98.76	4.4	4.7	0.9996
14	6-acetylmorphine	0.08	0.26	99.12	2.6	2.8	0.9986
15	Heroin	0.12	0.40	98.10	6.3	6.7	0.9987

The test results have been validated with an AB Sciex API 4000 LC-MS/MS instrument in Nov. 2014.

Total Homocysteine LC-MS/MS Analysis Kit
in Human Plasma Samples



2 MINUTES

NOW ***cost effective,***
sensitive and
quantitative detection

Suitable for any
LC-MS/MS System

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

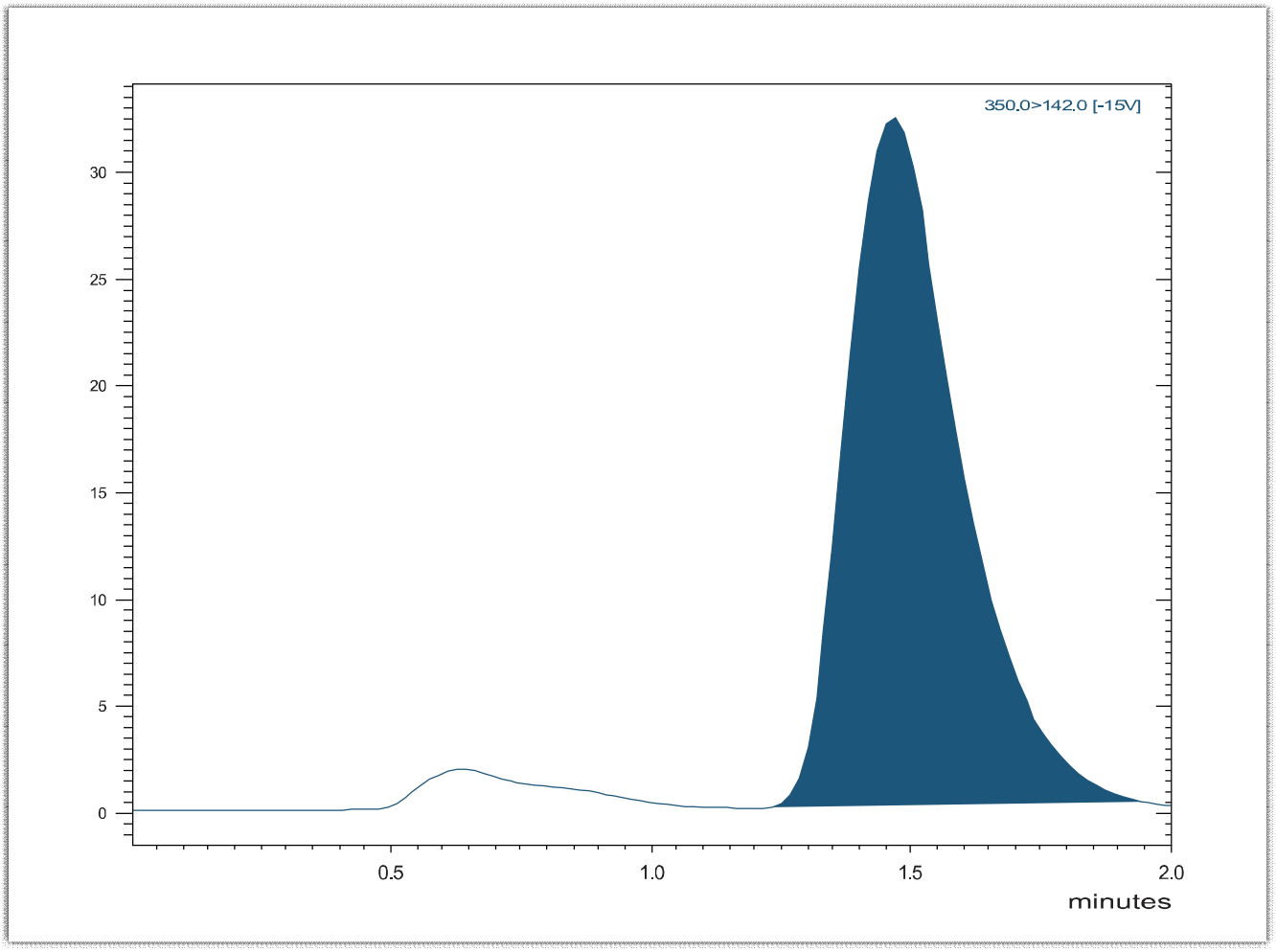
Properties of the analysis kit

- **2 minutes analysis time**
- **Sensitive separation with Zivak® Total Homocysteine HPLC column**
- **Deuterated internal standards**
- **No evaporation or SPE process**
- **Approximately 1000 analysis with one column**

Total Homocysteine LC-MS/MS Analysis Kit
in Human Plasma Samples

Sample Chromatogram and Validation Results

Sample chromatogram is for plasma control level 1 of Zivak® Total Homocysteine LC-MS/MS Analysis Kit



Homocysteine		
LOD	(µmol/L)	0.06
LOQ	(µmol/L)	0.18
Accuracy	(%)	98.5
Precision Intra-Assay	(%CV)	3.5
Precision Inter-Assay	(%CV)	3.8
Linearity	(R^2)	0.997

The test results have been validated with an AB Sciex API 4000 LC-MS/MS instrument in Nov. 2014.

LC-MS/MS Analysis Kit for the in-vitro Diagnostic Quantitative Determination of Phenylketonuria

in Human Serum & Plasma and Dried Blood Samples

NOW cost effective, accurate, sensitive and quantitative detection

Suitable for any **LC-MS/MS System**

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

Properties of the analysis kit

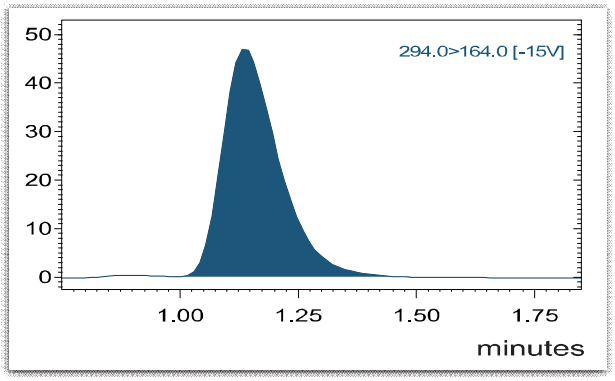
- 2 minutes analysis time
- Minimum sample preparation process
- Sensitive separation with Zivak® PKU HPLC column
- Approximately 1000 analysis with one column

LC-MS/MS Analysis Kit for the in-vitro Diagnostic Quantitative Determination of Phenylketonuria

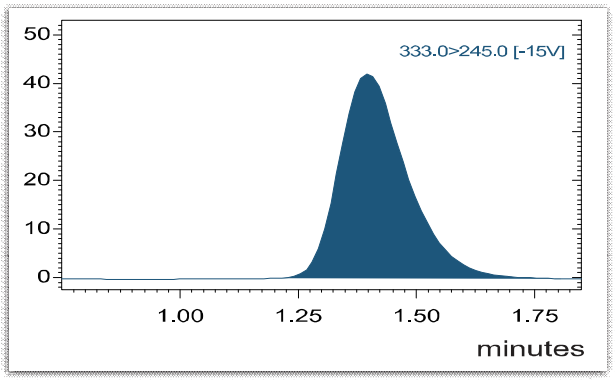
in Human Serum & Plasma and Dried Blood Samples

Sample Chromatograms and Validation Results

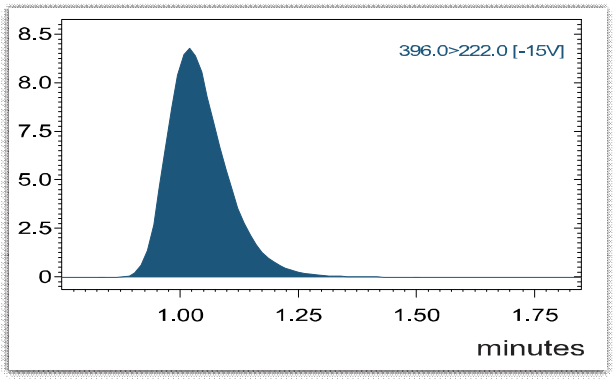
Sample chromatograms are for DBS calibrator of Zivak® PKU LC-MS/MS Analysis Kit



Phenylalanine (PHE)		
LOD	(µmol/L)	0.18
LOQ	(µg/L)	0.54
Accuracy	(%)	95
Precision Intra-Assay	(%CV)	2.3
Precision Inter-Assay	(%CV)	2.6
Linearity	(R^2)	0.998



Tryptophan (TRP)		
LOD	(µmol/L)	0.20
LOQ	(µg/L)	0.60
Accuracy	(%)	94
Precision Intra-Assay	(%CV)	2.1
Precision Inter-Assay	(%CV)	2.5
Linearity	(R^2)	0.996



Tyrosine (TYR)		
LOD	(µmol/L)	0.21
LOQ	(µg/L)	0.63
Accuracy	(%)	96
Precision Intra-Assay	(%CV)	1.9
Precision Inter-Assay	(%CV)	2.3
Linearity	(R^2)	0.997

The test results have been validated with an AB Sciex API 4000 LC-MS/MS instrument in Nov. 2014.

HPLC-UV ANALYSIS KITS

25-OH Vitamin D2/D3
in Human Serum Samples

Quantitative Determination of PKU
in Human Serum & Plasma and
Dried Blood Samples

ZIVAK®
TECHNOLOGIES
www.zivak.com

VD-200 Vitamin D2/D3 Analyser

World only fully automated analyser
with a barcode reader,
centrifuge, vortex,
dual parallel LC and more

3.5 MINUTES

NIST 2014

Accuracy **96%!**

25-OH Vitamin D2/D3 HPLC-UV Analysis Kit

in Human Serum Samples

NOW ***cost effective***
HPLC analysis kit
with reliable accuracy
in 3.5 ***minutes*** available

Suitable for any
HPLC System

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

Properties of the analysis kit

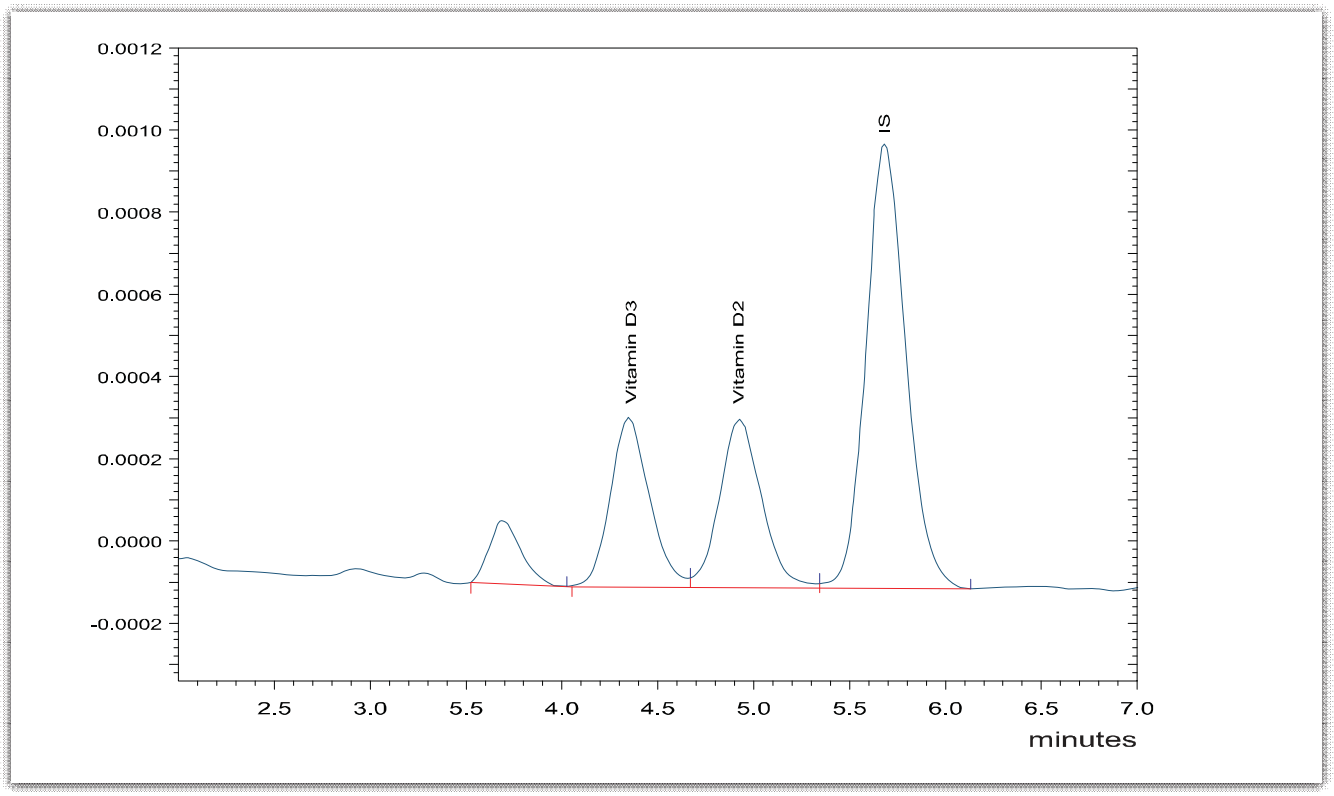
- Also *available* with Zivak® Multitasker Full Automated Sample Preparation AND Injection System
- 3.5 minutes analysis time
- Sensitive separation with Zivak® 25-OH Vitamin D HPLC column
- Approximately 1000 analysis with one column

*Reference upon request

25-OH Vitamin D2/D3 HPLC-UV Analysis Kit
in Human Serum Samples

Sample Chromatogram and Validation Results

Sample chromatogram is for serum calibrator of Zivak® Vitamin D2/D3 HPLC Analysis Kit



25-OH Vitamin D3		
LOD	(µg/L)	0.8
LOQ	(µg/L)	2.4
Accuracy	(%)	98
Precision Intra-Assay	(%CV)	2.7
Precision Inter-Assay	(%CV)	3.1
Linearity (R^2)	(0-200 µg/L)	0.9995

25-OH Vitamin D2		
LOD	(µg/L)	0.8
LOQ	(µg/L)	2.4
Accuracy	(%)	97
Precision Intra-Assay	(%CV)	2.4
Precision Inter-Assay	(%CV)	2.8
Linearity (R^2)	(0-200 µg/L)	0.9989

The results have been validated with a Zivak® COMET-4100 HPLC-UV system in Nov. 2014.

Tested by NIST* with an accuracy of 96%

HPLC-UV Analysis Kit for the in-vitro Diagnostic Quantitative Determination of Phenylketonuria

in Human Serum & Plasma and Dried Blood Samples

NOW ***cost effective,***
accurate, sensitive
and quantitative
HPLC analysis
in 8 minutes

Suitable for any
HPLC System

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

Properties of the analysis kit

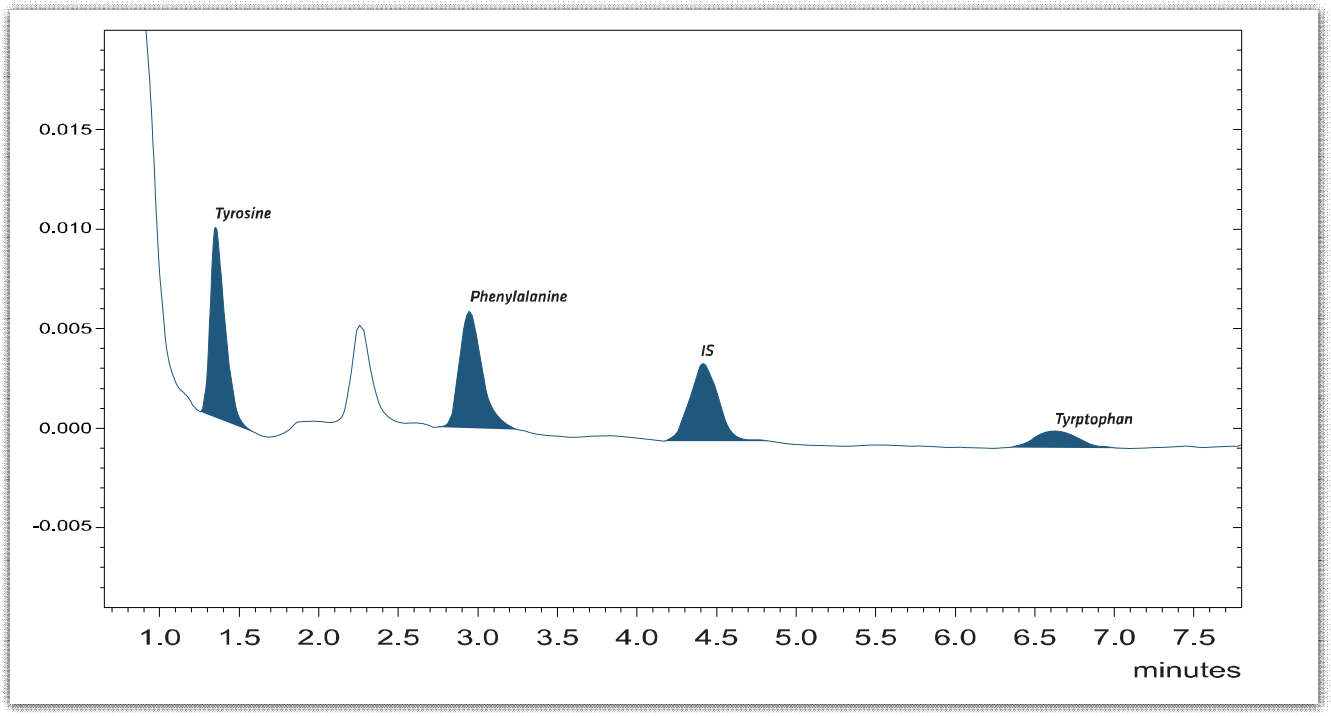
- **8 minutes analysis time**
- **Minimum sample preparation process**
- **Sensitive separation with Zivak® PKU HPLC column**
- **Approximately 1000 analysis with one column**

HPLC-UV Analysis Kit for the in-vitro Diagnostic Quantitative Determination of Phenylketonuria

in Human Serum & Plasma and Dried Blood Samples

Sample Chromatogram and Validation Results

Sample chromatogram is for DBS calibrator of Zivak® PKU HPLC-UV Analysis Kit



Phenylalanine (PHE)		
LOD	(µmol/L)	0.35
LOQ	(µmol/L)	1.05
Accuracy	(%)	97
Precision Intra-Assay	(%CV)	3.9
Precision Inter-Assay	(%CV)	4.2
Linearity	(R^2)	0.997

Tryptophan (TRP)		
LOD	(µmol/L)	0.60
LOQ	(µmol/L)	1.80
Accuracy	(%)	98
Precision Intra-Assay	(%CV)	3.4
Precision Inter-Assay	(%CV)	3.8
Linearity	(R^2)	0.996

Tyrosine (TYR)		
LOD	(µmol/L)	0.85
LOQ	(µmol/L)	2.55
Accuracy	(%)	97
Precision Intra-Assay	(%CV)	4.9
Precision Inter-Assay	(%CV)	5.3
Linearity	(R^2)	0.998

The results have been validated with a Zivak® COMET- 4100 HPLC-UV system in Nov. 2014.

HAEMOGLOBIN ANALYSIS KITS & ANALYSER

Haemoglobin A1c
in Whole Blood Samples

Haemoglobin Variants
in Whole Blood Samples

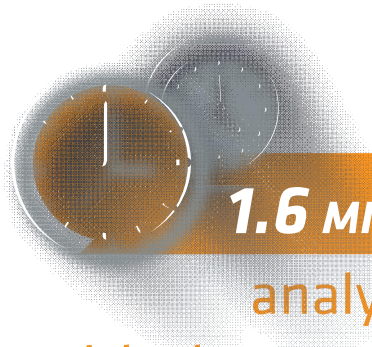
ZIVAK®
TECHNOLOGIES
www.zivak.com

HB-100 HbA1c/Variant Analyser

1,6 analysis run time with sample inversion,
rotational barcode reading and
200 sample capacity.

Haemoglobin A1c HPLC-UV Analysis Kit

in Whole Blood Samples



1.6 MINUTES

analysis of HbA1c with short program and minimum sample preparation process

Automated sample preparation AND injection from whole blood samples

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

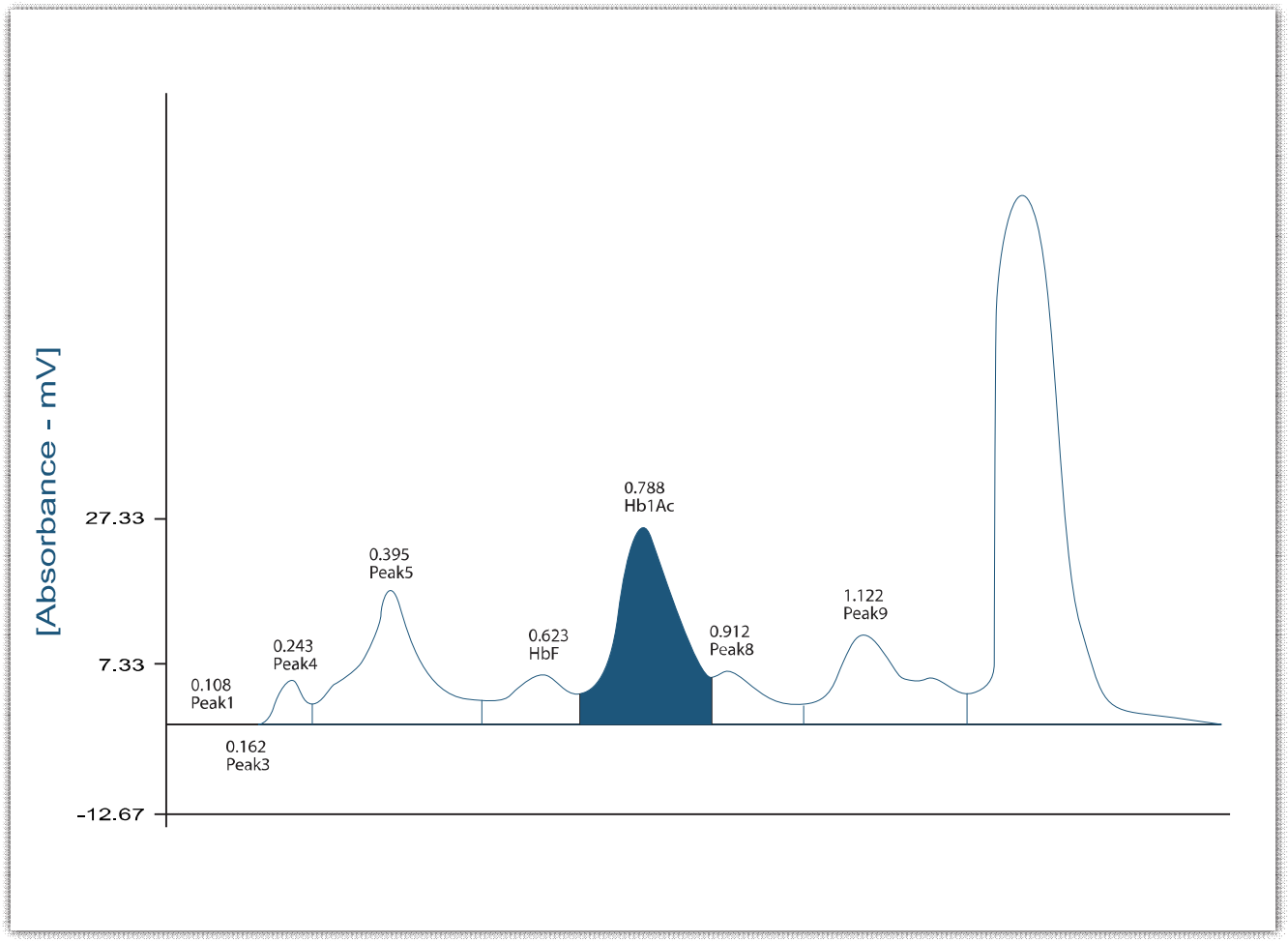
Properties of the analysis kit

- **Available with Zivak® Haemoglobin Analyser**
- **1.6 minutes analysis time**
- **Minimum sample preparation process**
- **Sensitive separation with Zivak® Haemoglobin HPLC column**
- **Approximately 1000 analysis with one column**

Haemoglobin A1c HPLC-UV Analysis Kit
in Whole Blood Samples

Sample Chromatogram and Validation Results

Sample chromatogram is for whole blood control level 2 of Zivak® Hb A1c HPLC-UV Analysis Kit



Component	Retention time
Hb_0	1.347

Component	Retention time
HbF	0.623

Component	Retention time
HbA_{1c}	0.788

(%)

The test results have been validated with a Zivak® Haemoglobin Analyser in Nov. 2014.

Haemoglobin Variants HPLC-UV Analysis Kit

in Whole Blood Samples

5 minutes analysis of
A1c, A0, A2, F, D, E, S, C variants
with minimum
sample preparation process

Automated sample preparation
AND injection
from whole blood samples

Main methods and procedures that have been selected are based on EN ISO 13485 and 98/79/EC.

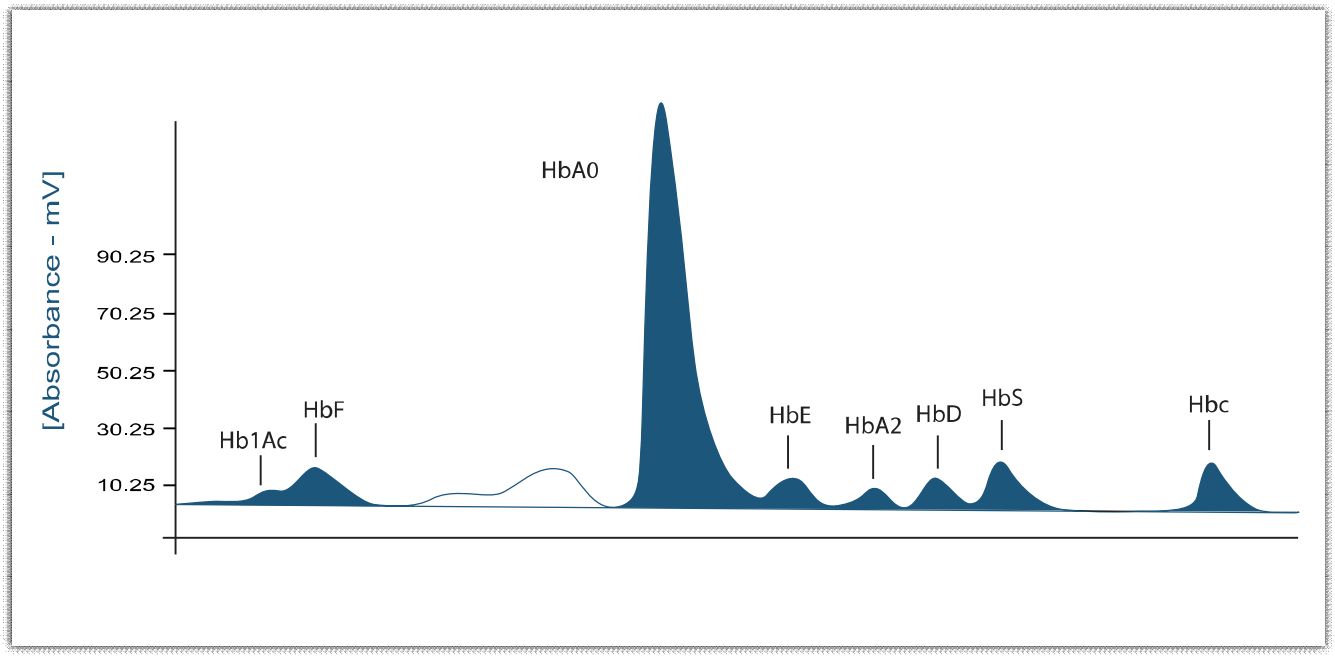
Properties of the analysis kit

- **Available with Zivak® Haemoglobin Analyser**
- **Minimum sample preparation process**
- **5 minutes analysis time**
- **Sensitive separation with Zivak® Haemoglobin HPLC column**
- **Approximately 1000 analysis with one column**

Haemoglobin Variants HPLC-UV Analysis Kit
in Whole Blood Samples

Sample Chromatogram and Validation Results

Sample chromatogram for whole blood control level 2 of Zivak® Hb Variants HPLC Analysis Kit



Component	Retention time
HbA1c	2.4

Component	Retention time
HbF	3.4

Component	Retention time
HbA_0	3.9

Component	Retention time
HbAE	4.2

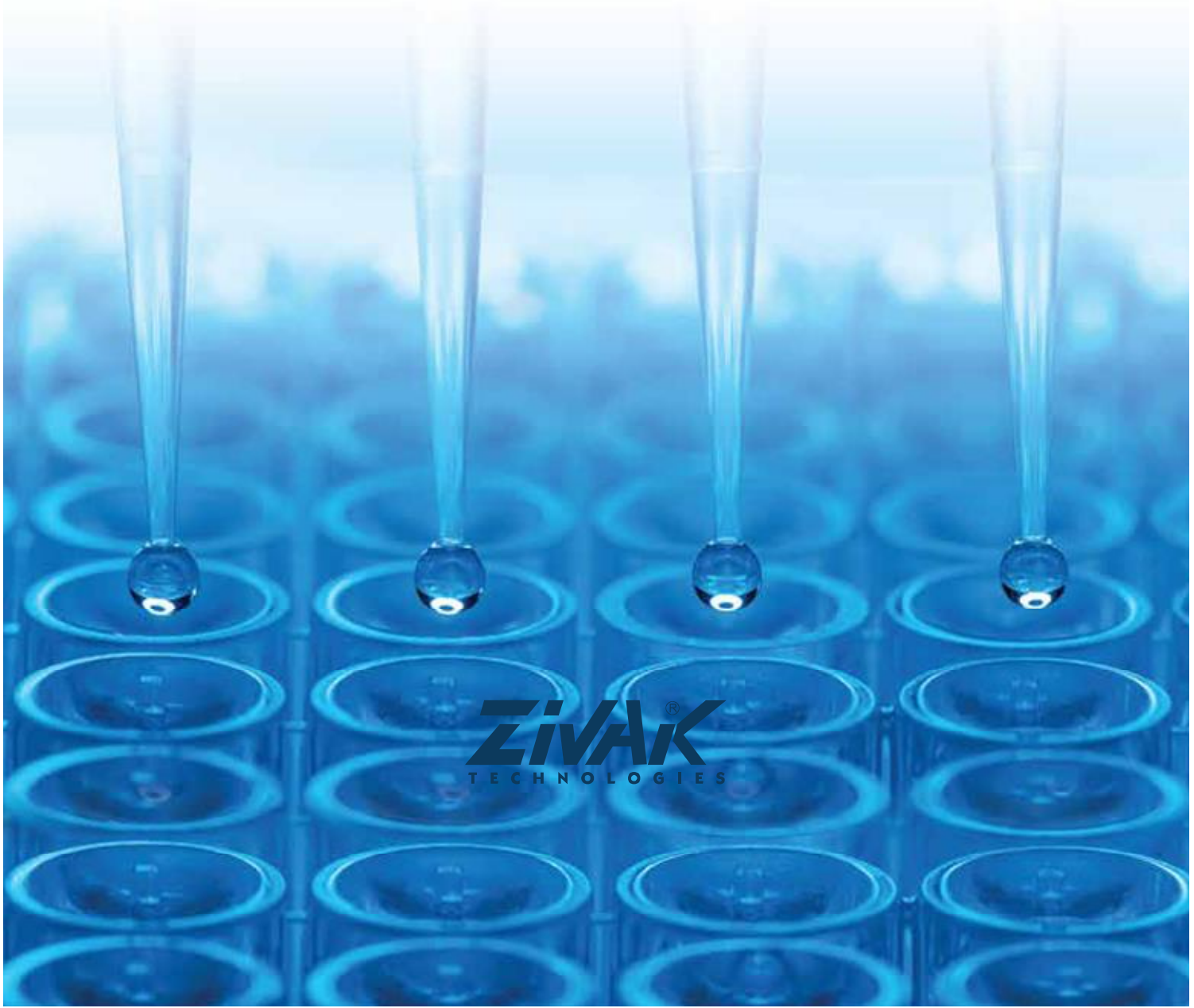
Component	Retention time
$HbA1_2$	4.5

Component	Retention time
HbD	4.7

Component	Retention time
HbS	5.535

Component	Retention time
HbC	2.2

The test results have been validated with a Zivak® Haemoglabin Anaylser in Nov. 2014.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